Research Demonstration Project on Homelessness & Mental Health:

Research Design for Two Randomized Controlled Trials in Vancouver, British Columbia
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1.0 Principal Investigators

- Julian M Somers, PhD, R.Psych. (Lead Applicant) Associate Professor, Simon Fraser University
- Michael Krausz, MD, PhD, FRCPC, Professor, University of British Columbia
- James Frankish, PhD, Professor, University of British Columbia

Three Principal Investigators provide research leadership and interdisciplinary expertise to the Vancouver consortium. The Lead Applicant (JS) is Director of the Centre for Applied Research in Mental Health and Addiction (CARMHA) and Associate Professor in the Faculty of Health Sciences at SFU. Both co-PIs are Professors at UBC, with appointments at the School of Population and Public Health (JF) and in Psychiatry and at the Centre for Health Evaluation and Outcome Studies (MK). All PIs have extensive experience directing research in mental health, homelessness, and addiction, including leading randomized controlled trials (MK), directing multi-site longitudinal interventions (JS and MK), and maintaining programs of qualitative and mixed-methodological research (JS, JF, MK).

Current or recent relevant initiatives involving the PIs include the NAOMI RCT; the German Heroin Trial; estimating the housing needs of British Columbians with severe mental disorders; and evaluating the impacts of service innovations designed to improve outcomes for homeless people with mental disorders (e.g., drug treatment court; residential treatment for concurrent disorders; intensive supervision of criminal offenders with severe mental disorders). The PI’s are actively engaged as advisors to branches of government and agencies dedicated to addressing the needs of homeless individuals with mental disorders, including the Victoria Mayor’s Task Force (JS, MK), the City of Vancouver’s Collaboration for Change (JS, MK), the Streethome Foundation (JF, JS), the BC Ministries of Health and Housing & Social Development (JS) and Vancouver Coastal Health Authority (JF, MK, JS).

SFU will serve as the administrative home for the proposed research. CARMHA’s offices are located in downtown Vancouver, and will provide the physical operating environment for project implementation, including established facilities and procedures for the secure stewardship of sensitive data.

Consortium members include additional academics from major universities, provincial and municipal decision-makers, key decision-makers from the Vancouver Coastal Health, Providence Health Care, the City of Vancouver, and key community housing and mental health service providers. All agencies and members have significant experience working on collaborative research and/or service delivery projects at the provincial and/or national level. All members are committed to the project principles and objectives and have been actively involved in the application development process. [Please see Addendum for CVs of Principal Investigator, co-PIs, Co-Investigators and Service Leads.] [Please see Appendix 1.0 for complete list of Consortium members and profiles of Service Lead organizations.]

2.0 Engagement of People with Lived Experience

The engagement of people with lived experience (PWLE) is critical to the planning and development of this project. Six round table sessions were held in December 2008/January 2009 to begin the process of inviting PWLE to participate in the project. These conversations informed the development of the application and how to meaningfully engage PWLE throughout the project. In total, 58 PWLE commented on the project design and shared their perspectives on issues for further research consideration as well as ways they could continue to contribute to the study (see Summary in Appendix 2.0). An engagement strategy for PWLE has been developed that outlines both direct and supportive roles, as well as processes and partnerships that create space for PWLE to remain at the centre of the
project in a number of Advisory, Research, Public Stakeholder, Service Provision and Project Infrastructure capacities. (See Engagement Strategy in Appendix 2.1)

3.0 Innovation and Relevance of the Study

3.1 Rationale
Over the past 30 years, there has been significant downsizing of long-stay psychiatric institutions, accompanied by inadequate investments in the growth and integration of community services responsible for mental disorders, substance use disorders, welfare, justice and housing. As a result, many cities, including Vancouver, have witnessed a significant increase in the number of homeless individuals with mental disorders (including addictions) with diverse housing and health-related needs that are complicated by physical health problems, trauma, and various social and occupational challenges.

Untreated psychiatric and physical health conditions both contribute to chronic homelessness and to poor quality of life. However, the services designed to address mental health, addiction and physical health are often segregated and incomplete. Physical health conditions tend to be treated in Emergency Departments where continuity of follow-up care is limited. On the other hand, mental health and addictions are most often addressed by diverse community-based agencies (Folsom et al., 2005); however, service agencies are often ill-equipped to address the multiple needs of individuals with concurrent mental and substance use disorders, possibly leading to incomplete care and further unmet need. Given the high rates of physical and behavioural health problems among homeless individuals and the inadequacy of services, there is a growing need for effective approaches that integrate housing with treatment and support services (Rosenheck et al., 2003).

A growing body of research demonstrates that supported housing has a positive impact on residential stability, regardless of the specific model of housing (Best, 2006; Rog, 2004). Recent work has indicated that a Housing First approach, which provides permanent, independent housing that is scattered throughout the community, is an effective approach for people who are homeless with mental disorders, including substance use (e.g., Tsemberis & Eisenberg, 2000). This model places few treatment demands on clients and provides intensive support services to help them integrate into their community. Despite this work, the impacts of supported housing on outcomes other than those related to residential stability and hospitalization have not been consistently studied, and existing studies have not yielded consistent results. A Cochrane review of supported housing for people with severe mental disorders (Chilvers, Macdonald & Hayes, 2008) found no studies that met the selection criteria (randomization). Furthermore, few, if any, studies of supported housing have incorporated randomization to ‘usual care’ that did not include some form of housing. Addressing this gap in the research literature is critical for the development of policies and well-defined intervention programs.

Given the shortage of affordable housing units, especially in urban areas, the implementation of scattered-site housing may not lead to the most effective use of available housing resources. Policymakers therefore should explore the relative advantages and disadvantages of various alternative strategies, including approaches that encourage re-housing of homeless persons with severe mental illness in congregate settings that include other persons. Few studies to date have examined the effect of moving into congregate arrangements on persons with severe mental disorders (see O’Flaherty et al., in progress; Walker & Seasons, 2002).
Evidence is emerging to suggest the characteristics of effective interventions for homeless individuals with psychiatric symptoms, including the importance of perceived choice (Greenwood et al., 2005; Nelson et al., 2007). Assertive Community Treatment (ACT) is a model of care for people with severe mental illness in which a multidisciplinary team provides treatment and rehabilitation in addition to case management functions. An extensive body of research has shown that ACT is effective in reducing hospitalization and improving symptoms of mental illness as well as social functioning (see Ziguras & Stuart, 2000). Intensive Case Management (ICM) is another model of care for people with mental illness in which services are brokered to community agencies by a case manager rather than delivered by a team (as in ACT). The evidence base for ICM is not as strong as that for ACT; however, it has been shown to be effective in improving symptoms of mental illness as well as social functioning (see Dixon & Goldman, 2003). Focusing on a subset of homeless people with severe mental illness, Coldwell and Bender (2007) used meta-analysis to assess the effectiveness of ACT versus standard case management. Overall, clients who received ACT had a 37% reduction in homelessness and a 26% improvement in psychiatric symptom severity compared to standard case management. These results suggest that homeless people with highly disabling conditions may best be served by a service model such as ACT.

Despite the body of evidence in favour of ACT and, to a lesser degree, ICM, little is known regarding the effectiveness of different intensities of intervention for homeless individuals with differing levels of need. For example, are the ACT and ICM models effective for individuals with concurrent disorders? Can ACT-like services be effectively integrated into a congregate housing setting? What models of care are effective for homeless people with moderate needs? It is our hope that the evidence gathered through the proposed trials will promote an informed evolution away from reactive programs (e.g., shelters, emergency medicine) and toward long-term, community-based solutions.

3.2 Background
In Vancouver, the overlap between mental disorders, substance use, and homelessness has become a civic crisis. When compared to the rest of British Columbia and Canada, Vancouver is unique in terms of the heterogeneity, multi-morbidity and concentration of its homeless population. The extent of chronic medical conditions, including infectious disease, has historically been well-documented among Vancouver’s homeless population (Acorn, 1993; Wood, Kerr et al., 2003). Furthermore, many homeless individuals are not connected to the formal health care system, and are at elevated risk of adverse outcomes, including overdose (Kerr et al., 2005).

The 2008 Metro Vancouver Homeless Count found 1,372 people who were homeless in the City of Vancouver¹. This number of homeless represents a 23% increase since the previous count in 2005. Notably, between 2005 and 2008, the percentage of people who have experienced homelessness for a year or more increased by 65%, representing 48% of people counted in 2008. In addition, over this period, self-reports of both mental illness and addictions increased significantly, by 86% and 63% respectively. A 2007 Provincial estimate of the population of adults with severe mental disorders (including substance use disorders) estimated that 1,800 adults in Vancouver are absolutely homeless and an additional 2,280 adults are at-risk for homelessness (see Figure 1 in Appendix 3.0; Somers, 2008). These reports suggest not only a significant increase in the rates and severity of homelessness in Vancouver, but that a substantial number of people are affected.

¹ The 2008 Metro Vancouver Homeless Count also identified an additional 1,037 homeless individuals in suburban areas adjacent to the City of Vancouver.
Homeless Outreach Teams), and investments to stabilize housing stock (e.g., purchase of SROs and development of additional supportive housing). If these activities and commitments fulfill their promise, they will significantly improve the standard of “usual care” for homeless people with mental disorders in Vancouver.

In summary, this proposal addresses a critical gap in the research evidence surrounding housing and services for a growing population of vulnerable individuals. In light of the limited housing resources and options available in Vancouver, this study not only responds to the MHCC’s national multi-site initiative, but offers a unique opportunity to evaluate an alternative model of services that may be more feasible and sustainable. Alternative models are important to consider in light of concerns about a growing economic crisis.

4.0 Research Design

The proposed research design includes the utilization of randomized controlled trial methods in order to evaluate integrated health and housing services. The project involves two sub-populations of homeless individuals, characterized by different eligibility criteria: one group with “high needs” and a second group with “moderate needs”. The project thus consists of two related but distinct RCTs which differ with regard to the severity of participants’ needs, the number of intervention arms, and the type of intervention services. Despite these differences, many of the major methodological features of each RCT will be the same. These include: participant recruitment and retention strategies, tests and measures of outcomes of interest, study hypotheses, and plans for data analysis. In addition, both RCTs incorporate qualitative and quantitative methods along with the secondary analysis of administrative data.

Participants with high needs will be randomized to one of two Housing First program variations (Scattered-site + ACT or Congregate + ACT*) or to a Treatment as Usual (TAU) group (see Figure 2). Participant choice will be maximized in all study conditions, and all study participants who are randomized to an intervention group will receive some form of low-barrier housing as well as intensive support services. Moderate need participants will be randomized to one of two groups, an intervention (Scattered-site + ICM) or TAU group. Please see Section 4.4 for details on the housing and support interventions as well as the TAU group.

![Figure 2. Study Group Interventions by Need](image)
*Intensive treatment services will be integrated into the congregate housing condition. In the event that an ACT team cannot be developed in this condition, the service component will consist of a comparable range and intensity of services.

All study participants will be followed and re-interviewed every 6 months for a period of 2 years from baseline. A field office will be established to facilitate tracking and interviewing of participants. The field office will be utilized as a confidential location for conducting follow-up interviews as well as a place where participants can ask questions about the project, their next interview (e.g., date, time, etc.), and update their contact information.

Overall, the design follows accepted standards, including adherence to Good Clinical Practice (GCP). In conformity to GCP, it is necessary to develop Standard Operating Procedures, an audit protocol, and trials monitoring procedures. These details are not presented in the present application, pending the further specification of treatment components (e.g., ICM) and resolution of additional design details across sites. The unique elements of the Vancouver study site will also be articulated and submitted for trials registration to complement the activities registered as part of the multi-site trial.

4.1 Hypotheses

This study provides a rich opportunity for examining a broad range of hypotheses. The key primary and secondary hypotheses are outlined below.

**Primary hypotheses:**

In comparison to individuals in the Treatment as Usual groups, individuals assigned to Housing First groups will:

(1) attain **stable housing**; and

(2) realize improved **mental health** outcomes in terms of both number and severity of symptoms.

**Secondary hypotheses:**

In comparison to individuals in the Treatment as Usual groups, and when compared to their own baseline (within subjects), individuals assigned to Housing First groups will demonstrate:

(1) improved general **quality of life**;

(2) a different distribution of service **costs** (and the component services themselves) between the health, justice, and income assistance systems;

(3) attenuation of **trauma symptoms**;

(4) reduced **victimization** (financial, sexual, physical);

(5) reduced incidents of **harm** to self and harm to others;

(6) reduced rates of **justice** system involvement (i.e., police contacts, Provincial court sentences);

(7) increased **employment** and more stable receipt of appropriate income assistance benefits; and

(8) improved **physical health**.

In comparison to individuals in the Treatment as Usual group and, when compared to their own baseline (within subjects), individuals assigned to Housing First + ACT groups (incorporating contingency management) will demonstrate:

(9) reduced **substance use** and related problems.

In addition to the above, a final hypothesis is that:

(10) local **media** accounts of homelessness and mental illness will change over the course of the project in frequency and quality (e.g.: reduced stigma; more promising regarding potential solutions), based on analyses of newsprint and video.
4.2 Eligibility Criteria
Criteria for inclusion in the project are as follows: (1) Legal adult status (age 19 in BC); (2) Meets definition of ‘absolute homelessness’ or ‘precariously housed’ set by MHCC; (3) Presence of any serious mental disorder with or without a concurrent substance use disorder. (N.B. Formal diagnosis is not required at time of entry into the project.)

Participants will be excluded from the study if they do not meet any of the inclusion criteria and if any of the following conditions are met: (1) Inability to communicate in English; (2) Incarceration or institutionalization (current or imminent); (3) Incompetent to give informed consent; or (4) Refusal to comply with the research protocol.

4.3 Recruitment
Recruitment will rely on referral from a variety of sources (e.g., Community Court; mental health and addiction services; Emergency Departments; shelters) and outreach. Outreach workers and service providers will be asked to inform homeless people about the project. Recruitment materials (e.g., posters, brochures) will be distributed in the community and displayed in organizations that serve the target population (e.g., soup kitchens, shelters, drop-in centres, health clinics, etc.). Recruitment will also rely on word-of-mouth among friends and associates (“snowballing”). The research team will conduct information sessions with community organizations and professionals who serve the target population to inform them about the project and gain support. Specific organizations that target women and ethnic minorities will be contacted to encourage diversity in the sample. Screening will be conducted via laptop computer within community agencies and the field office will be used for baseline and follow-up interviewing.

Recruitment to the full sample is estimated to take 18 months (1 year following a 6 month implementation phase). However, two potential issues related to our ability to recruit participants may extend this period: (1) the randomization process, and (2) compliance with the research protocol. Participants may perceive randomization to intervention and comparison groups as being ‘good’ or ‘bad,’ respectively, possibly leading to refusal to participate. Further, some participants may be hesitant to comply with the rigors of the protocol.

Screening and Baseline Evaluation: The screening process will consist of two primary steps:

1. **Pre-Screening:** Due to the nature of chronic homelessness in the DTES, it is likely that most individuals will have an addiction and/or mental illness (Goldner et al., 2007). Thus, the basic criteria needed to conduct pre-screening will be age 19 years or older, competence to sign the screening consent form, proficiency in spoken English, and absolute homelessness or precarious housing (as defined by the MHCC).

2. **Full Screening:** If pre-screening criteria are satisfied, participants will be asked the full set of screening questions. This will include evaluation of full inclusion and exclusion criteria, including classification as high or moderate need. Classification as high-need will correspond to Section 3 of Ontario Standards for ACT, as set forth by the MHCC. Classification as moderate-need will also be based on the same criteria; however, participants will be excluded if their score on the Symptom Checklist-90-R exceeds a threshold (to be determined) appropriate for the ICM condition. The
proportion of potential participants who fall into the high vs. moderate needs groups will be tested empirically during the implementation phase of the project².

Screening will be computer-based and will inform the interviewer whether or not the participant meets the study inclusion criteria as well as their level of need. Participants will be asked to return to the field office the following day to complete the baseline evaluation and then to receive notification of group assignment. In order to facilitate follow-up, participants will be asked to provide locations/services they frequent regularly. This requirement to return the following day may pose a barrier to recruitment and recruiters will be trained to actively seek people who do not return.

Randomization will be performed separately for the two need groups (high and moderate). To control for initial differences among groups, randomization strata will include with or without substance use problems and absolute homelessness or precariously housed. Randomization will be performed using a block technique with variable block size using prepared tables. When participants return the next day to complete the baseline evaluation, they will receive notification of group assignment in a sealed envelope along with an information package; at this time, a field office worker will accompany participants who are assigned to an active intervention to the service provider’s location. Those randomized to TAU will be informed about available services in the community. All participants will be invited to use the field office as a resource centre.

Blinding: It is not possible to blind the interventions given that participants, researchers and service providers will know the kind of intervention received. However, data analysts will be blind; a code will be provided for each condition that will not be identified until the end of the study.

4.4 Interventions

Given the study design, it will be important that each intervention maintains fidelity to its key ingredients. The Housing First Fidelity Scale (Tsemberis et al., in preparation) will be used with all intervention sites to assess fidelity to the principles of Housing First. The Dartmouth ACT Scale (DACTS; Teague, Bond & Drake, 1998) will be used to assess the fidelity of the ACT team to the principles of this program. Any modifications made for the target population will also be included in the fidelity assessment (see Tsemberis, 1999; Drake, McHugo, et al., 1998). Fidelity criteria for ICM and Congregate interventions will be developed in concert with other study sites. Given that none of the proposed service models operate in isolation, it will be important to assess the sufficiency of resources in the community. Finally, for all clinical interventions, Standard Operating Procedures will be established according to the guidelines of GCP to ensure standardized provision of care.

4.4.1 Housing First

Housing First is an well-documented approach that focuses on housing people directly from the street in scattered-site, independent units; provides services that are client-centred and solution-focused; and provides a range of innovative programs designed to meet the needs specific to homeless people (Tsemberis & Eisenberg, 2000). Scattered-site units (200+) in Vancouver will be developed by the Motivation, Power & Achievement (MPA) Society across the city through partnerships with private landlords, and local permanent housing agencies including BC Housing. For over 15 years, MPA has

² There are some concerns that the OSACT criteria may be inadequate given the severity of mental illness and substance use in Vancouver’s homeless population, possibly resulting in under-sampling of moderate-need individuals.
been establishing relationships with a large and varied portfolio of landlords and currently administers 188 private market rental housing subsidies.

**Mechanisms for Administering Housing Subsidies:** Rent will be paid directly to landlords on behalf of clients on a specified date each month. The client’s portion of rent will be sent directly to MPA from the BC Ministry of Human Resources and/or calculated based on income. MPA will also administer damage deposits on behalf of clients, and facilitate the return of deposits and the cost of repairs to landlords, if necessary. A program-specific rental database will be created and maintained. MPA will ensure flexibility of rent supplements should clients move addresses; provide key contacts in accounts payable to respond to landlord queries; and provide monthly reporting of client rent subsidies. Based on the experience of Pathways to Housing, Inc. (a well-established non-profit organization that provides Housing First to people who are homeless in New York City), we anticipate that 15-20% of people housed in scatter-site housing will require at least one relocation over the course of the project.

**Plan to Secure a Housing Portfolio:** A challenge for the Vancouver site will be in securing sufficient scattered-site units during the recruitment phase (Sept. 2009-Aug. 2010) which coincides with the 2010 Winter Olympics. Strategies to address this challenge will be developed by MPA in collaboration with the Project Team, BC Housing, the City of Vancouver and other formal and informal partners. The following actions will be taken to secure an adequate housing portfolio for the project:

- Hire a full-time property and portfolio Manager under the direction of the Program Director;
- Work with BC Housing, the City of Vancouver and other non-profit social housing providers to secure housing units;
- Focus on portfolio development and relationship-building with landlords; build on existing relationships and support landlords towards successful tenancies; facilitate landlord round-tables and education forums, and form associations with landlord groups;
- Develop a dispute resolution process for landlords, and respond quickly to incidents via investigation, mediation and resolution;
- Engage people with lived experience in landlord education and relations;
- Develop procedures and checklists to ensure housing quality; monitor landlords’ care and attention to clients; respect for tenancy agreements; etc.
- Support both ACT and ICM providers with immediate access to housing for clients; maintain ongoing communication with case workers and appropriate intervention with landlords;
- Liaise with Ministry of Human Resources regarding damage deposits and rent as necessary;
- Develop memos of understanding regarding roles and responsibilities with ACT and ICM leads.

With regard to access to housing facilities for the congregate intervention, discussions with BC Housing and the City of Vancouver regarding the provision or acquisition of sufficient congregate units have been ongoing. Both agencies are interested in continuing the dialogue and exploring partnerships around the availability of housing units within their respective portfolios. It is unclear whether congregate housing will consist of one building with 100 units or two buildings with a total of 100 units (where a significant number of units will be available by September 2009 and an additional number of units at a later time consistent with the overall period of recruitment). The StreetoHome Foundation is also interested in exploring partnerships to ensure that a congregate intervention is possible. (See Appendix 4.0 for letters of support).
4.4.2 Assertive Community Treatment (ACT)

ACT will be delivered by Raincity Housing & Support Society (see Appendix 1.0 for profile).

Intake, Admission and Discharge: Raincity has significant experience in the assessment of clients’ suitability and services needed for housing stability and independence. In partnership with the client, the ACT team will develop a detailed housing and service plan, based on a recovery orientation that respects the client’s personal preferences and autonomy. Clients must agree to two requirements: (1) Rent paid directly to the landlord; (2) A minimum of one home visit a week for the duration of the project. Transition and discharge from housing and services will be coordinated among the ACT team and other agencies. It is anticipated that discharge from ACT will occur only in exceptional circumstances. The local ACT team will develop a process for discharge decisions similar to that developed by Pathways to Housing, Inc which includes the following steps: (1) ACT team first makes a recommendation to discharge; (2) team and clinical director meet to discuss and explore options; (3) team meets with the client to discuss and explore options; (4) If discharge is confirmed then discharge proceeds with referral.

Service Intensity & Capacity: ACT teams use a multidisciplinary approach to provide intensive clinical services and supports directly to the client. The team will be closely involved in confirming housing and supporting all aspects of moving in and connecting to the local community. The client/staff ratio will be 10:1 or less and the team will be available 24 hours a day, 7 days a week, and 365 days per year to respond to client emergencies. At least 80% of services provided by the ACT team will be provided in the community. Client-centred assessment and individual treatment planning is a key ingredient of ACT. Clients’ responses to interventions and supports are closely monitored so that interventions can be adjusted to meet changing needs. Close monitoring may include medication management; representative payeeships; and urine drug screens (Drake et al., 1993). The team will also be involved in any hospital admissions and discharges. We are currently developing a memo of understanding between the ACT team and St Paul’s Hospital.

Staffing: The 8 to 12 member ACT team will consist of a social worker(s), substance abuse counselor, nurse(s), psychiatrist, peer specialist, family specialist, and employment specialist. The team will meet daily to review clients’ status and jointly plan team members’ daily activities. Team members will be cross-trained in each other’s areas of expertise to the maximum extent feasible. Recruitment, hiring, training and staff orientation will occur during the study’s implementation phase.

Program Organization & Communication: Services and team structure will adhere to the BC ACT Standards (MOHS, 2008) and guidelines provided by Pathways to Housing, Inc. The standard ACT model will be augmented in order to meet the needs of homeless individuals with concurrent mental and substance use disorders. For example, staff will be trained in contingency management, motivational enhancement and other strategies for managing poly-substance use. During the implementation phase, specific program procedures, communication materials and policies will be developed. Follow-up support will require multi-agency collaborations. Raincity has a long history of collaborative partnerships (e.g., addictions, mental health, primary care, other non-profits, police, Government and the local Health Authority) and will continue to build these relationships through presentations with community providers, the development of information and referral packages, and the coordination of regular meetings with outreach programs throughout the city. The ACT team will have access to information technology, meeting space, administrative services, fundraising, communications and human resources through Raincity.
**Services Offered:** ACT team services include: psychiatric treatment; substance abuse treatment; illness management; support with daily living skills including budgeting and money management skills; advocacy for benefits and entitlements; and community integration supports including linkages to health, wellness and recreational activities; family repatriation; vocational and supported employment services and supports. The team will also provide Contingency Management programs to address stimulant drug use. Other important approaches include enhancing motivation (e.g., motivational interviewing), teaching of cognitive-behavioral skills for relapse prevention, harm reduction and psychoeducation about addiction and concurrent disorders.

### 4.4.3 Intensive Case Management (ICM)
In this project, ICM will be delivered by Coast Mental Health, which has provided supported housing services to vulnerable populations since 1974. Through the formal implementation of outreach services as well as front-line advocacy, psychosocial and volunteer programs, they have a proven track-record in providing quality, client-centred services for people who are homeless and have mental health or substance use problems. (See Appendix 1.0 for profile).

ICM will be based on Toronto’s Streets To Homes model, which provides intensive outreach and follow-up of homeless people. In ICM, services are brokered to other agencies by a Case Manager. Outreach workers work with clients to develop housing plans and facilitate housing continuity. Follow-up supports assist with community integration, life skills, and financial stability.

**Intake, Assessment & Discharge:** Clients with moderate needs who are randomized to this condition will be directed to the ICM team after they have completed the research screening and assessment. Coast has significant experience in the assessment of clients’ suitability and the supports needed for housing stability and independence. In partnership with the client, the ICM team will develop a detailed housing and service plan that respects the client’s personal preferences and autonomy. Clients must agree to two requirements: (1) Rent is paid directly to the landlord; (2) Once housed, regular contact with ICM staff for a minimum of one year. Transition and discharge from housing, if necessary, will be coordinated among the ICM team and other community and clinical agencies.

**Service Intensity & Capacity:** The client-to-staff ratio will be approximately 20:1 (individual caseloads), seven days per week, and 12 hours per day. In the event that intensive 1:1 support is necessary, it will be tapered as needed. If clients are struggling to maintain their housing, provisions and contingencies will be addressed by the team. The assessment will inform the level of support necessary. In general, in Phase I (months 0-4), the client and Case Manager meet at least twice per week. The primary goal of this stage is to help the client become familiar with their new community via community mapping. In Phase II (months 4-8), the frequency of meetings is reduced, if appropriate. In Phase III (months 9+), next steps will be discussed and planned with the client. Throughout this process, the Case Manager works closely with the landlord and other community service providers to ensure that the client is well supported.

**Staffing:** The ICM team will be comprised of experienced Coast personnel who transfer into the new positions as well as new hires with the required competencies. In additions to training provided by the National Project Team, Coast provides in-house training in concurrent disorders, non-violent crisis intervention, first aid and psychosocial rehabilitation skills. Coast also has a long history of including
and engaging people with lived experience in their program planning, as peer support workers and in other forms of paid employment.

Program Organization & Communication: Recruitment, hiring, training and staff orientation will occur during the project implementation phase. Specific program procedures, communication materials and policies will be developed and refined during this implementation phase. Follow-up support will require multi-agency collaborations. Coast has a long history of collaborative partnerships and will continue to build these relationships through presentations with community providers, the development of information and referral packages, and the coordination of regular meetings with outreach programs throughout the city. Coast is a large organization which has a comprehensive infrastructure to support a range of programs and services. The ICM team will have access to IT, meeting space, administrative services, fundraising, communications and HR.

Services: Programming is based on a psychosocial rehabilitation/recovery model as well as strong harm reduction principles. The ICM model will broker services outside the team and will closely follow services provided through Coast’s existing outreach teams, with further development in collaboration with other study sites (e.g., use of common tools and outcome measures such as the Outcome Star). Coast has established many services which clients from the ICM group could access, including meal and basic needs programs, employment and vocational programs, educational funds, training and employment in Coast Landscapes (social enterprise), access to recovery groups, art programs, volunteer opportunities, and various social programs.

The interventions for clients with concurrent disorders will include motivational enhancement strategies such as enhancing motivation for treatment and discussing the interactive effects of mental and substance use disorders; referral to providers of integrated substance abuse and mental health services or, if integrated services are not available or accessible, facilitating communication between separate brokered mental health and substance abuse service providers; and coordinating with community-based services to support the client's involvement in mutual self-help groups and outpatient treatment activities.

4.4.4 Congregate Housing with Supports:
Congregate housing and supports will be provided by the Portland Hotel Society (PHS). PHS has been operating since 1993 to serve individuals who are the hardest-to-house (e.g., those with mental illness, HIV, criminal history, substance abuse problems). PHS runs a number of innovative services including congregate, low-barrier housing. (See Appendix 1.0 for profile). The Congregate Housing with Supports condition was included given the difficulty of obtaining affordable rental stock in the current rental market (vacancy rate <1.0%) and in recognition that, in Vancouver, this is the dominant housing model for people who are homeless and mentally ill. Congregate housing will operate based on the Housing First model and will focus on building community acceptance.

Admission/discharge: Individuals who meet the project inclusion criteria for a high-level of need and are randomized assigned to Congregate Housing with Supports will be directed to PHS for intake. As in all conditions, tenant needs will drive service planning and decision making. The congregate model will focus on fostering community and bringing relevant services and supports to the tenant. The congregate model works from the principle that housing is a human right and is the foundation for stability in all other aspects of tenants’ lives. Discharge based on negative outcomes is very unlikely
(e.g., extreme levels of violence). If a tenant is incarcerated for an extended period of time, they will be considered ‘inactive’ rather than discharged. If the support team decides that discharge is an appropriate course of action, a documented process will be followed. There is no time-limit imposed on tenancy.

**Service intensity/capacity:** In the first six months of the program, the Case Manager (or related staff) will make frequent visits to engage with tenants and build trust, and to ensure that the necessary community links are being established or maintained at the tenant’s pace. The Case Manager will work with tenants to modify service plans (if applicable) on an ongoing basis as their needs change. All changes to service plans will be developed jointly by the Case Manager along with the tenant.

**Staffing:** Basic business management of the building(s) (i.e., housekeeping, property management, meal provision, etc.) will be funded through the operational budget provided by BC Housing or another partner organization. A minimum two staff will be present in the building 24-hours per day, 7 days per week. Additional staff may be required on the evening shift if significant crisis intervention and supports are needed. Clinical care will be provided by a team of primary care practitioners (nurse or family physician), psychiatry, counseling, case manager, a physician who can administer methadone, concurrent disorders specialist, and psychosocial rehabilitation (community integration and programming, etc.). Staff will be recruited, trained and supported within the organizational culture of the PHS.

**Program organization & communication:** Programming will be based on the philosophies and values of the PHS: helping marginalized individuals stabilize their lives by understanding and accepting the tenant’s reality and through community development, ownership and integration.

**Assessment & treatment planning:** Significant issues in many domains of daily living will need to be addressed via on- and off-site supports. If appropriate, tenants will have an individual service plan that addresses risks, needs and strengths in order to help them maintain housing and gain independence. Community participation and reintegration will form the backbone of individual service plans. The plans will be created and modified in full collaboration with tenants.

**Services:** The Congregate housing condition will be developed to include services that are standardized and comparable in their range, intensity and likely effectiveness to those described in the ACT condition, above. Many clients will require medications for physical and/or mental health conditions; medications can be administered via an on-site program or an external delivery program or nearby administration site. Some clients may use IV substances; needles should be available on-site, whether via a formal exchange or a more individualized approach. Some tenants will need a meal program. An off-site meal program, available nearby, will be the most cost-effective option.

Many clients will need their finances administered. This is best provided via an external service but can be provided on-site. A money management plan may also be developed, including how and when benefits are received, and a budget for rent and other necessities. Staff will work with the tenant and the financial lead at PHS to ensure that all necessary payments are made on time to the client or any other payee necessary. A significant number of tenants will pursue education, employment and volunteer activities. These services will be provided externally, although on-site supports will encourage clients and help them problem-solve participation issues. Tenants will be encouraged to
participate in social activities in their communities that relate to their own experiences and interests. Staff will ensure that tenants are aware of peer supports in their communities, including groups and clubs that focus on clients’ personal interests. Services will be embedded in a continuum that allows priority access for tenants to enter “next step” housing, if they wish.

For each of the interventions described above (i.e., ACT, ICM, Congregate), accurate and timely record keeping (based on an electronic health record system) is critical for all work and communications with or about a client. Record keeping should be completed within 5-7 business days of the service/meeting. Accountability to clients, landlords and the community is achieved via ensuring follow-through on roles, responsibilities and expectations and being accessible. The service provider lead organization will be responsible for the delivery of their respective intervention.

4.4.5 Treatment as Usual (TAU)

Given recent innovations in housing and supports in Vancouver, many opportunities for housing and supports will be available to individuals in the TAU condition. The Vancouver Coastal Health Authority and several Provincial Ministries have initiated innovative programs designed to improve outcomes for people with mental disorders, housing, and other diverse challenges in the DTES (e.g., Community Court, the Burnaby Centre for Mental Health & Addiction). The City of Vancouver and BC Housing have purchased eighteen SROs, and additional supported housing is being developed through additional partnerships. The Ministry of Employment & Income Assistance was recently reconstituted as the Ministry of Housing & Social Development, with responsibility to integrate housing and other publicly funded services. Monitoring the outcomes associated with this group is important for comparison to those in the intervention groups as well as to assess fluctuations in the course of homelessness.

4.5 Follow-up and Retention Procedures

Careful tracking will be critical to ensure a high response rate and to minimize attrition bias, particularly for the TAU group. Steps to retain participants will include regular contacts with all participants at 6-month intervals over the course of the 2 year follow-up and regularly updating contact information gathered from administrative data, participating service providers and public records. The TAU group will be encouraged to visit the field office on a monthly basis to check in with staff and to update their contact information. In addition to the remuneration they receive for participating in the five interviews, participants in this group will receive a $10 honorarium for each month that they check in. Food will also be available to further encourage field office visits. For those participants who cannot be located in-person or reached by phone, outreach workers in the community will inquire about their whereabouts. Locating these participants will require the full-time efforts of trained field workers (e.g., peer researchers) who are well-embedded in the community and are familiar with following homeless individuals over a period of time.

4.6 Outcome Measures and Timelines

Data collection will occur in three main areas, which are detailed below: (1) Physical and mental health (including substance use); (2) Psychosocial determinants of health and consequences of change; and (3) Cross-sector administrative data and cost outcomes. Unless otherwise indicated, data collection will occur at baseline and every six months for two years. A number of instruments are suggested in the following sections but will not be finalized until after discussion with the National Team. The focus will be on instruments that are used internationally and have sound psychometric properties. Please see Addendum B for a copy of all proposed instruments.
4.6.1 Physical and Mental Health

Mental health symptoms and severity (including substance use and all Axis I and II diagnoses) will be assessed using the Symptom Checklist (SCL-90) and the MINI or the Psychiatric Diagnostic Screening Questionnaire (PDSQ). Other instruments suggested for the assessment of substance dependence/abuse include the Global Appraisal of Individual Needs (GAINS) – Substance Problem Scale, the Diagnostic Interview Schedule (DIS) and the Opiate Treatment Index. Adverse events, stress, and trauma symptoms are additional variables of interest and could be measured using the START Outcome Scale\(^3\), Childhood Trauma Questionnaire and/or Adverse Childhood Events Scale, and the Trauma Symptom Checklist-40.

Given the known high mortality and the dearth of data regarding physical health conditions among people who are homeless, 20% of participants (a random sample of 20 per group, for a total of 100) will be accompanied by peer researchers to a research office at St. Paul’s Hospital where physical assessments will be coordinated. If participants are in treatment or have received a recent physical examination, we will ask the participant for permission to access relevant details from their health record. The specific assessments and timelines proposed for physical health examinations are summarized in Table 1. If a participant in any treatment group is identified as having a medical condition that is in need of treatment, appropriate referrals will be made. Participants will receive an honorarium of $50 for each physical examination.

**Table 1. Proposed Physical Health Assessments and Timelines**

<table>
<thead>
<tr>
<th>Physical Health Assessments</th>
<th>T-1 (Inclusion)</th>
<th>T0 (Intake, Assignment)</th>
<th>T1 (+6)</th>
<th>T2 (+12)</th>
<th>T3 (+18)</th>
<th>T4 (+24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opiate Treatment Index</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Chronic Health Scale</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical exam [subsample] including electrocardiogram, X-Ray, MRT, derma exam, basic blood work, infection screen (HIV, HCV, STD), basic urine toxicology, TB skin test</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

4.6.2 Psychosocial Determinants and Consequences of Change

Both qualitative and quantitative data will be collected through three core methods: semi-structured interviews, surveys/questionnaires and focus groups. The initial data will be largely descriptive. Over time, it will be possible to collect longitudinal data from health professionals, service and housing providers and clients. Whenever possible, data collection procedures will be triangulated to ensure accuracy and validity (e.g., base rates). All interviewers will be trained to administer the survey instruments in a consistent and standardized manner.

4.6.2.1 Surveys and Questionnaires

The survey instruments consist of previously validated measures recommended by the National Project Team. We have also proposed a number of additional relevant measures. Copies of instruments are presented in Addendum B. Please see Appendix 5.0 for a summary of the timing of administration.

Housing status over the preceding 6 months will be determined at baseline and at the time of each follow-up interview using the Housing Timeline Follow-Back Calendar (HTFBC). The primary outcome variable will be housing status at the time of the 2 year follow-up interview, defined as being either: (1) Homeless, or (2) Stable Housing (living for a continuous period of at least 90 days in a house,

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\(^3\) The SOS is based on the core of the modified Overt Aggression Scale (see Addendum for a copy of this instrument).
apartment, SRO hotel, rooming house, or any other place of one’s own for which one pays rent; Ontario MCFS, 2004). Other outcome variables to be derived from the HTFBC will include: (1) housing status at each follow-up period; (2) number of housing transitions over the previous 6 months; (3) number of nights spent homeless over the previous 6 months. The Housing Quality Score will be used to determine self-reported quality of current living conditions in terms of comfort, safety, spaciousness, privacy, friendliness and overall quality.

Demographic characteristics will be collected using subsections of the Community Mental Health Evaluation Initiative (CMEI). Quality of life will be assessed using two instruments: (1) The Quality of Life for Homeless & Hard to House Individuals (QOLHHI) Instrument (Hubley & Palepu, in preparation); and (2) the EuroQol (EQ5D), a standardized health-related quality of life instrument that generates a composite score reflecting the preference value associated with a given health state, and a global rating of current health using a visual analog scale. General functioning will be assessed using the Multnomah Community Ability Scale (MCAS). Resiliency will be assessed using the 3-item Sense of Coherence Scale. Vocational outcomes will be assessed using a timeline follow-back interview from the Montreal IPS study (indicated by MHCC), which examines work status and various details of work (e.g., setting, timing, hours, compensation, etc.).

The Sarason Social Questionnaire (SSQ-Short form) will be used to measure perceived number of social supports and satisfaction with available social supports. Family history and critical life events will be assessed using items developed by Roy et al. for the Montreal Street Youth Cohort Study. The Objective Social Outcomes Index (SIX) will be used to assess social outcomes related to mental illness.

4.6.2.2 Semi-Structured Interviews

We propose to interview individual participants and, where possible, services providers, and health professionals in relation to our hypotheses. Interviews will be in-person or by telephone. A draft interview protocol will be developed in collaboration with the local/national team and will be pilot tested with clients to ensure clarity, appropriate length, inter-rater reliability and lack of redundancy. Experienced graduate students and/or service providers or peer interviewers will conduct the interviews. This component of the data collection should take about 90 minutes to complete.

**Personal Stories:** Following the baseline quantitative interviews, study participants will be invited to participate in a second set of interviews that will focus on their life story. Approximately 10 participants from each study “arm” will be randomly selected to participate in semi-structured interviews that will address personal experiences with homelessness and mental illness. An equal distribution of men and women will be attempted (20 from the moderate needs group and 30 from the high needs group).

Two personal life story interviews will be conducted. The first interview will take place approximately 30 days after the participant entered the study and will focus on particular events, memories or episodes in their lives (one high point, one low point, one turning point) that occurred prior to and in the early stages of their participation in the study. The second interview will take place 18 months later and will focus on specific experiences related to their housing, support and clinical services. For participants who have been randomized to one of the intervention groups, questions will focus on their experiences with service providers and will include seeking permission to also interview their service providers. For participants who have been randomized to one of the TAU groups, a parallel set of questions will focus on their experiences with community service providers.
Interviews will be conducted by graduate students or service providers paired with a peer interviewer. During the interviews, respondents will be encouraged to address each topic in their own way and using their own words. This approach is essential for obtaining valid data on potentially sensitive issues by facilitating rapport between interviewer and participant. An open-ended approach allows participants to introduce substantive topics not considered by researchers (Berg 1995). Interviews will last approximately two hours and, with permission, will be recorded for full transcription and analysis. If participants refuse permission to record, researchers will take detailed notes during the interview. An honorarium of $50 will be provided for participation.

Qualitative interviews and focus groups will be conducted to illuminate issues regarding individuals’ experience of homelessness and service provision. Interviews will be conducted with a subset of randomly selected participants, staff, and other key stakeholders as outlined in the RFP.

4.6.2.3 Focus Groups

It is important to examine group perspectives on homelessness. Focus groups will be used with subsets of participants, service providers and key stakeholders to gain a better understanding of homelessness, mental illness and service provision/utilization. We propose an annual focus group with clients randomly selected from each housing/treatment condition. Each group will begin with an introduction followed by a discussion about participants’ behavioural intentions for dealing with psychosocial issues. A facilitator and a recorder (trained collaborators or graduate students) will lead each group. Key points will be recorded on flip charts and audio-taped for in-depth analysis. The facilitator and recorder will meet before and after each session to ensure quality and consistency.

**Planning & Proposal Development:** Data will be gathered in the following areas via focus groups, key informant interviews, and review of program planning documents: (a) Planning processes; (b) Principles and values guiding the planning process; (c) Planning actions, and (d) Stakeholder relationships. This data will be gathered by graduate research assistants during the recruitment and baseline data gathering phase (Sept/09 – March/10).

**Implementation Phase:** Data will be gathered from key stakeholders in the housing and clinical components of the project in the following areas: (a) Implementation processes; (b) Principles and values guiding the implementation process; (c) Implementation actions; and (d) Stakeholder relationships. Data collection will include focus groups, key informant interviews, and review of program planning documents after the project has been running for one year (September 2010).

4.6.3 Cost Outcome Analyses & Administrative Data

All study participants will be asked to provide consent for the research team to utilize their personal identifiers (i.e., name, date of birth, personal health number) to obtain administrative data reflecting their health care utilization (hospital, physician services, prescriptions), social services utilization (income assistance, disability and unemployment benefits) and criminal justice encounters (arrests and Provincial sentences). The research team at CARMHA has extensive experience collaborating with government agencies in the linkage and analysis of these data. The costs associated with service events have been established through previous studies by CARMHA and the Provincial Government, and will be the basis for econometric analyses in the current study.

Data will be sought retrospectively to 1996, enriching our understanding of the trajectories of service utilization preceding study participation. These data will be refreshed and updated each year through
the active study period (2009-2013), and then bi-annually until 2019. Funds to support research following the study period will be sought separately.

4.6.4 Additional Outcomes of Interest

The core data collection will be leveraged for other outcomes of interest. Participating service providers and health professionals will be asked to complete the Health Professionals’ Attitudes to Homeless Inventory (HPATHI) which assesses comfort/attitudes, interest, and confidence of health professionals in work with homeless and at risk persons.

Employment and income assistance trajectories will also be examined over time, with particular attention paid to the experiences of women. These will be important outcome measures given their contribution to individual self-sufficiency and housing stability.

4.7 Good Clinical Practice

As an RTC, by design, we are obliged to comply with the Guidelines for Good Clinical Practice (GCP; 1996), an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve human subjects. Components of GCP are addressed at various points throughout this application; however, a thorough review of GCP, including Standard Operating Procedures, training, reporting, external audits, will need to be developed for all three intervention conditions as well as the TAU group outside the scope of this application.

4.8 Data Integrity and Management

All data will be retained in established, secure data facilities created at CARMHA at the downtown campus of Simon Fraser University. Data collection infrastructure will be provided by a professional information systems vendor and will include equipment for field data collection, secured mechanisms for transmission and processes for quality control. Protocols for data security and integrity are maintained by CARMHA and would be extended to include the data gathered from this study.

- Processes for the involvement of consumers as co-investigators and interviewers
- Partnerships with multiple Provincial Ministries, health agencies, and non-profits in order to gather, maintain, and analyze primary data and linked administrative data
- On site facilities for secure data input, verification, archiving, back-up, analysis
- Expertise on site to design and direct chain of custody for all data, sharing with relevant investigators in Vancouver and the National team

We will also develop additional resources for key operational tasks, including data collection and entry (graduate research assistants); data verification and management (Data Analyst/Manager); analytic consultant(s) specific to distinct methodological areas, including path analysis and econometrics (e.g., health economist); and additional computational resources, as needed.

4.9 General Approach to Data Analysis

Quantitative Data Structure

The data structure for the quantitative analyses is outlined in Table 2 below (which presents the general structure of this data file for a single participant [case 01] who is assumed to have been interviewed in each of the five waves of data collection). The first row (shaded) shows the structure of the baseline study used for cross-sectional analyses. The five rows taken together represent the repeated data over the course of the study period. All analyses will be based on an intent to treat.
Table 2: Structure of the RCT Longitudinal Quantitative Data

<table>
<thead>
<tr>
<th>Case ID</th>
<th>Time</th>
<th>Stable Covariates</th>
<th>Time-Varying Covariates</th>
<th>MH/SA Status</th>
<th>Homelessness Status</th>
<th>Service Utilization</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Baseline</td>
<td>X</td>
<td>Y₁</td>
<td>Z₁</td>
<td>H₁</td>
<td>S₁</td>
</tr>
<tr>
<td>01</td>
<td>6 mos</td>
<td>X</td>
<td>Y₁</td>
<td>Z₂</td>
<td>H₂</td>
<td>S₂</td>
</tr>
<tr>
<td>01</td>
<td>12 mos.</td>
<td>X</td>
<td>Y₁</td>
<td>Z₃</td>
<td>H₃</td>
<td>S₃</td>
</tr>
<tr>
<td>01</td>
<td>18 mos.</td>
<td>X</td>
<td>Y₁</td>
<td>Z₄</td>
<td>H₄</td>
<td>S₄</td>
</tr>
<tr>
<td>01</td>
<td>24 mos.</td>
<td>X</td>
<td>Y₁</td>
<td>Z₅</td>
<td>H₅</td>
<td>S₅</td>
</tr>
</tbody>
</table>

Definitions:
X = A vector of variables and/or indicators representing individual characteristics whose values do not change over time. Examples include gender, age at entry, race/ethnicity and group intervention.
Yᵢ = A vector of variables and indicators whose values at baseline may need to be repeatedly updated. Examples are psycho-social indicators such as family structure, income, indicators of social capital (family, marital status and social network indicators), human capital (schooling and employment status), indicators of resiliency (sense of coherence) and other events (e.g., a serious illness or injury) that occurred in the 6months prior to the iᵗʰ interview.
Zᵢ = A vector of indicators of alcohol, drug and mental health status as of the iᵗʰ interview. The time frame for these measures extends from “past week” or “last 30 days” to “last 6 months”.
Hᵢ = A vector of indicators of housing circumstances in the 6 months prior to the iᵗʰ interview year. See the discussion of these measures under Aim 1 below.
Sᵢ = A vector of indicators of services used during the 6 months prior to the iᵗʰ interview. These include services connected to receipt of the interventions (e.g., substance abuse treatment or work programs). These data will consist of information from records as well as self-reports.

Quantitative Data Analysis

In its most basic form, each RCT can be viewed as a mixed-effects 2 by 5 model (or in the case of the high needs group, a 3 by 5 model) with a number of different outcome measures of interest based on specific hypotheses (see section 2.3 for the outcome measures) and a number of potential covariates. The hypotheses address comparisons of specific sub-groups within the overall model.

The general analysis plan proposes several broad strategies of data analysis that will build upon the data as it is collected over the study period. The approach to analysis will begin with a baseline examination of the distribution of key factors across each sub-group. This univariate comparison of the distributions of key individual characteristics (e.g., demographic characteristics, substance abuse and mental health indicators) across each RCT sub-group will provide for an assessment of the effectiveness of the randomization process as well as identification of potential confounding factors that need to be accounted for in further analyses. Preliminary steps for all analyses will also involve assessing bivariate cross-tabulations and correlation matrices for relationships among variables. All variables will be checked with regard to their distribution (e.g., for normality and departures from normality) using frequency distributions, scatter plots and histograms. Statistics such as means, standard deviations, ranges, modes, medians and estimates of skewness and kurtosis will be computed.

We propose to assess our primary and secondary hypotheses using two approaches. The first (and simplest) is to perform cross-sectional analyses at each of the five measurement points (baseline, 6 months, etc.) comparing the 5 distinct intervention groups on the measure of interest at each point in time. Depending on the measure, this can be done using a non-parametric comparison for the categorical measures such as physical health status or parametric comparison (with confidence intervals) for the continuous measures (such as number of days housed). Plotted over time, this approach can provide a straight-forward and visual assessment of the relationship between the various interventions and the outcomes of interest. This approach, however, does not take into account the role of time or the variation within-groups over time specified in the hypotheses. Thus, we propose to conduct a number of longitudinal repeated measures analyses with the choice of the exact model depending on the intent of the individual hypotheses. We will begin with Generalized
Estimating Equations (GEE), adding in the specific interaction terms of interest as specified in the various hypotheses. This approach is based on specific assumptions around the pattern of missing data and will be adjusted as need be. An alternative approach is in the assessment of individual trajectories and draws from random effects models. Random effects models allow for a measure of variability in individual trajectories around the average group trajectory and are especially useful when it is reasonable to think of individual trajectories as a sample from the population of homelessness trajectories. All models will be implemented utilizing software applications which have the capability of modeling complex error structures at both the across individual (e.g., each person has their own trajectory of homelessness) as well as the within-individual (e.g., auto-correlated error structures of individuals’ responses within their across time homelessness trajectory) levels.

**Analytic Limitations: Missing Data.** A concern throughout the analyses is the effect of missing data due to item non-response as well as panel attrition. In the case of missing data due to item non-response among persons who participate in a cycle of data collection, we plan to implement imputation methods, particularly for critical variables utilized in the cross-sectional presentation of the results. In general, we will use multiple imputation methods (Rubin, 1987) involving MCMC simulations. Available methods (Rubin, 1987) will be used to combine analysis results from multiple imputations that incorporate the uncertainty due to item non-response in the estimates of parameter variances. Models based on GEE (or related) approaches do not require the estimation of missing data.

*Panel attrition.* This is often more influential than item non-response on the comparison of groups. We will begin with a comprehensive investigation of baseline characteristics associated with patterns of participation will be examined by study follow-up wave to help identify the characteristics associated with trends in participation over time. Variables found to be significantly associated with attrition will be included as covariates in the models.

*Power considerations.* In light of the well-defined criteria established by the MHCC surrounding the sample size of each intervention arm as well as the understanding that the MHCC criteria takes account of panel attrition, no power calculations were conducted within the context of this application.

*Administrative Data.* The administrative data will be linked and incorporated with the quantitative data based on the appropriate vector of variables (see Table 2 above). Quantitative data analyses will be conducted drawing from these data in the same manner as that of data collected in the study.

**Qualitative Data.** We will begin constructing the qualitative database by entering and coding field notes, and transcribing the audio-taped interviews using NUD.IST and/or NVIVO software. One of the PIs (JF) has extensive experience in qualitative data analyses and has successfully used this software in prior studies. Simultaneous and iterative conduct of data collection and coding is central to qualitative research as it allows investigators to take advantage of insights that emerge during the course of fieldwork (Strauss, 1987). As data accumulates, the coding scheme will change to reflect the generation of new insights and the accumulation of increasingly detailed information. Thus, the outline presented above is an initial coding scheme that will change and expand over the course of the project.

Once we have identified and coded field note and interview data, the next step in analysis will be to distinguish repeated patterns from idiosyncratic individual statements and actions. This will be done by identifying which codes appear only infrequently in our database and which recur in a wide variety of interview transcripts and field notes. To enhance reliability, multiple analysts will examine the content of coded statements to ensure their accuracy and coding discrepancies will be identified
and addressed. Conducting analysis simultaneously with ongoing fieldwork will allow us to follow up on important statements, observations, and behaviors in later interviews and fieldwork (Glaser & Strauss, 1967). As observations and interviews progress, we will compose analytic memos that summarize the in-progress findings in the qualitative database, and help to identify areas for ongoing fieldwork. As the database grows, we will begin to identify similarities and differences across service settings and different groups of participants in the study.

5.0 Ethical Considerations

This project will be conducted in accordance with the Research Ethics Boards of SFU, UBC and the Tri-Council Policy Statement on Research Involving Human Subjects. The research team at CARMHA has extensive experience managing large databases of sensitive information. No identifying personal information about the study participants will be kept with any of the interview or administrative data. All electronic and paper records will be maintained using existing protocols and facilities at SFU Harbour Centre. Dedicated server rooms, work stations, and filing systems are all maintained in a secure environment that is audited for security and compliance with best practice. Records linking participants’ study identification number and personal data will be kept under lock by the Research Coordinator at CARMHA, in a location separate from where questionnaires will be stored. Identifiers will be removed from all data as soon as possible. Furthermore, all research personnel who have access to raw data will be bound by confidentiality agreements.

5.1 Quantitative Data

Risks to subjects. Human subjects involvement. Baseline interviews will be conducted with 500 participants with four follow-up interviews over a period of 2 years. All participants will be of legal adult status. Potential risks associated with the interviews are embarrassment and discomfort from discussing matters such as personal mental health problems or drug use. However, past research with similar surveys indicates that such risk is minimal. Further, these potential risks can be minimized by training interviewers carefully and by assuring subjects that interviews will be conducted in private. Another potential risk involves updating contact information at each follow-up interview with respondents who had nearly been lost to follow-up. This information is given voluntarily, and respondents will be familiarized with this process.

Within the context of this study, it is expected that the mental health problems and symptoms of both the moderate and high needs groups will diminish over time. Given the target population and the chronic nature of mental illness, it is likely that some individuals will, over time, move between the high and moderate needs group. However, there is a possibility that some individuals in the moderate need group could experience a significant escalation in their symptoms. In this event, the individual’s case will be brought forward to an as yet to be determined committee of researchers and service providers, including a physician, in order to evaluate whether or not the individual or others are in significant danger. In the event that the committee determines the individual is a risk to self or others, the individual will be referred for more intensive treatment.

Physical health examinations (PHE) will be completed with a subset (20%) of study participants at baseline and at 24 months following baseline. PHEs will be carried out by qualified physicians who have expertise providing care to homeless and seriously ill urban patients. Participants will have the option of refusing or discontinuing PHEs at any point. The PHE are anticipated to reveal untreated or undertreated health conditions, which may require immediate or urgent treatment. Good clinical practice will govern the follow up and treatment of medical conditions identified in PHEs.
**Adequacy of Protection Against Risks.** *Informed Consent.* Prior to the baseline interview, all respondents will be evaluated for competency with regard to their ability to understand informed consent. Once competency has been established, signed informed consent will be obtained from all respondents. A lengthy consent form will be read to the respondent authorizing consent to be interviewed, to be randomized to a housing and services group, to have administrative records accessed by the study team, to participate in the qualitative interviews, and to be re-contacted for the follow-up or longitudinal tracing through personal contact information and through public records. As part of the informed consent process, individuals will be informed that: (a) participation is voluntary, and that there are no consequences for refusal to participate; (b) they could be randomized to a condition of ‘usual care’; (c) participation will involve answering questions about their background, health problems, housing circumstances, and their experiences with services; (d) even after consenting to participate, participants can interrupt the interview at any point or refuse any treatment, services or to answer any question; (e) all responses and results will be entirely confidential, and no identifying information will appear in any material associated with the study; and (f) no information about respondents as individuals will be shared with parties outside the research team. At each subsequent follow-up interview, verbal consent will be obtained after providing study participants with a description of the general content of the interview, notifying them that all information will remain completely confidential, and that participating in the study will be completely voluntary. After the interview, information relevant to tracing and the next follow-up will obtained. Respondents will receive a $40 honorarium for their participation in each quantitative interview.

5.2 Qualitative Data.

**Human Subject Involvement.** The second component of this study includes in-depth interviews (one approximately 30 days following baseline study enrollment and the other approximately 18 months later) with 50 participants from the RCT. Respondents will be encouraged to address topics of interest using their own words. The baseline interview protocols, yet to be developed, will have an introductory discussion of the respondent’s background and current situation. After establishing rapport, interviewers will turn to potentially more-sensitive topics, such as attitudes towards homelessness, substance abuse and interactions with service providers. Participants will receive an honorarium of $50 for their participation.

**Potential risks.** This study component involves minimal risks to participants. Again, potential risks associated with the interview are embarrassment and discomfort in providing information about matters such as homelessness, mental health and drug use. However, the research team’s past experience with similar populations indicates that such risk is minimal. Furthermore, these potential risks will be minimized through interviewer training and by assuring that the interviews will be conducted in private. Since we do not require respondents’ names for this component of the study, we will seek a waiver of written informed consent and develop an oral informed-consent procedure.

**Adequacy of protection against risks.** *Informed consent and confidentiality.* All required components of informed consent will be included and reviewed with participants. To further minimize risks, we will maintain strict respondent confidentiality by conducting interviews in private locations, by employing an ID system to assure that respondent names are never associated with transcripts, by storing interview tapes and transcripts in secured locations and password-protecting computer files. Only select research staff will ever have access to identifying information.
5.3 Administrative Data.

**Risk to Subjects: Human Subject Involvement.** All study participants will be asked to provide consent for the researchers to utilize their personal identifiers (i.e., name, date of birth, personal health number) to obtain administrative data reflecting their health care utilization (hospital, physician services, prescriptions), social services utilization (income assistance, disability and unemployment benefits) and criminal justice encounters (arrests and Provincial sentences). Data will be sought retrospectively to 1996 and will be refreshed and updated each year through the active study period (2009-2013), and then bi-annually until 2019.

**Potential risks.** This study component involves minimal potential risks to participants. However, a potential risk associated with collection of the administrative data surrounds embarrassment and discomfort in the event that the individual’s identity is compromised. In order to minimize this potential risk, the electronic dataset used for the analyses proposed here will include no personal identifying information. Results will be reported in ways that do not reveal respondent identities.

**Adequacy of protection against risks.** *Informed consent.* During the consent procedures we will emphasize that: a) participation is completely voluntary; b) even after consenting to participate, they may refuse access to their administrative data; c) and no personal identifying information will appear in any materials associated with the study. No identifying personal information about the study participants will be kept with any of the administrative data. Records linking participant’s study identification number and administrative data will be kept under lock by the Project Manager at CARMHA. All personal identifiers will be removed from the administrative data as soon as possible.

5.4 Procedures for REB approval

Upon notice of grant award, an application for human subjects approval will be submitted to the Research Ethics Boards at SFU and UBC. The applications will be submitted simultaneously and will be identical with the exception of institutional requirements that vary. The application for ethics approval will include both the RCT studies as well as a request to utilize and publish the results drawn from the key informant interviews with persons with lived experience that were conducted under contract with the MHCC. Contact with human subjects will not proceed until REB approval has been obtained from both SFU and UBC.

6.0 Sustainability

We are committed to ensuring that all participants are able to maintain their housing and receive the supports required beyond this project. We have had initial discussions with BC Housing regarding the sustainability of housing subsidies for those in scattered-site units as well as possible transitional options for people housed in the congregate setting. It is possible that we will not be able to secure sufficient ongoing housing subsidies for all participants and transition to alternative housing and supports may be necessary. We will work with individuals and link to the BC Housing Coordinated Access to Housing team in Vancouver to ensure successful transitions as needed. It is anticipated that a significant number of the new housing units currently under development will be available both before and after the end of the project and we will explore these options with BC Housing as they become available. We will continue to forge a partnership with the Streetohome Foundation and link to its work on housing and service reform locally. We have also held initial conversations with the BC Ministry of Health to explore ways to ensure sustainability of funding for the services required for participants post-project, particularly with respect to the ACT intervention. Through engagement of our advisory and oversight committees as well as through meetings with provincial and local decision makers, academics and service providers, and people with lived experience, we will create and sustain
momentum for the project. The local oversight committee, composed of senior decision-makers will also provide a mechanism to leverage funds both during and post-project. It will be critical to actively engage additional key stakeholders locally in order to successfully build a strong local environment for sustainability. In this regard, Vancouver Coastal Health Authority and Providence Health Care – which operates the hospital that provides the majority of emergency and acute hospital-based services to people who experience homelessness and mental illness – are key partners with whom we will need to build strong and formal partnerships both at a governance and operational level. Both organizations have been well represented throughout the Consortium development process. Now that we have identified service leads, it will be critical in the next month to work with both Vancouver Coastal Health Authority and Providence Health Care to clarify their respective roles in supporting implementation of all three of our identified interventions. Moving forward, we will actively explore evidence-based models such as networks/communities of practice to facilitate service integration and knowledge exchange within and between relevant partners and stakeholders.

7.0 Integrated Knowledge Translation Strategy

Effective knowledge translation (KT) is a central goal of this study. We are committed to engaging researchers, research users and people affected by research at all phases of the project including developing questions, defining research methods and interpreting and disseminating results. Our strategy will include knowledge dissemination and dialogue about the research process, findings and policy implications, aimed at a wide range of audiences. The Vancouver site is committed to participating in any cross-site knowledge translation activities as required.

Our team of investigators and collaborators has strong connections to a wide range of research, policy, government, institutional, service-provider and advocacy networks, operating at multiple levels. Our community-based collaborators are leaders of best practices within their field and strong advocates of health equity and change. Their experience in public education, advocacy and their well established community coalitions, media contacts, and policy networks will enable them to be a vital conduit for translating research findings into policy and program implications. KT will also be achieved through activities such as managing partnerships, implementing training and professional development sessions (e.g., on-line training, communities of practice), a frequently updated website, sharing of partnership best practice, providing partnership expertise to all stakeholders involved, and developing and implementing a framework and tools for collecting input from stakeholders. People with direct experience will be centrally involved in all KT activities both as members of the advisory committee and as integral parts of all KT initiatives (i.e., symposia, public stakeholder engagement and ongoing ad hoc round tables regarding ethical considerations, service process and sustainability strategies).

Initial conversations have taken place with the Provincial Health Services Authority who has specific responsibilities in KT provincially. It is envisioned that the project will be able to partner with PHSA effectively to ensure strong and meaningful KT throughout the project. CARMHA and the local site coordinator are involved in the ACT Provincial Advisory Committee and will work with the committee to share learning, build communities of practice and focus on ACT implementation and evaluation.

A central focus of our strategy will be to synthesize research findings into clear and meaningful messages that are tailored to specific stakeholder audiences and their concerns. Our findings will be disseminated through written materials aimed at a variety of audiences including peer-reviewed journals, plain language reports, and media releases. Our team will also engage in a range of
interactive strategies to engage key stakeholders, including presenting our findings at academic, community and policy conferences and workshops; meeting with key decision makers; engaging in media work; and organizing a series of research dialogues in Vancouver. A comprehensive KT strategy will be developed in collaboration with the National Knowledge Broker during the implementation phase of the project.

7.1 Media and Communications
A detailed communication plan will be developed that includes the general public, public affairs/government, internal relations, and media relations. For SFU-affiliated staff, local media and communications will be managed through the President’s Office and SFU Media Relations, collaborating in full with the National Communications Liaison. Media relations will be focused around proactive issues that are identified at the Project Team level, Advisory or Oversight Committees. A formal protocol detailing key spokespersons will be developed and monitored. Key messages will be defined and confirmed collectively whenever possible in order to ensure consistency and quality of messaging. A comprehensive communications strategy will be developed in concert with the National communications person during the course of the implementation phase.

8.0 Project Structure and Governance

8.1 Committees/Teams
The following committees/teams will be necessary for this project:

<table>
<thead>
<tr>
<th>Committee</th>
<th>Purpose of Committee</th>
<th>Membership</th>
<th>Timeframe / Frequency</th>
</tr>
</thead>
</table>
| Project Team                   | • Provides project direction & retains operational responsibility locally  
<pre><code>                            | • Develops and implements a project management structure           | • PI                                   | Bimonthly (more or less frequently if needed) |
</code></pre>
<p>|                                | • Facilitates the development of memos of understanding         | • Co PIs                                                                 |                                        |
|                                | • Develops and uses an issue-resolution mechanism               | • Site Coordinator (Chair)                                               |                                        |
|                                | • Accountable for day-to-day management &amp; execution of the project | • Research Coordinator                                                    |                                        |
|                                |                                                                  | • ACT Lead                                                               |                                        |
|                                |                                                                  | • ICM Lead                                                               |                                        |
|                                |                                                                  | • Housing Lead                                                           |                                        |
|                                |                                                                  | • Congregate Lead                                                        |                                        |
| Research Team                  | • Provides research guidance and expertise                       | • PI &amp; Co-PIs                                                            | Bimonthly (more or less frequently if needed) |
|                                |                                                                  | • Co-investigators                                                       |                                        |
|                                |                                                                  | • Site Coordinator                                                       |                                        |
|                                |                                                                  | • Research Coordinator                                                   |                                        |
| Sub-Research Teams (Physical Health; Psychosocial; Administrative Data) | • Design, conduct and analyze research in respective areas | Individual research teams (Project Manager/Coordinator; research assistants, data analysts, etc.) | Weekly                                 |
| Advisory Committee             | • Provides strategic advice and                                  | • People with Direct Experience                                          | Quarterly                              |</p>
<table>
<thead>
<tr>
<th>Committee</th>
<th>Purpose of Committee</th>
<th>Membership</th>
<th>Timeframe / Frequency</th>
</tr>
</thead>
</table>
| Feedback to Project Team                       | • Provide as needed help with operations  
• Information feedback loop for Project Team and member agencies | • Government  
• Health Authority  
• Service Providers  
• Community Agencies |                                                     |
| Oversight Committee                            | • Ensure high-level awareness and buy-in  
• Discuss sustainability issues (leveraging funds), systems-level changes, etc. | CEOs of health and housing organizations         | Twice annually        |
| Housing Portfolio Lead (MPA)                   | • Secure 200 scattered-site units  
• Administer rental subsidies  
• Build and manage relationships with landlords  
• Property management | • David MacIntyre  
• Sue Baker  
• Housing portfolio development staff | Weekly                                             |
| ACT Team (Rain City Housing)                   | • Establish team  
• Ensure service delivery, | • Greg Richmond  
• ACT team staff | Daily                                                 |
| ICM Team (Coast Mental Health)                 | • Establish team  
• Ensure service delivery | • Darrell Burnham  
• Tracy Schonfeld  
• ICM team staff | Weekly                                             |
| Congregate + Supports Team (Portland Hotel Society) | • Establish team  
• Ensure service delivery, etc. | • Liz Evans  
• Congregate housing and supports staff | Weekly                                             |

### 8.2 Scientific Advisors

A number of senior academics have agreed to provide high-level scientific advice throughout the project including Dr. Alan Marlatt, University of Washington; Dr. Brian Rush, Centre for Addictions and Mental Health; Dr. Ernest Drucker, Montefiore Medical Center and Albert Einstein School of Medicine.

### 8.3 Project Management Capacity/Structure

CARMHA has demonstrated capacity to administer large, interagency research initiatives. Further, all consortium members have established records of multi-agency, multi-disciplinary research projects. Given the Consortium’s decision to not select an overall service lead (see Section 2.2), key service coordination and service-research coordination responsibilities have been assigned to the local site coordinator. Additional staffing resources will be required by the site coordinator to ensure sufficient project management capacity and support.

### 8.4 Project Organization Chart

The following illustrates the reporting structure of the project.
8.5 Roles and Responsibilities of Stakeholders and Project Team

The following descriptions define the general roles and responsibilities of the resources to support this project.

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
</table>
| Principal Investigator      | - Attend meetings of Project Team  
|                              | - Ensuring the delivery of the final product and all interim deliverables as agreed in the RFP  
|                              | - Liaising with National Team and other sites.                                    |
| Co-Principal Investigators   | - Attend meetings of Project Team  
|                              | - Responsible for delivery of products within sub-project or component.            
|                              | - Identifies resource requirements within sub-projects                             |
| Site Coordinator            | - As part of the Project Team, plan and implement project activities              
|                              | - Identifies and acquires resources                                               
|                              | - Manages issues, decisions, changes, and problems to resolution.                  
|                              | - Communicates status and project information to sponsor, committees, and project stakeholders on a regular basis as agreed. |
| Research Coordinator        | - As part of the Project Team, plan and implement research activities             
|                              | - Manages issues, decisions, changes, and problems to resolution.                  
|                              | - Ensures all project tasks and deliverables conform to quality management standards where they exist and are appropriate to the project |
| Co-Investigators            | - Provide guidance and expertise on research-related issues                       
|                              | - Participate in Research Team meetings as needed                                 |
| Service Leads (MPA, Rain City, Coast, PHS) | - Share seat and attendance at National Working Group  
|                              | - Work with Site Coordinator to collaborate with other Service Leads and          |

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## Responsibilities

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assistants, Recruitment Training Purchase Finalization</td>
<td>- Assistants, Recruitment Training Purchase Finalization Secure Registration Submit Recruitment Sub Consortium TBD Denise &amp; Services) (Health - Continuous Relationship - Intake - Screening - Research - Research - Planned and development of Good staff and with leaders: - Interviewers, - examinations National and in assignment - project. - waste management - functioning - adaptation - service - an enabling environment for researchers</td>
</tr>
</tbody>
</table>

### 9.0 Workplan

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Estimated Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year 1 (Commencing April 1, 2009)</strong></td>
<td></td>
</tr>
<tr>
<td>Recruitment of key research personnel (Research Coordinator, Research Assistants, Peer Interviewers, Programmers/Data Analysts)</td>
<td>April – July 2009</td>
</tr>
<tr>
<td>Submit (and refine) Research Ethics Application (SFU and UBC)</td>
<td>April – August 2009</td>
</tr>
<tr>
<td>Develop Good Clinical Practice Guidelines (e.g., Standard Operating Procedures)</td>
<td>April – August 2009</td>
</tr>
<tr>
<td>Registration of Randomized Controlled Trial</td>
<td>April – August 2009</td>
</tr>
<tr>
<td>Secure recruitment sites and a community-based research office</td>
<td>April – August 2009</td>
</tr>
<tr>
<td>Service Planning and Implementation</td>
<td>April – Dec. 2009</td>
</tr>
<tr>
<td>- Infrastructure building and commitment</td>
<td></td>
</tr>
<tr>
<td>- Relationship building and communication (including team building and development of joint leadership)</td>
<td></td>
</tr>
<tr>
<td>- Continuous quality management</td>
<td></td>
</tr>
<tr>
<td>- Service delivery practices</td>
<td></td>
</tr>
<tr>
<td>Finalization of screening, intake, and outcome measures (including discussions with National Project Team),</td>
<td>April – July 2009</td>
</tr>
<tr>
<td>Purchase equipment and set up software</td>
<td>April – June 2009</td>
</tr>
<tr>
<td>Training of research staff in administration of measures (including qualitative interviews)</td>
<td>July – Aug. 2009</td>
</tr>
<tr>
<td>Recruitment of Participants</td>
<td>Sept./09 – Mar/11</td>
</tr>
<tr>
<td>- Screening</td>
<td></td>
</tr>
<tr>
<td>- Intake and group assignment</td>
<td></td>
</tr>
<tr>
<td>- Physical examinations</td>
<td></td>
</tr>
<tr>
<td>Milestone</td>
<td>Estimated Completion Date</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Training and initial validation of interventions</td>
<td>April – Dec. 2009</td>
</tr>
<tr>
<td>- Local training</td>
<td></td>
</tr>
<tr>
<td>- Joint site training</td>
<td></td>
</tr>
<tr>
<td>Establishment of initial core of housing units and sites</td>
<td>April – Dec. 2009</td>
</tr>
<tr>
<td>- Scattered-site units (100 units)</td>
<td></td>
</tr>
<tr>
<td>- Congregate units (approx. 50 units)</td>
<td></td>
</tr>
<tr>
<td>Conduct baseline personal narrative interviews</td>
<td>Sept. 2009 – Sept. 2010</td>
</tr>
<tr>
<td>Gather data on planning process</td>
<td>April – Dec. 2009</td>
</tr>
<tr>
<td>Integration of ACT Team with Provincial ACTPAC</td>
<td>Sept./09 – May/10</td>
</tr>
<tr>
<td>Creation of Linked Administrative Database</td>
<td>January – April 2010</td>
</tr>
<tr>
<td><strong>Year 2 (Commencing April 1, 2010)</strong></td>
<td></td>
</tr>
<tr>
<td>Analyze qualitative data from client narrative interviews</td>
<td>Jan. – March 2010</td>
</tr>
<tr>
<td>Complete qualitative report on Planning &amp; Proposal Development</td>
<td>April 2010                                      (2010) (based on 12 months to full sample)</td>
</tr>
<tr>
<td>Complete acquisition of housing units and sites</td>
<td></td>
</tr>
<tr>
<td>- Scattered-site units (100 additional units)</td>
<td></td>
</tr>
<tr>
<td>- Congregate units (possible second building)</td>
<td></td>
</tr>
<tr>
<td><strong>Primary Data Collection #1: Completion of All Baseline Measures (Wave 1)</strong></td>
<td>Oct. 2010</td>
</tr>
<tr>
<td>Fidelity Verification ACT, ICM, Housing First</td>
<td>Sept. 2010</td>
</tr>
<tr>
<td>Retrospective Analysis of Linked Administrative Data</td>
<td>April – July 2010</td>
</tr>
<tr>
<td>First Annual <em>Housing First &amp; Housing For All</em> Symposium: Envisioning Success</td>
<td>July – August 2010</td>
</tr>
<tr>
<td>Conduct Follow-up (18 month) Personal Narrative Interviewers</td>
<td>July – Nov. 2010</td>
</tr>
<tr>
<td>Gather and analyze qualitative data for Implementation Phase</td>
<td>July – Dec. 2010</td>
</tr>
<tr>
<td><strong>Year 3 (Commencing April 1, 2011)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Primary Data Collection #2: Completion of Follow-up Data Collection (Wave 2)</strong></td>
<td>April 2011</td>
</tr>
<tr>
<td>Completion of sample recruitment</td>
<td>April 2011</td>
</tr>
<tr>
<td>Complete data entry for all baseline measures</td>
<td>May 2011</td>
</tr>
<tr>
<td><strong>Primary Data Collection #3: Completion of Follow-up Data Collection (Wave 3)</strong></td>
<td>Oct. 2011</td>
</tr>
<tr>
<td><strong>Second Annual <em>Housing First &amp; Housing For All</em> Symposium: Lessons Learned</strong></td>
<td>July – Aug. 2011</td>
</tr>
<tr>
<td>Sustainability Planning</td>
<td>(ongoing but intensified in end of Year 3 and through Year 4)</td>
</tr>
<tr>
<td><strong>Year 4 (Commencing April 1, 2012)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Primary Data Collection #4: Completion of Follow-up Data Collection (Wave 4)</strong></td>
<td>April 2012</td>
</tr>
<tr>
<td><strong>Primary Data Collection #5: Completion of Follow-up Data Collection (Wave 5)</strong></td>
<td>Oct. 2012</td>
</tr>
<tr>
<td><strong>Third Annual <em>Housing First &amp; Housing For All</em> Symposium: Preserving What Works</strong></td>
<td>July – Aug. 2012</td>
</tr>
<tr>
<td>Analysis and Major Project Report</td>
<td>Jan. – April 2013</td>
</tr>
</tbody>
</table>
10.0 Budget (See Attached Spreadsheets)
11.0 References (See Appendix 6.0)
Vancouver’s Downtown East Side (DTES) is home to about 16,000 residents. Vancouver Coastal Health (n.d.a) estimated that 3,200 individuals in the DTES have significant health problems and an additional 2,100 have more substantive disturbances that require intensive support and services. However, other estimates suggest an even greater level of need: Eby and Misura (2006) estimated that 5,000 injection drug users are infected with Hepatitis C or HIV/AIDS. Many infected individuals do not receive treatment for their conditions other than medical care through Emergency Departments (Kerr et al, 2005). Furthermore, many of these individuals are homeless or live in unstable housing conditions.

The high concentration of Single Room Occupancy (SRO) hotels in the DTES is also unique to the Vancouver context and has contributed to the urban ghettoization of poverty, mental illness and addiction. A high demand for low income housing is evidenced by the 0.5% vacancy rate for bachelor suites in Vancouver. As a result, affordable housing is far beyond the shelter allowance of people receiving income assistance. The average rent for a bachelor apartment is $736/month, almost double the $375 monthly shelter allowance. In response to the growing levels of homelessness and the related issues in health and social problems, several non-profit organizations have established housing and other supportive services, many of which are in the DTES.

Estimates of the clinical, social and housing service needs within the population of people who are homeless with mental disorders vary widely. Evidence from other urban centres suggests that about one-third of homeless persons have a mental disorder (e.g., Toro, 2007). Goering et al. (2002) found that 64% of first-time shelter users in Toronto had a history of drug abuse and 64% had other psychiatric problems. For those who had previously used shelters, 71% had drug abuse histories and 69% had other psychiatric problems. Despite a lack of precision and consistency among these results, it is clear that mental and substance use disorders are highly prevalent among the homeless. The variability and complexity of need within the homeless population requires evidence-based interventions that respond to individuals with both high and moderate levels of need. Furthermore, diverse behavioural and public health services (e.g., needle exchange, consumption facilities) are in need of expansion. Although Provincial ACT Standards have been developed and a Provincial Advisory Committee has been established to initiate ACT province-wide, currently, there are no Assertive Community Treatment (ACT) teams in Vancouver, and only two in all of BC.

In general, housing in Vancouver for people with multiple barriers due to substance use and other mental disorders has been in *congregate* settings, and this trend is continuing with the purchase and renovation of a number of SROs and the development of congregate housing on 12 city sites. Growing civic commitment and public concern in Vancouver has been directed toward improving the health, autonomy, and quality of life among those who are homeless and have mental disorders. Nevertheless, progress in providing services for this population is hampered by limited resources. Agencies and institutions have also struggled to overcome differences of organizational cultures, mandates and styles of work. Indeed, the preparation of this application has encouraged diverse stakeholder groups to work together and establish a common framework. For the RDP to be successful and, ultimately, for the country to gain the knowledge needed to provide effective services to people who are homeless, a philosophy of shared leadership among high-performance teams that transcend organizational boundaries is vital.

Vancouver’s newly elected Mayor has struck a Task Force to address the issue of homelessness. Numerous city- and province-led initiatives have recently addressed challenges related to homelessness, including reforms to the justice system (e.g., Community Court), expanded mental health services (e.g., Burnaby Centre for Mental Health & Addiction), access to income assistance (e.g.,
Research Demonstration Project in Mental Health and Homelessness (Winnipeg): Full Study

UNIVERSITY OF MANITOBA BANNATYNE CAMPUS
ETHICS SUBMISSION

Project Title: Research Demonstration Project in Mental Health and Homelessness (Winnipeg): Full Study

Principal Investigators:

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103-520 Portage Avenue, Winnipeg, MB, R3C 0G2

Sponsor:

Mental Health Commission of Canada, 10301 Southport Lane, SW. Suite 800, Calgary, Alberta, Canada, T2W 1S7

Duration of Human Subjects Involvement: September 1, 2009 – March 31, 2013

1. Introduction

The goal of this project is to examine the benefits and costs of supported housing programs designed for adults who are homeless and who may have mental illness (including addictions). Specifically, research will examine (a) what this population needs in order to maintain housing and community-based support as well as (b) how homelessness and supported housing impact people in terms of mental and physical health, service utilization criminal justice involvement, independent living skills and quality of life. Ultimately, we hope this research (which is being conducted simultaneously in four other Canadian cities-Vancouver, Toronto, Montreal and Moncton) will influence policy-makers across the country to create more long-term evidence-based housing and supports for people who are homeless and who have mental illness.

This project will be conducted in accordance with the Research Ethics Boards of University of Manitoba (Bannatyne) and the Tri-Council Policy Statement on Research Involving Human Subjects. An Instrument Pre-Test application was submitted on August 4, 2009.

2. Overview of Research Design

Two program variations within the Housing First model (Figure 1) are proposed as the minimum core components that will be funded and studied in all sites for a defined target
population. *Housing First* creates a recovery oriented culture that puts consumer/tenant choice at the centre of all its considerations with respect to the provision of housing and support services. It operates on the principle that all homeless individuals with mental illness should be offered the opportunity to live in permanent housing of varying types that is otherwise available to people without psychiatric, other disabilities or drug and/or alcohol addictions. Assertive in-reach and outreach identifies and engages potential participants.

The research design includes the utilization of randomized controlled trial (RCT) methods in order to evaluate integrated health and housing services. The project involves two subpopulations of homeless individuals, characterized by different eligibility criteria: one group with “high needs” and a second group with “moderate needs”. The project thus consists of two related but distinct RCTs which differ with regard to the severity of participants’ needs, the number of intervention arms, and the type of intervention services. Despite these differences, many of the major methodological features of each RCT will be the same. These include: participant recruitment and retention strategies, tests and measures of outcomes of interest, study hypotheses, and plans for data analysis. In addition, both RCTs incorporate qualitative and quantitative methods along with the secondary analysis of administrative data. (NOTE: a separate ethics application will be submitted for the use and linkage of administrative data by the Manitoba Centre for Health Policy –University of Manitoba).

The Winnipeg Demonstration project will work towards randomizing a total of 540 participants. The sample is considered a stratified proportional sample consisting of 70% Aboriginal participation in each group except the *Ni-Apin* model which is proposed to be 100% Aboriginal. Figure 2 displays the sample structure and the Aboriginal Component.

Three Winnipeg-based service agencies will be involved in the delivery of the various intervention models:

Ma Mawi Wi Chi Itata Centre is a non-mandated, Aboriginal child and family services organization that offers a diverse array of culturally relevant services and programs. Ma Mawi Wi Chi Itata Centre will deliver the Intensive Case Management (ICM) service model.

Mount Carmel Clinic is a community health and wellness centre that provides primary health care services and support programs to people living in the inner city of Winnipeg. Mount Carmel Clinic will deliver the Assertive Community Treatment (ACT) service model.

The Aboriginal Health and Wellness Centre is a mandated primary health care centre that provides service to Aboriginal peoples in the inner city. Aboriginal Health and Wellness Centre will deliver a third housing first intervention that incorporates elements of both the ICM and ACT service models. This third intervention has been referred to as the “Made in Winnipeg” *Ni-Apin* Aboriginal focus model.
Figure 1: Description of Housing First, and Core Intervention Models

<table>
<thead>
<tr>
<th>Housing First Model</th>
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<tbody>
<tr>
<td>• Recovery oriented culture</td>
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<tr>
<td>• Based on consumer choice for all services</td>
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<tr>
<td>• Only requirements: income paid directly as rent; visited at a minimum once a week for pre-determined periods of follow-up supports</td>
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<tr>
<td>• Rent supplements for clients in private market: participants pay 30% or less of their income or the shelter portion of welfare</td>
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<tr>
<td>• Treatment and support services voluntary - clinicians/providers based off site</td>
</tr>
<tr>
<td>• Legal rights to tenancy (no head leases)</td>
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<tr>
<td>• No conditions on housing readiness</td>
</tr>
<tr>
<td>• Program facilitates access to housing stock</td>
</tr>
<tr>
<td>• Apartments are independent living settings primarily in scattered sites</td>
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<tr>
<td>• Services individualized, including cultural adaptations</td>
</tr>
<tr>
<td>• Reduce the negative consequences of substance use</td>
</tr>
<tr>
<td>• Availability of furniture and possibly maintenance services</td>
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<tr>
<td>• Tenancy not tied to engagement in treatment</td>
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<table>
<thead>
<tr>
<th>Assertive Community Treatment (ACT) - High Need</th>
<th>Intensive Case Management (ICM) - Moderate Need</th>
</tr>
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<tbody>
<tr>
<td>• Recovery-oriented ACT team</td>
<td>• Intensive case management for a minimum of one year once housed</td>
</tr>
<tr>
<td>• Client/staff ratio of 10:1 or less and includes a psychiatrist and nurse</td>
<td>• Client/staff ratio of 20:1 or less</td>
</tr>
<tr>
<td>• Program staff are closely involved in hospital admissions and discharges</td>
<td>• Integrated efforts across multiple workers and agencies</td>
</tr>
<tr>
<td>• Teams meet daily and include at least one peer specialist as staff</td>
<td>• Workers accompany clients to appointments</td>
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<tr>
<td>• Seven day a week, 24 hr crisis coverage</td>
<td>• Centralized assignment and monthly case conferences</td>
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</tbody>
</table>

**Moderate** need participants will be randomized to one of three groups; one of two Housing First intervention groups (Scattered-site housing + Intensive Case Management (ICM) or Scattered-site housing + Ni-Apin) or a Treatment as Usual (TAU) group.
Participants with high needs will be randomized to a Housing First program variation (Scattered-site housing + Assertive Community Treatment (ACT) or to a Treatment as Usual (TAU) group (see Figure 2). Participant choice will be maximized in all study conditions, and all study participants who are randomized to an intervention group will receive some form of low-barrier housing as well as intensive support services.

<table>
<thead>
<tr>
<th>Moderate Need</th>
<th>Non-Aboriginal</th>
<th>High Need</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aboriginal</td>
<td>Non-Aboriginal</td>
<td>Aboriginal</td>
</tr>
<tr>
<td>Scattered-Site + ICM Ma Mawi Wi Chi Itata Centre (n=60)</td>
<td>Treatment as Usual (TAU) (n=100)</td>
<td>Scattered-Site (Ni-Apin-Aboriginal Health and Wellness Centre) (n=100)</td>
</tr>
<tr>
<td>Scattered-Site (Ni-Apin-Aboriginal Health and Wellness Centre) (n=100)</td>
<td>Scattered-Site (Ni-Apin-Aboriginal Health and Wellness Centre) (n=100)</td>
<td>Treatment as Usual (TAU) (n=100)</td>
</tr>
</tbody>
</table>

Participants assigned to Housing + ACT will be offered the services of a multi-disciplinary team (nursing, social work, psychiatry, substance use treatment, vocational rehabilitation) in their home and community. Those assigned to Housing + ICM or Housing + Ni-Apin will be followed by a case manager who, if the participant wishes, will help connect them with available health and social services in the community. In all conditions, health and social services are voluntary. The only requirement is that participants meet with a case worker once a week. Participants in the TAU group will not receive housing or health services through this project; however, they will be informed of existing and new services and initiatives from other sources. All study participants will be re-interviewed every 3 months for a period of 2 years from baseline (for a total of eight interviews). A field office will be established to facilitate tracking and interviewing of participants. The field office will be utilized as a confidential location for conducting follow-up interviews as well as a place where participants can ask questions about the project, their next interview (e.g., date, time, etc.), update their contact information and learn about other programs and services in the community.

3. Human Participants
Two categories of human participants will be involved in this study. The majority of participants (n=540) will be adults who are homeless. The second category includes project stakeholders who have been involved in the development and implementation of the project (n=40).
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**Homeless adults**

**Criteria for inclusion** in the project are as follows: (1) Legal adult status (age 18); (2) Meets definition of ‘absolute homelessness’\(^1\), or ‘precariously housed’\(^2\); (3) Presence of any mental disorder with or without a concurrent substance use disorder. (N.B. Formal diagnosis is not required at time of entry into the project.)

**Exclusion criteria:** Failure to meet any of the inclusion criteria and if any of the following conditions are met: (1) Inability to communicate in English; (2) Incarceration or institutionalization (current or imminent); or (3) Refusal to comply with the research protocol (4) inability to give informed consent\(^3\)

**Project Stakeholders**

Individuals who were instrumental in the development and implementation of this project (housing and service providers, researchers, decision-makers, project team members, landlords) will be asked to participate in an individual interview, talking circle\(^4\) or focus group in order to identify challenges and key success factors. Project stakeholders will be identified and invited by the research team by telephone or email to participate.

4. **Recruitment of Homeless Participants**

Recruitment into the project will be completed using a variety of strategies. It is expected that referrals and active street recruitment by research team will be the primary method by which to draw in participants. The research team will actively engage various agencies such as shelters, soup kitchens, drop in centres and food banks in order to make agency staff aware of the project and the way in which participants can be connected to the research team for initial screening (see attached *Advertisement_ Service Providers/Clinics* document). Community agencies, shelters, etc. will be provided with a referral form for potential study participants. The project will be explained to participants by agency workers as well as be given a written information poster. The agencies will then complete a Referral Form (see attached *Referral Form*) to be given to the Research Coordinators who will then be contacted. The Research Coordinator will meet the potential participant and either conduct the screening immediately or arrange for a convenient time in the near future. If the participant is eligible for the study, arrangements will be made to escort the participants to either the appropriate service provider based on high or moderate need, or to the Community Liaison Coordinator at the Main Street Project if the participant is randomized to the Treatment as Usual group.

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1 Absolute homelessness is defined as no secure accommodation for at least 7 nights with a low probability of obtaining housing in the upcoming month.

2 Precariously housed is defined as living in a single room occupancy hotel or similarly inadequate accommodation with at least two episodes of absolute homelessness in the past year.

3 In cases where participants are legally unable to give their informed consent, it may be necessary for the research team to seek the authority from a Legal Decision-maker or a Public Trustee.

4 For a discussion and additional resources on the use of Talking Circles from both a traditional as well as mainstream approach see: [http://firstnationspedagogy.ca/cirtalestalks.html](http://firstnationspedagogy.ca/cirtalestalks.html)
The Downtown Winnipeg Business Improvement Zone’s Downtown Outreach program is anticipated to play a central role in introducing the research team to potential participants and accompanying the interview team on active recruitment in the streets. The street knowledge and presences of Downtown Outreach members is seen as a vital means to establish introductions to some of Winnipeg’s homeless population. It is also an effective way of ensuring the safety of the research team.

It is also expected that the Main Street Project will play a significant role in that its staff will be most aware of potential participants. A number of additional agencies and groups will need to be further consulted to ensure that the Winnipeg sample adequately reflects the population.

Recruitment will also focus on two additional means. The first being the Emergency wards of inner city hospitals and community clinics. In particular, the research team members will be present in the city’s biggest hospital (Health Sciences Centre). It is anticipated that the research team will explore how best to facilitate recruitment from the emergency wards, psychiatry ward discharges and local clinics. The same process will be used for recruitment from clinical sources as is outlined above for community agencies. A second means of recruitment will focus on the Downtown Prosecutor. This individual deals with criminal code violations that include panhandling and other offences such as repeat intoxication charges. The research team is exploring whether the Downtown Prosecutor could assist with referrals (Recruitment Script attached). In addition, a toll-free number will be established for recruitment purposes.

The field research team will conduct information sessions with community organizations and professionals who serve the target population to inform them about the project and gain support. Specific organizations that serve Aboriginal populations have been contacted to encourage a representative sample. Screening will be conducted via laptop computer within community agencies and the field office will be used for baseline and follow-up interviewing. Recruitment to the full sample is estimated to take 18 months (1 year following a 6 month implementation phase).

5. Screening and Baseline Evaluation

Participants having been referred or found by the research team using the above methods will proceed into the study through three initial steps (screening for eligibility, baseline assessment to determine high or moderate need and randomization). The screening of potential participants will be done by the research team who will first determine eligibility based on inclusion criteria (18 or older, legally able to give consent and meeting the definition of homelessness). In order to ensure participants are legally able to give consent, interviewers will be trained to recognize whether a participants is in a state adequate to provide consent. In addition, if the participant is under the supervision

5 The research team has begun to work with the Downtown BIZ Outreach with team members walking the streets and building an awareness of the study population. This preliminary work will be exploratory in nature but ensure that at project commencement, we are aware of issues and the locations of participants and best times for recruitment.
of a Public Trustee, based on consultation with the Office of the Public Trustee, the appropriate steps will be taken to contact the individual’s Trustee who can then determine the level of consent the individual is legally able to provide. In addition, on the Consent Form (ICF), there is an optional section for Assistance with Informed Consent, which could be completed by the Public Trustee on the individual’s behalf.

If participants meet the preliminary eligibility criteria, the full prescreening and baseline assessment will be completed (See attached document ‘Eligibility Screening’). Screening will be computer-based and will inform the interviewer whether or not the participant meets the study inclusion criteria as well as their level of need. Classification as high-need will be based on meeting two or more of the following criteria: high use of hospital-based services, concurrent severe addiction, frequent contact with the corrections system, persistent and intractable symptoms of mental illness, and difficulty performing tasks of daily living. Classification as moderate-need will also be based on the absence of or presence of only one of these criteria. (See attached document ‘Eligibility Screening’).

Screening will be computer-based and will inform the interviewer whether or not the participant meets the study inclusion criteria as well as their level of need. If a participant is eligible for the study, they will be guided through the informed consent process (attached) and will then be asked to complete the baseline evaluation (included in quantitative instrument package) before receiving notification of group assignment.

6. Randomization
Randomization will be performed separately (using a block technique) and an automated process of assignment for the two need groups (high and moderate). Once the assignment has been established the research team will connect those in the treatment group with the service team. The intent will be to “physically connect” participants with the service team and this may include: Walking the participant to the service team office; Waiting for the service to meet the participant (at a local coffee shop); Meeting at the Main Street Project (where the research team will have a space). Those randomized to TAU will be informed about available services in the community. All participants will be invited to use the field office as a resource centre.

7. What will participants be asked to do?

Homeless participants will be required to participate in a 2-hour baseline survey (see attached, ‘Core/National Measures) that will address service utilization, justice system contacts, mental and physical health symptoms, housing and employment status, independent living skills and quality of life. (Note: all 5 sites will use the same core instruments). Subsequent to the baseline interview, participants will be randomly assigned to one of three supported housing conditions or a treatment as usual condition. Participants will be asked to provide their Personal Health Card number so that researchers can examine participants’ contact with provincial health, income assistance and education attainment (included in Homeless Participant consent form). This administrative data will be collected for a 20 year period of time prior to entering the study and for two years after entry into the study.
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All participants will be contacted at 3-month intervals over the course of two years to re-assess their housing status and various areas of functioning (see attached Follow-up Interview Script). Interviews will be conducted by trained research assistants in locations that are comfortable for the participants (i.e., service agencies, coffee shops, field office).

A subset of 40 participants will be invited to participate in in-depth qualitative interviews within one month of entering the study and again after 18 months.

Service providers, landlords and other key individuals involved in the development and implementation of this project will be asked to participate in a 1 to 2-hour individual interview or focus group about the related challenges and successes.

8. What will happen to participants in the Treatment as Usual (TAU) group?
All members of the TAU group will be provided with information about available services in the community and will be welcome to use the field research office as a resource centre. Plans are being developed to have a Community Liaison Coordinator located at the Main Street Project who would be a connecting point for participants who are randomized into the Treatment as Usual (TAU) group. Participants in this group will be encouraged to maintain monthly contact with the field research office Community Liaison Coordinator and will receive $10 per month for staying in contact. In addition, participants will receive a $10 to $30 honorarium at three month intervals upon completion of follow-up interviews.

9. Participant Monitoring
A key challenge for this project will be conducting follow-up interviews with the treatment as usual group (TAU). To help offset these challenges, the research team will use partnerships with the various agencies providing care and support to this group to reconnect as needed throughout the study. In addition to the remuneration they receive for participating in the interviews participants in this group will receive a $10 honorarium for each month that they check in.

For participants in the ACT, ICM and Ni-Apin Model, it is anticipated that they will have access to a phone. Researchers will provide participants with multiple options for meeting and most likely will conduct interviews in a public place. However, a key to the success of ongoing monitoring of participants is to build a relationship of trust not only with the participants but also with the service providers and the agencies to whom participants will be most known to. For those participants who cannot be located in-person or reached by phone, staff will contact outreach workers and service providers in the community to inquire about their whereabouts. During the informed consent process, all participants will be asked to provide the names and contact information of family members and friends as well as public agencies (e.g., health clinics, income assistance offices) who could be contacted for the purpose of reconnecting with the participant.

10. Survey instruments, Questionnaires & Other Means of Data Collection
Core Battery: A series of surveys will be used to examine symptoms of mental and physical health, service utilization, independent living skills and quality of life. (See attached copies of all measures including screening instruments and intervention fidelity assessments).

Personal Stories: A subset of 40 participants will be asked to participate in a 1-2 hour in-depth interview within one month of entering the study and again 18 months later. Narratives can be used to build an individual’s sense of identity, purpose, and meaning, and when individuals experience traumatic circumstances, such as homelessness and all the stressors associated with it, narratives can help to reconstruct a sense of order and coherence in identity for the individual. Narratives can help in reorganizing and reconstructing identity, purpose, and meaning at times of adversity, conflict, hardship, and confusion. Following the baseline quantitative interviews, participants will be asked if they wish to participate in a second interview focusing on their life story. From those who agree to a second interview, we will randomly sample 10 individuals in each of the moderate and high need intervention groups and 10 in the two usual care groups at each site, for a total estimated sample of 200 across the five cities. We will first prompt individuals to think about particular events, memories, or episodes in their lives (one high point, one low point, and one turning point), and we will then ask them to incorporate these events into their life stories (interview guide under development).

Focus Groups and Key Informant Interviews: Approximately six focus groups/talking circles and 15-20 individual interviews will be conducted with project stakeholders over the course of the project. The first wave of interviews (September 2009 – January 2010) will focus on the planning and proposal stage of project development (see attached interview guides), and the second wave of interviews (March – September 2010) will focus on the implementation stage (interview guides attached).

Administrative Data: All study participants will be asked to provide consent for the research team to utilize their personal identifiers (i.e., name, date of birth, personal health number) to obtain administrative data reflecting their health care utilization (hospital, physician services, prescriptions), social services utilization (income assistance, disability and unemployment benefits) and education attainment. The research team at the Manitoba Centre for Health Policy (MCHP) has extensive experience collaborating with government agencies in the linkage and analysis of these data. The costs associated with service events have been established through previous studies by MCHP and the Provincial Government, and will be the basis for econometric analyses in the current study. Data will be sought prior to entry into the study, enriching our understanding of the trajectories of service utilization preceding study participation.

11. Training of Research Personnel
All research staff will undergo training in how to conduct research interviews with individuals who are homeless and have mental illness. Specific training will be provided around conducting quantitative and qualitative interviews, confidentiality and informed consent, non-violent crisis management, and personal safety. The field office will be
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co-located at the Main Street Project, thus ensuring that support and persons experienced working with this population will be accessible at all times.

Research assistants will be hired based on their experience with research and working with individuals who have mental illness and addiction. As part of this project, we are also planning to hire people with lived experience of homelessness and/or mental illness as research assistants. These peer researchers will be paired with other research assistants to conduct interviews, track participants, and provide feedback to the research team. All peer researchers will be encouraged to attend a weekly team meeting which will allow interviewers an opportunity to debrief and discuss their experiences.

12. Data Integrity and Management
All data will be retained in established, secure data. Data collection infrastructure will be provided by a professional information systems vendor and will include equipment for field data collection, secured mechanisms for transmission and processes for quality control (see description below). At the earliest opportunity, identifiers will be removed from data and a file linking subject name and ID number will be stored in a secure location at the University of Manitoba, Department of Psychiatry and/or the University of Winnipeg, Institute or Urban Studies and with the central data vendor. A data classification schema will be used to identify risk and to sort data for appropriate access, use and retention. All data will be securely retained for 7 years, at which time it will be disposed (paper material will be shredded and data stored on computers will be permanently erased).

Description of Information System - Privacy and Security Design
The national research team project leads and staff, through a competitive process, selected a vendor to provide data collection software and information systems equipment and services for the study. The chosen vendor is HealthDiary, a Canadian-owned company based in Toronto which has a track record in providing similar systems for other multi-site health research studies across provinces in Canada which have been submitted to and received ethics approvals from relevant academic ethics review boards, including the Canadian Healthy Infant Longitudinal Development Study (CHILD) and the Christmas Epidemic of Exacerbations of COPD. Specific details of HealthDiary’s compliance with industry standards are attached (Central Data Vendor Specifications-Health Diary attached).

System Design. The system is designed as a secure web-based application that will provide the data collection and storage services required for the project. It includes features for secure access control, secure data management, data encryption, network security and privacy. The system, described below and shown in the attached document (‘MHCC Hosting Diagram’), will be assessed by an information systems security expert external to the company at the design stage, and security testing will be completed and documented by the core development team (which includes Health Diary staff, information systems staff of the Mental Health Commission of Canada and National Research team staff) prior to initiating data collection. The research database application will run on a cluster of dedicated servers that provide database, application and web
services only for HealthDiary’s clients. These servers are located in a Tier 3+ commercial data centre in Toronto provided by Bell Canada. The data centre environment provides high levels of physical and network security, redundant Internet connections, redundant power supply, fire suppression systems and heating and ventilation systems. This environment provides the robust, resilient and secure environment required for hosting the application. Physical access to the hardware that comprises the system will be restricted to authorized personnel only. The servers reside behind a dedicated hardware firewall and all network access to the application and servers is protected by security policies that include role based access controls, strong password and authentication, anti-virus/anti-malware filtering and encryption of all traffic using Secure Sockets Layer (SSL). All hardware and operating systems are monitored and maintained on a regular basis for security and availability purposes. All data within the application will be encrypted and protected with strong passwords and authentication. All identifiers in the data will be removed once the data has been collected and verified. The master list linking data with identifiers will be segregated and stored secured from the data. The application data is backed up daily to a secure storage location in the data centre. Physical access to these backups is highly restricted and the backups are password protected. Data backups are also taken offsite from the data centre by a secure transport service to a secure storage location provided by Iron Mountain. Physical access to the data backups at Iron Mountain is restricted to authorized personnel only.

**Data Collection.** In the field, quantitative data will be collected from participants by trained research assistants (RAs) via interviews and directly entered into laptops configured specifically for and dedicated to the project. To access the HealthDiary application only an Internet browser is required and the application does not store any study data on the laptop’s local hard drive. Microsoft’s ReadyState technology will be used to prevent users from installing software, restricting access to features such as Control Panel, or storing data on local hard drives. A computer reboot will automatically restore the computer to the original configuration. The laptops will connect via the internet using Broadband Wireless technology and communication between the laptop computers and servers will be encrypted using SSL technology.

If, for any specific interview in the field, an RA is unable to connect to the central database (the likelihood of this circumstance is expected to be rare), the information will be collected on hard copy, carried directly back to the research office by the RA, entered and then shredded. RAs will be trained on security procedures around paper records, i.e. the records will be kept on their person at all times and returned to the research office the same day. Storage at home or in a car will not be permitted. Personal information, e.g. for the purposes of scheduling and attending interview appointments with participants may be printed from the central database via office-based desktop computers and will be similarly protected while in the field, and filed in a locked, limited access file cabinet in the research office, which will also have limited keyed access with no public access. Interviews that are conducted in the field office will be conducted in a separate, private space.
Connection under strict access controls will also be permitted via existing desktop computers, but only by authorized staff using specified desktop computers in the field office or at the Universities of Manitoba or Winnipeg and governed by specific security and confidentiality procedures for the study and the sites.

* Note that qualitative data for the national qualitative questions will be collected using digital recorders in a subsample of participants, transcribed and uploaded to a separate directory of the database. Study identifiers will be used to allow for connection of quantitative variables (e.g. demographics) to the qualitative data at the time of analysis; this will be done outside the central database, in other software, by the lead researchers for the qualitative components of the national study (Dr. Geoff Nelson and Dr. Myra Piat).

**Access.** Access to the application and data will be limited to authorized users only, using a multi-level, permissions protocol that will specify roles and types of data access permitted, using the need to know principle. A small group of national research team members (Dr. Jayne Barker, Dr. Paula Goering, Dr. Carol Adair and Dr. David Streiner) will have access to the full dataset from all sites. Because the profile data (i.e. identifying information) is kept separate in the database, access can be restricted centrally and within sites to those with a specific need for it only. When the data are exported for analysis, only study numbers will be present in the file. Site researchers with specific roles such as participant follow-up or data review and management will have access to data for such specified purposes; but not to any data collected by other sites.

All users will have unique usernames and will be required to use strong passwords. The system has protection against brute force attacks on the authentication pages. In addition, the system will automatically record the details of system security in the form of user access logs, data access logs and system logs. User access logs will be reviewed at least weekly and the other logs will be preserved for the duration of the study for special audits if needed.

All investigators and research personnel that have access privileges will receive specific orientation to the system procedures and sign a Confidentiality and Security declaration outlining their duties and responsibilities in accessing the system. In most locations, staff conduct in relation to the system will also be governed more generally by policies and procedures of the local site academic institution. Data from other sources, e.g. provincial or regional administrative databases at each site will not be linked with participants' records in the central database; the subset of data for each site will be output from the central database in SAS format and linked in local databases for analysis, in compliance with the ethics and organizational regulations governing each site.

### 13. Confidentiality and Risks of Participation

The research team at the University of Manitoba, Departments of Psychiatry and Community Health Sciences has extensive experience managing large databases of sensitive information. No identifying personal information about the study participants
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will be kept with any of the interview or administrative data. All electronic and paper records will be maintained using existing protocols and facilities at Universities of Manitoba and Winnipeg. Dedicated server rooms, work stations, and filing systems are all maintained in a secure environment that is audited for security and compliance with best practice. Records linking participants’ study identification number and personal data will be kept under lock by the Principal Investigators in a location separate from where questionnaires will be stored. Identifiers will be removed from all data as soon as possible. Furthermore, all research personnel who have access to raw data will be bound by confidentiality agreements.

**Quantitative Data**

**Risks to subjects**

Baseline interviews will be conducted with 540 participants with eight follow-up interviews over a period of 2 years. All participants will be of legal adult status. Potential risks associated with the interviews are embarrassment and discomfort from discussing matters such as personal mental health problems or drug use. However, past research with similar surveys indicates that such risk is minimal. Further, these potential risks can be minimized by training interviewers carefully and by assuring subjects that interviews will be conducted in private. Another potential risk involves updating contact information at each follow-up interview with respondents who had nearly been lost to follow-up. This information is given voluntarily, and respondents will be familiarized with this process. Within the context of this study, it is expected that the mental health problems and symptoms of both the moderate and high needs groups will diminish over time. Given the target population and the chronic nature of mental illness, it is likely that some individuals will, over time, move between the high and moderate needs group. However, there is a possibility that some individuals in the moderate need group could experience a significant escalation in their symptoms. Similarly, a participant could experience a relapse in substance use including possible overdose. In this event, the individual’s case will be brought forward to the Project Team (including researchers and service providers) in order to evaluate whether or not the individual or others are in significant danger. In the event that the Project Team determines the individual is a risk to self or others, the individual will be referred for more intensive treatment.

**Protection Against Risks.**

*Informed Consent.* Prior to the baseline interview, all respondents will be informally evaluated for competency with regard to their ability to understand informed consent. Signed informed consent will be obtained from all respondents (see attached consent form). A consent form will be read to the respondent authorizing consent to be interviewed, to be randomized to a housing and services group, to have administrative records accessed by the study team, and to be re-contacted for the follow-up or longitudinal tracing through personal contact information and through public records. As part of the informed consent process, individuals will be informed that: (a) participation is voluntary, and that there are no consequences for refusal to participate; (b) they could be randomized to a condition of ‘usual care’; (c) participation will involve answering
questions about their background, health problems, housing circumstances, and their experiences with services; (d) even after consenting to participate, participants can interrupt the interview at any point or refuse any treatment, services or to answer any question; (e) all responses and results will be entirely confidential, and no identifying information will appear in any material associated with the study; and (f) no information about respondents as individuals will be shared with parties outside the research team. At each subsequent follow-up interview, verbal consent will be obtained after providing study participants with a description of the general content of the interview, notifying them that all information will remain completely confidential, and that participating in the study will be completely voluntary. After the interview, information relevant to tracing and the next follow-up will be obtained. Respondents will receive a $10 to $30 honorarium for their participation in each quantitative interview (depending on duration, between 15 min and 1 ½ hr).

Quantitative Data Analysis

The primary analysis will be a hierarchical linear model using housing stability as the dependent variable, comparing the two treatments within each severity group. This approach allows inclusion of participants even if they miss two of the five assessment sessions, or if they are late for the assessment. Although data from the 5 sites will be pooled to give sufficient sample size, the data with participants nested within sites will also be analysed to determine if there are differences among the sites. Secondary analyses will examine sites -specific subgroups, and look at risk factors for the outcomes (e.g., gender, length of time being homeless, etc.).

Qualitative Data

Human Subjects Involvement

The second component of this study includes in-depth interviews (one approximately 30 days following baseline study enrollment and the other approximately 18 months later) with 40 participants. Respondents will be encouraged to address topics of interest using their own words. The baseline interview protocols, yet to be developed, will have an introductory discussion of the respondent's background and current situation. After establishing rapport, interviewers will turn to potentially more-sensitive topics, such as attitudes towards homelessness, substance abuse and interactions with service providers. Participants will receive an honorarium of $30 for their participation.

Potential risks

This study component involves minimal risks to participants. Again, potential risks associated with the interview are embarrassment and discomfort in providing information about matters such as homelessness, mental health and drug use. However, the research team’s past experience with similar populations indicates that such risk is minimal. Furthermore, these potential risks will be minimized through interviewer training and by assuring that the interviews will be conducted in private.
Adequacy of protection against risks

All required components of informed consent will be included and reviewed with participants. To further minimize risks, we will maintain strict respondent confidentiality by conducting interviews in private locations, by employing an ID system to assure that respondent names are never associated with transcripts, by storing interview tapes and transcripts in secured locations and password-protecting computer files. Only select research staff (PIs, Research Coordinators, three members of the National Research Team) will ever have access to identifying information.

Qualitative Data Analysis

(1) Data Analysis: A Priori Codes - The qualitative data analysis will focus on both a priori codes that will be quantified using the procedures developed by McAdams (2006), and emergent codes. A priori codes will include affect transformation (calculated by subtracting affect reported early in the story from affect reported later in the story), coherence, meaning-making, story presence, specificity, and personal growth, which can be quantified. National Research Team Qualitative Leads and their assistants will be responsible for the a priori coding and statistical analyses regarding differences between intervention and controls on these codes. These quantified data will be included in the larger quantitative data set, so that we can determine if these narrative dimensions are related to other quantitative variables used in the outcome assessment.

(2) Data Analysis: Emergent Codes and Themes - Researchers from each of the sites are responsible for inductive coding and identification of emergent codes and themes. The use NVIVO or Atlas.ti or either one for data processing will be determined.

Administrative Data

Risk to Subjects

All study participants will be asked to provide consent for the researchers to utilize their personal identifiers (i.e., name, date of birth, personal health number) to obtain administrative data reflecting their health care utilization (hospital, physician services, prescriptions), social services utilization (income assistance, disability and unemployment benefits) and education attainment. Data will be sought retrospectively and will be refreshed and updated each year through the active study period (2009-2013).

Potential risks

This study component involves minimal potential risks to participants. However, a potential risk associated with collection of the administrative data surrounds embarrassment and discomfort in the event that the individual’s identity is compromised. In order to minimize this potential risk, the electronic dataset used for the analyses proposed here will include no personal identifying information. Results will be reported in ways that do not reveal respondent identities.
Adequacy of protection against risks
During the consent procedures we will emphasize that: a) participation is completely voluntary; b) even after consenting to participate, they may refuse access to their administrative data; c) and no personal identifying information will appear in any materials associated with the study. No identifying personal information about the study participants will be kept with any of the administrative data. Records linking participant’s study identification number and administrative data will be kept under lock by the Research Staff at the Universities of Manitoba and Winnipeg. All personal identifiers will be removed from the administrative data as soon as possible.

14. Other Adverse Events or Critical Incidents
In addition to the above-noted risks to participants, there is the rare chance that research personnel may be harmed by a participant (e.g., assault). As noted above, all research personnel will participate in two days of training which will include non-violent crisis interventions and how to maintain personal safety.

If, during the course of this research, we learn that a minor is being harmed, the appropriate authorities will be informed. This is communicated to the participant during the informed consent process. An Adverse Events Task Group will be convened and will review all adverse events for appropriate follow-up action. All adverse events and critical incidents will be recorded using the following headings and brought to the attention of the Adverse Events Task Group.

- Subject ID
- Intervention arm
- Start and end date of event
- Description of event (provide supporting documentation, if possible, such as hospital records, contributing factors, how subject and other individuals were affected, followup details, etc.)
- Notification (date of notification of Adverse Events Committee, Project Team and PIs)
- Signature of recorder

Attachments
1. Consent Form – Homeless Participants
2. Consent Form – Stakeholders
3. Recruitment information & script
4. Follow-up interview script
5. Quantitative measures (National)
   a. Copies of measures (Screening; Core Battery; Fidelity Assessments)
   b. Psychometric properties
6. Copies of Winnipeg Site measures
7. Qualitative interview guide
   a. Key Informant Interviews – Proposal & Planning Stage
   b. Focus Groups/Talking Circles – Proposal & Planning Stage
8. Central Data Vendor Information
   a. Data Hosting Infrastructure (Figure)
Research Demonstration Project in Mental Health and Homelessness (Winnipeg): Full Study

b. Central Data Vendor Specifications (HealthDiary)
National Core Measures (Quantitative)
**these measures will be pre-tested as per previously submitted (August 4, 2009) “Research Demonstration project in Mental Health and Homelessness (Winnipeg): Instrument Pre-Test” REB application.

Eligibility Measure:
MINI: Mini International Neuropsychiatric Interview

Demographic Assessment:
CMHEI: Community Mental Health Evaluation Initiative

Health Status Assessment:
CSI: The Comprehensive Severity Index (CSI®) may be thought of as a multi-tiered classification system that stratifies signs and symptoms of disease for patients in multiple health care settings; successive tiers reflect increased specificity.

GAIN SPS:
GAIN: Global Appraisal of Individual Needs
SPS: Substance Problem Scale

SF-12 v.1 The SF-12® Health Survey includes 12 questions from the SF-36® Health Survey (Version 1). These include: 2 questions concerning physical functioning; 2 questions on role limitations because of physical health problems; 1 question on bodily pain; 1 question on general health perceptions; 1 question on vitality (energy/fatigue); 1 question on social functioning; 2 questions on role limitations because of emotional problems; and 2 questions on general mental health (psychological distress and psychological well-being).

NPHS: National Population Health Survey

CCHS: Canadian Community Health Survey

NART: National Adult Reading Test

Functioning:
MCAS: Multnomah Community Ability Scale

Quality of Life:
EQ-5D: EQ-5D is a standardized instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. EQ-5D was originally designed to complement other instruments but is now increasingly used as a 'stand alone' measure.
Research Demonstration Project in Mental Health and Homelessness (Winnipeg): Full Study

**SF-6D:** The SF-6D is a classification for describing health derived from a selection of SF-36 items. It is composed of six multi-level dimensions. Any patient who completes the SF-36 or the SF-12 can be uniquely classified according to the SF-6D. The SF-6D describes 18,000 health states in all.

**QOLI:** Quality of Life Inventory Lehman Disease specific

**Winnipeg Site Measures**
- Residential Schools Attendance Survey
- Foster Care Experience Survey
- Trauma (PTSD) Events Survey
1. Background and Rationale

Homelessness is a significant social problem that affects thousands of people every night in cities across Canada. A study by the City of Toronto indicates that at least 5,052 individuals are absolutely homeless in Toronto on any given night [1].

The prevalence of mental health problems and addictions among homeless people is significantly higher than in the general population. The literature suggests that between one-fourth and one-third of the homeless have serious mental illnesses such as schizophrenia, major depressive disorder or bipolar affective disorder [2,3]. Research also suggests that homeless people in Toronto have complex, and often unmet, mental health needs [4,5].

Almost half of Toronto's 2.6 million residents are immigrants including a large proportion of refugee claimants in Canada. A 1999 report by the City of Toronto, identified immigrants and refugees as one of five groups that are particularly vulnerable and in need of targeted strategies [6]. However, the literature concerning the overlap between homelessness, mental illness and ethnicity, race or culture is scant, particularly in Canadian settings.

Overall, there have been only a small number of studies that have examined the effectiveness of housing and support interventions for people with mental illness who are homeless and all of these studies have been conducted in the United States. Research in this area reveals that programs that provide housing and support to people with severe mental illness are effective in reducing homelessness and hospitalizations and in producing other positive outcomes [7]. More data are needed that considers both the unique circumstances of ethno-racial groups and homeless people generally within the services and systems available in Canada.

2. Study Overview and Objectives

This goal of this study is to examine the effectiveness and cost effectiveness of providing housing and support services for homeless adults in Toronto who have serious mental health issues. Specifically, the study will examine the effectiveness of the Housing First model plus either (1) Assertive Community Treatment services or (2) Intensive Case Management services, compared with usual care. A particular focus of this study will be to examine the effectiveness of Housing First with Intensive Case Management services designed specifically for homeless adults from racialized ethno-racial groups. For details about the models being examined see 3-I & 3-J below and Appendix L: Study Intervention and Usual Care Group Details.

This research is part of a larger multi-site study sponsored by the Mental Health Commission of Canada. The Mental Health Commission of Canada is a federally funded, arms-length, non-profit organization with a mandate to focus national attention on mental health. Toronto is one of five cities (including Vancouver, Winnipeg, Montréal and Moncton) across Canada where research projects with a common core research design will take place. The Mental Health Commission of Canada’s National Research Team manages the multi-site study and works
Appendix B: Study Protocol

collaboratively with investigators at each site to implement and support the research activities. In Toronto, the research coordination lead is the Centre for Research on Inner City Health, St. Michael’s Hospital. The service coordination lead is the City of Toronto’s Shelter, Support and Housing Administration Division.

The overall goal of this multi-site national demonstration study is to provide policy relevant evidence and contribute to developing best practices that will be applicable to future efforts aimed at addressing mental health and homelessness across Canada.

This study has several guiding research questions:
- What are the effectiveness, cost/benefit, and cost-effectiveness of a Housing First approach plus Assertive Community Treatment supports in comparison to care as usual for single homeless adults with high need living in urban settings?
- What are the effectiveness, cost/benefit, and cost-effectiveness of a Housing First approach plus Intensive Case Management supports in comparison to usual care for homeless adults with moderate needs living in urban settings?
- What are the effectiveness, cost/benefit, and cost-effectiveness of a Housing First approach plus Ethno-Specific Intensive Case Management supports in comparison to usual care for homeless adults with moderate needs living in urban settings?
- What are the demographic, clinical, behavioral and social characteristics that moderate the effectiveness of the interventions?
- What are the critical ingredients of each model and modifications needed to effectively implement it in different cities and to effectively serve particular sub-populations?
- How do personal stories and lived experience of participants in the intervention and control conditions over time and how can those stories inform the practice, service delivery and policy implications of the study?

3. Study Design and Methods

A) Overview
This study is an impact evaluation that will be conducted using an experimental design in which multiple longitudinal mixed-methods measures will be collected on both the intervention and control groups. The intervention includes the provision of independent housing (based on the principles of ‘Housing First’) plus the development and implementation of three new services: a recovery-oriented Assertive Community Treatment (ACT) Team (based on the Pathways to Housing model in New York City), an Intensive Case Management (ICM) Team (based on the Streets to Homes model in Toronto); and an Ethno-Specific Intensive Case Management Team (developed in Toronto by a variety of stakeholders). The target population for this study is homeless adults with serious mental health issues.

B) RCT Design
The randomized controlled trial design involves a total of 560 participants stratified by level of service need and ethno-racial group membership.

Participants with high needs (n=200) will be randomized into one of two groups, the intervention (Rent Allowance plus Assertive Community Treatment) or Usual Care.
Appendix B: Study Protocol

Participants with moderate needs (n=360) will be stratified by ethno-racial group membership and then randomized into one of two intervention options (Rent Allowance plus Intensive Case Management or Rent Allowance plus Ethno-Specific Intensive Case Management) or Usual Care. Study entry will be stratified to ensure that 240 of the 360 moderate needs participants are from ethno-racial groups. For more details see Appendix U: Randomization Flow Chart.

Moderate needs participants who are eligible for the ethno-specific intervention and who are randomized to intervention will be able to choose if they would like to receive Ethno-specific or regular ICM while there is still space in each intervention arm.

Participants in the Usual Care Group will be still be able to access the broad collection of services available in Toronto for homeless people with mental health issues. Participants in this group will be provided with information about available services in the community.

Data will be collected from participants in both groups approximately every 3 months for a period of 2 years from enrollment (see Data Collection – Section K below for details).

C) Target Population/Eligibility Criteria

The main criteria for inclusion in the project are as follows: (1) legal adult status (age 18) or older; (2) meets definition of 'absolute homelessness' or 'precariously housed'; (3) presence of any serious mental health disorder; (4) not currently receiving Assertive Community Treatment (ACT) or Intensive Case Management (ICM) services.

(2) Absolute homelessness is defined as: having no fixed place to stay for at least the past 7 nights and little likelihood of obtaining accommodation in the upcoming month; OR currently being discharged from an institution (e.g. jail, hospital) with no fixed address. No fixed place to stay is defined as: living rough in a public or private place not intended for human habitation (e.g. parks, vehicle, squats, and doorways), as well as those whose primary night-time residence is a supervised public or private emergency shelter.

(3) A candidate for inclusion demonstrates the presence of a serious mental illness when (i) the threshold for a diagnosable illness is met as established by the Modified MINI International Neuropsychiatric Interview or (ii) at least one psychotic behavior is observed/reported by the referring source in the past month or (iii) has documentation of a diagnosed mental health condition AND serious functional impairment is observed/reported by the referring source in the past month.

(4) Unmet ACT or ICM need will be determined using conversational interviewing to elicit what services the potential participant is receiving for help with their health or mental health, in getting a place to stay or to secure income. Participants will be asked for the names of programs and agencies where they receive services. This will be checked against a list of ACT and ICM programs in Toronto. Anyone receiving services from an agency or program on this list within the last 8 weeks will not be eligible for the study.

Please see Appendix C: Screening Tool for detailed definitions and eligibility cut-off scores.
Because women are often underrepresented among the absolutely homeless population, from which we are recruiting, they will be targeted to ensure they make up 25% of the total sample. Study entry will also be stratified to ensure that 320 of the 560 participants are from ethno-racial groups, 80 among the high needs group and 240 among the moderate needs group.

Eligibility for the ethno-racial intensive case management group will be based on self-reported responses to demographic racial identity questions obtained at baseline. See Appendix D: Survey Instrument for details.

Study participants will be classified as high or moderate need using criteria that correspond to Section 3 of the Ontario Standards for Assertive Community Treatment teams. Study participants who meet two or more of the criteria will be determined to be high need. All other study participants will be classified as moderate need. For criteria details please see Appendix L: Study Intervention and Usual Care Group Details.

D) Participant Recruitment
Concerted effort will be made to recruit participants from a range of living situations (e.g. shelter, street) and will aim to approximate the distribution of living situations documented among homeless people in Toronto in the 2006 Street Needs Assessment [1]. Recruitment to full sample is expected to take up to 18 months.

Recruitment to the study may come from several points of entry. Toronto's extensive network of organizations that serve homeless people will be the primary source of referrals. Any agency organization will be able to refer persons to the research coordinator for assessment of eligibility. This network includes but is not limited to: shelters, drop-in centres, street outreach programs, housing help offices, community health care centres, and emergency departments. Referrals by individuals will not be accepted. People who self-refer or individuals who are not affiliated with health or social service agencies but who would like to refer potential participants, will be directed by the Research Coordinator to agencies on the study’s referral work group (see next paragraph) who will ensure that the potential study participant is connected to existing social services and, if appropriate, will then refer this person to the study.

To maximize the appropriateness of referrals to the project and to ensure that the entire range of potentially eligible individuals from across Toronto are referred to the project, the research team has convened a Referrals Work Group made up of representatives of likely referral sources (e.g. the Toronto Drop-in Network, the ER Alliance, the Shelter Network). Communication materials have been developed for targeted distribution to potential referral sources to ensure common understanding of the study's target population and eligibility criteria and appropriate referrals. Project staff will visit key referral agencies and organizations prior to study enrollment and during the early stages of the study to provide an overview of the study and discuss eligibility criteria and referral process.

A two-page referral form that can be faxed or emailed to the research coordinator will be distributed to potential referral sources. Referrals can also be provided to the coordinator over the phone. The referral form will request: the contact information of the referral source, the
individual’s name, evidence of a mental health diagnosis if available, observed behaviours related to the study eligibility criteria, and some basic demographic information (necessary for study stratification) and information required to contact the individual. Referral sources will be directed to obtain verbal permission from potential participants before referring them to the study and will document that this has been obtained on the referral form.

Where participants give permission, referral sources will be notified if the person they referred has been enrolled in the study and to which arm. This is necessary in order to maximize continuity of service and to minimize participant vulnerability.

See Appendix G: Referral Information for Service Providers and Appendix H: Referral Information for Participants.

E) Screening/Eligibility Assessment
Initial contact with potential participants will be made in person primarily by health and social services providers who will have been provided with study information and referral materials including a script for approaching potential participants about the study. Please see Appendix G for the referral script.

Referrals will be made to a single individual (the study Research Coordinator) who will store any information collected for the purposes of recruitment in a locked filing cabinet. Access to this information will be restricted to this individual and the study intake coordinator.

An intake coordinator will receive referrals from the research coordinator and will work on a mobile basis to meet with individuals who have been identified as potential participants. Once referred to the study, potential subjects will be assessed in-person by the study intake coordinator who will establish eligibility and obtain consent. Assessments will take place at a safe and private location (possibly at the field office where the intervention service providers will be located) that is convenient to the potential subject.

Because the screening form collects personal health information, a verbal consent process will take place prior to the screening interview. Also, as part of the study we intend to analyze referral and screening data to understand more about who was not eligible or decided not to participate in the study. All referral data will be retained for a period of 10 years after the study has been closed and will subsequently be destroyed. Verbal permission will be obtained from participants prior to screening for permission to retain this information. Please see Appendix O: Screening Consent Script.

The verbal screening consent process will not replace the written consent process for the study itself. Because the study involves explaining multiple possible study assignments (i.e. high needs intervention, moderate needs intervention, ethno-specific intervention, and care as usual groups), we have decided to conduct the full study written consent after eligibility has been determined so as not to unnecessarily burden potential participants who may or may not be eligible for the study with an additional hypothetical situation (i.e. that they may or may not even be eligible to consider the full range of study participation assignments).
Appendix B: Study Protocol

If a potential participant is screened but found to be ineligible for any reason (e.g. not ‘absolutely’ homeless, already receiving ACT or ICM services within the last 8 weeks), they will be able to be re-screened only once every 3 months while enrollment to the study is still open. Once someone has been enrolled to the study, they cannot be re-screened.

F) Consent Process
Written consent will be obtained from participants. Consent forms are crafted in an accessible, plain language format. The form will be read aloud to ensure that all participants, regardless of literacy level, will have been given the information required for them to be able to give informed consent.

Where potential subjects do not speak English, we will hire professional, certified translators who are competent in the required languages. In these cases, the study information and consent will be verbally translated. Translators will be asked to sign an oath of confidentiality and a declaration that the study was adequately explained and that consent was freely given. The study may also involve participants who are illiterate or have low literacy levels. Consent forms have been crafted in accessible, plain language and will be read aloud and explained to all survey participants, regardless of literacy level. For participants who are unable to write, consent will be given orally and a witness will be present during the entire process to ensure that all aspects of the consent process are understood and that consent is given freely. A witness declaration and signature line has been included as part of the consent form.

Please see Section 4 below for additional protocols around consent and capacity.

G) Randomization Process
Participants will be randomized to either the intervention or control group after eligibility screening, consent process, and baseline interview (which will include classification of high v. moderate need).

The data vendor (described below in Section 5) contracted to provide data management and security for the national study will manage randomization for each site centrally. The study software will assign each participant’s random selection, which will be generated using random number tables and stratified into 3 groups by level of need and ethno-racial group membership: (1) high need; (2) moderate need/non-ethno-racial group member; and (3) moderate need/ethno-racial group member. Tests of balance will be conducted to assess the success of the randomization procedures for both the high and moderate needs clients.

H) Sampling Strategies for Sub-Studies
Chart Review: At baseline, all participants will be asked to name their 5 most frequently used sources of health care in the past 3 years and for permission to obtain health records from these sources. Participants for chart review will be randomly selected from the larger sample stratified by gender, racialized ethno-specific group membership and treatment versus usual care assignment. Charts will be reviewed at all of the most frequently used sources of health care for the selected sub sample. Approximately 100 participants will be selected up to the entire sample, as budget and time allow.
Qualitative Interviews (Personal Narratives): Participants will be randomly selected from the larger sample stratified by gender, high need versus moderate need, ethno-racial group membership, proportional to the larger sample.

I) Usual Care Group
Homeless individuals with serious and persistent mental health issues may access a broad collection of health and social services available in Toronto that includes: inpatient and outpatient clinical service, peer support, crisis services, intensive case management, Assertive Community Treatment Teams (ACT), supportive housing, vocational programming, street outreach programs, drop-in services and shelters. Participants in the Usual Care Group will be still be able to access the broad collection of services available in Toronto for homeless people with mental health issues. Participants in this group will be provided with information about available services in the community. Please see Appendix U: Resource Guide.

It is recognized that some individuals in the usual care group may over time, through new or existing programs, access services that are similar to the experimental intervention. Health and social services use will be measured through the common protocol of health service use and included in the analyses of process and outcomes.

For additional information about Usual Care, please see Appendix L.

J) Intervention Group
The experimental intervention includes the development and implementation of three new services: a recovery-focused Assertive Community Treatment (ACT) team; and two Intensive Case Management (ICM) teams, one with a focus to serve homeless people from specific ethno-racial groups. Each of these teams will serve 100 participants and will be based at community-agencies.

In addition, participants in the experimental intervention will receive a rental allowance of $600 per month and support to obtain immediate access to housing. Participants will be allowed to choose their own housing after it meets minimum City of Toronto standards for acceptability, including property standards, affordability. The City of Toronto's Shelter, Support and Housing Administration Division will administer rent allowances and provide housing support to the ICM and ACT teams.

Participants who are randomized to the intervention group (N=300) will receive the rental allowance ($600 per month) plus support services (either an Assertive Community Treatment team or Intensive Case Management) until March 2013 and possibly beyond (if continued funding becomes available). Participants in the intervention group will be required to have weekly visits by a case manager or member of ACT team.

For additional details of the intervention, please see Appendix L.

K) Data Collection
Multiple longitudinal mixed-methods measures will be collected on both the intervention and usual care groups.

**Quantitative Survey Component**
All study participants (in both the intervention and usual care groups) will be interviewed by phone or in-person every 3 months for a period of 2 years from baseline (for a total of 8 interviews). This includes: one 80-minute baseline survey interview followed by three 70-minute interviews (at 6 months, 12 months and 18 months), four 10-minute interviews (at 3 months, 9 months, 15 months and 21 months) and one 75-minute final interview. Participants will be asked questions about their housing situation, physical and mental health status, use of drugs or alcohol and overall quality of life. In addition, data on housing situation will be collected during monthly 5-minute check-ins by phone. See Appendix D: Survey Instrument.

**Physiological measures**
Select physiological measures will be collected from all participants at 5 points throughout the study: as part of the baseline interview and at every 6-month interview. The measures being collected are: systolic and diastolic blood pressure, height and weight (to calculate Body Mass Index), and waist and hip circumference.

**Data Linkage**
Links will be made to administrative data for all participants to obtain corroborative information on health care utilization in Ontario, prescription drug use, justice system contacts, shelter utilization in Toronto, disability and welfare benefits and official disability diagnoses. Participants will be asked for permission to the use of their personal identifiers (name, date of birth and Ontario Health card number) for this purpose. Linkages will be made with databases at the Institute for Clinical Evaluative Sciences (ICES), the Ministry of Community and Social Services, Correctional Service of Canada, the Ministry of Community Safety and Correctional Services, the Toronto Police Service, and the City of Toronto’s Division of Shelter, Support and Housing Administration. The period of observation using these databases will include the 1-year prior to study enrolment and 5 years from enrollment. Individuals who do not have a health card in their possession at the time of the interview will be asked to provide us with contact information for recent health care providers, who can provide us with the individual’s health card number. Individuals who decline permission for linkage to databases will still be eligible to participate in the study.

**Chart Reviews**
The health records of another subset of at least 100 participants will undergo review at baseline and at 24 months. Data will be collected retrospectively for a period of 3 years at study enrollment and at 24 months. Data collected from chart review will focus on diagnosis data, preventative health measures (screening and treatment), and select physiological measures where available. See Appendix F: Chart Abstraction Guide.

**Qualitative Interviews (Personal Narratives)**
A subset of 50 participants (20 from the intervention, 20 from the usual care group and 10 from the Ethno-Specific Intervention) will be randomly selected from the larger study group and be invited to participate in 2 in-depth qualitative interviews; the first within one month of entering
the study and the second at 18 months. Each interview will last approximately 90 minutes. Participants will be asked to discuss their experiences of homelessness and mental illness and to identify and discuss particularly memorable life events. See Appendix E: Qualitative Interview Guide

L) Follow-up Methods
Our goal is to retain 75% of participants over 2 years of follow-up, based on estimates and using methods that have proven to be effective in tracking and retaining homeless and marginalized study participants [8-14]. Efforts will be made to establish trust and rapport with participants at first contact and to explain the importance of their participation in follow-up interviews. All participants will be given a laminated card with a toll-free contact number for the study. Participants will be asked to call the contact number once every month. During the call, they will be asked to provide a brief update on their current living situation and location as well as updated contact information. A $10 cash incentive will be paid to the participant for each monthly contact.

To further minimize loss to follow-up between interviews, at the time of enrollment, participants will be asked to provide contact information not only for themselves but also for friends, relatives, service providers and case workers who are most likely to know the participant’s whereabouts and who may be contacted in order to locate them. Participants will also be asked to give consent for the Ontario Ministry of Community and Social Services to provide us with their updated contact information or the contact information of their payee/trustee to the research team for participants receiving welfare or disability benefits. Contact persons will only be contacted when other means of finding study participants have been exhausted. A script for contact with these individuals is attached in Appendix K.

M) Honorarium
Participants will be paid an honorarium after each interview (lasting between 10 minutes and 1 1/2 hours) and for the monthly check-ins to recognize the value of their time, to encourage follow up and to help reduce barriers to participation. Honorarium amounts will be between $10 and $30 (depending on length of interview).

N) Data Analysis
Quantitative Data
Differences in the intervention and control groups will be examined by conducting t-tests and chi-square analyses at the individual level on a range of baseline outcomes and other demographic and risk factor characteristics. Power will be calculated for a range of effect sizes and intra-class correlations for the implemented longitudinal experimental design. Multi-level models will be implemented to estimate program effects and to study the trajectories of outcomes as a function of both between individual and time varying covariates. Robustness of results will be evaluation through propensity scoring methods used to match individuals in the treatment group with individuals from the control group on a number of baseline measures.

Because the Toronto sample alone is likely to be underpowered to address if the intervention has had differential impacts for each of the groups, we will work closely with the Mental Health Commission of Canada's national research team to implement a group-based approach for
analyzing developmental trajectories. This methodology applies finite mixture modeling to identify groups of individuals following similar trajectories on a variable measured (e.g. housing stability) repeatedly over time.

Analysis of data obtained from health care and social service databases in key areas will include: (1) identification and costing of all inputs (ii) identification and costing of outputs (iii) quantification of outcomes (iv) comparison of costs with outcomes (v) direct and indirect benefits of the intervention (based on program theory) (vi) potential short, immediate and long term benefits of the program.

Interim Analysis
Service utilization and participant survey data will be analyzed to examine differences in treatment and control group services delivery processes at the study’s half way point. In the areas of safety monitoring, we will examine whether there have been any systematic negative consequences of the trial such as loss of services, poorer access to services than prior to enrollment into the study. We will have protocols in place to guide acute safety events (e.g., eviction from housing).

Outcome measures
The primary outcome measures of interest for measuring cost-benefit, effectiveness and cost-effectiveness for this study are:

- Housing Stability (Residential Time-Line Follow-Back Calendar)
- Quality of Life (EQ-5D and SF-12 Health Survey 1.0)
- Mental Health Status (Modified Colorado Symptom Index and Global Assessment of Individual Need - Substance Problem Scale)
- Community Functioning & Integration (Multnomah Community Ability Scale)
- Health care System Use and Costs (Standard health service utilization schedules, administrative data linkage).

Qualitative Data
Information from the personal stories from 50 individuals will be explored using qualitative longitudinal research methods with a focus on explaining the pathways by which the intervention affect the outcomes. Qualitative data analysis will follow a systematic, comparative grounded theory method of analysis. Line-by-line coding of transcribed text from in-depth interviews will identify key concepts and will be facilitated by the constant comparative method involving the comparison of themes and concepts as the analysis progresses.

Chart Review
Analysis will focus on comparisons between intervention and usual care groups on rates of adherence with preventive health service guildlines and measured physiological parameters. Analysis will also examine the accuracy of self-reported health status compared with chart documented diagnosis.

D) Instrument Pre-Test
Quantitative survey instruments were pre-tested (see REB #09-161) using conventional and cognitive interview techniques to: (i) identify concerns related to face validity, timing, flow, and general acceptability of the proposed survey tools; and (ii) explore issues of meaning, comprehension, recall, and disclosure. The results of pre-testing will be used to make modifications to the survey tools that will improve the content and administration process. In the case of highly standardized instruments, where item changes were not possible, the information collected will be used at the analysis stage to inform the interpretation of findings for specific items and scales.

P) Sample Size Justification

RCT Study:
It has been estimated that a clinically meaningful and realistically achievable effect size (the between group difference in the mean value of continuous normally distributed outcome variables), is approximately half of the within group standard deviation. This also corresponds to what Cohen refers to as a moderate effect size (between 0.3 and 0.5) [15]. While there are potentially multiple outcomes for the proposed study, the MCAS provides an excellent outcome to use in a sample size calculation as it captures multiple dimensions of well-being and functioning of participants and we have data on standard deviations on many samples [16,17]. Such studies have reported standard deviations of approximately 9.0.

We performed separate sample size calculations to address each of the following research questions: (1) Among high needs homeless adults: to compare ACT with usual care; (2) Among moderate needs homeless adults: to compare ICM with usual care; (3) Among moderate needs homeless adults from ethno-racial groups: to compare ES-ICM with usual care. For question (2) we will conduct sample size calculations for treatment comparisons among ES-eligible and among Not ES-eligible, as well as treatment comparisons among the pooled the ES- and Not ES-eligible groups.

Among the moderate needs, ES-eligible stratum, our design allows for a participant randomized to treatment to be able to choose between ICM or ES-ICM up to a maximum to 40 ICM participants and 100 ES-ICM participants (see Appendix V: Randomization flow chart). These limits are determined by the ability of the service providers to offer the experimental treatments to at most 100 clients during the study period.

The following table shows the minimum MCAS mean difference at the end of the study for the proposed sample sizes, assuming within group standard deviation=9, power=90%, alpha=5%, 2-sided two-sample t-test to compare means.

<table>
<thead>
<tr>
<th>COMPARISON</th>
<th>N_T</th>
<th>N_C</th>
<th>MEAN DIFFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Needs: ACT vs usual care</td>
<td>100</td>
<td>100</td>
<td>4.1</td>
</tr>
<tr>
<td>Moderate Needs: ICM vs usual care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not ES-Eligible</td>
<td>60</td>
<td>60</td>
<td>5.4</td>
</tr>
<tr>
<td>ES-Eligible</td>
<td>40</td>
<td>100</td>
<td>5.5</td>
</tr>
<tr>
<td>All</td>
<td>100</td>
<td>160</td>
<td>3.7</td>
</tr>
<tr>
<td>Moderate Needs- ES-ICM vs usual care</td>
<td>100</td>
<td>100</td>
<td>4.1</td>
</tr>
</tbody>
</table>

N_T = sample size of experimental arm; N_C = sample size of usual care arm
Appendix B: Study Protocol

Thus we seek overall differences between our experimental and control arms of between 3.7 and 5.5 points on the MCAS, representing moderate to large effect sizes of 0.4 to 0.6. Similar or larger differences have been observed in comparing high risk to low risk populations for example [18].

Finally, we anticipate that there will be uniform attrition across all groups and estimate it to be approximately 25%. Our power will no longer be 90% to detect each of the differences in the table above at the 5% significance level: we estimate it to be 79.1%, 80.3%, 80.0%, 79.5% to detect a mean differences of 4.1 with 75 in each group, 5.4 with 45 in each group, 5.5 with group sizes of 30 and 75, and 3.7 with sizes of 75 and 120. Loss of power when comparing MCAS means at the end of the study with t-tests in presence of attrition will be remedied by using other statistical techniques, such as mixed modeling, that consider all repeated measures, rather than summary measures, in this longitudinal study.

Qualitative Component (Personal Narratives): We expect that 50 interviews will provide a large enough sample to achieve saturation of codes and themes [18], as well as a minimum level of statistical power.

Chart Review
We plan to review as many charts as possible, contingent on budgetary restrictions. We currently have 1,220 hours of staff time allocated for chart review and expect to be able to review at least 100 charts.

4. Ethical Issues

Study Design
There have been no experimental studies of this housing and support model in Canadian settings. In order to influence policy we need a strong design to find out whether this intervention works, at what cost and for whom in our local contexts. In order to determine which models work best for whom, we need to compare people who are receiving housing with supports with people who are not receiving these services. Individuals in the ‘care as usual’ group will be offered referrals to existing services and will not be placed at any greater risk of harm than they face in their current circumstances.

Risk to Participants
There are no additional risks associated with the study as compared to usual standard of care. Subjects may experience some discomfort as a result of being asked about personal health experiences, which may have been painful. A referral/resource list will also be part of each interview kit so that interviewers will be able to make referrals to appropriate community services if participants require support during or after the interview process. A safety/risk protocol has been established by the national research team which will give Research Assistants a back-up clinician to contact based on a specific operational decision around responses on risk items, a referral card for a contact clinician, and a number for crisis services. Please see Appendix S:

Safety Protocol.
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Individuals who are randomized into the usual care group may feel some disappointment over not receiving the intervention benefits (housing and supports). This will be minimized by providing all members of the care as usual group with information about existing available services in the community. Where permission is given, the Research Coordinator will notify the referral source that the participant was randomized to the usual care group so that this health or social service provider is aware that the individual will still need support to find housing and supports outside of the study.

Privacy and Confidentiality
This study proposes to use multiple and varied data sources (including charts, Ministry of Health data, and primary data collection) for each participant. This comprehensiveness is critical to the scientific objectives of the study, yet may increase invasion of individual participant privacy. This privacy concern will be clearly communicated to potential participants, as will the measures for protection of security and confidentiality, prior to consent. Any potential vulnerability of participants will be minimized since study findings will be kept confidential, de-identified soon after collection, and because participants are not required to answer any questions that they do not want to and they may stop the interview at any time.

Data protection measures are outlined in Section 5.

Consent and Capacity
Participants will be enrolled in the study only if they are able to give informed written consent. Assent will not be accepted. Having a mental illness does not automatically make an individual incapable to consent to treatment or to participation in research studies [19]. Several studies have shown better decisional capacity among individuals with severe mental illness, even while actively symptomatic, then previously believed [20-22]. Nevertheless, it is acknowledge that some potential participants may be compromised in their ability to provide consent or that this may fluctuate over time.

In an effort to alleviate any lack of understanding of study involvement, we propose to take some extra educational and communicative steps that have been recommended in the literature [23,24]:
- use a simple, clear and repeated informed consent process
- document observations about understanding of participation at the time of consent

If a potential participant is temporarily unable to provide consent at the time of their initial referral (e.g. due to intoxication, acute exacerbated psychosis, acute medical illness), the study intake coordinator will ask the participant to contact the research coordinator at a later date.

Undue Inducement
While it may seem that the possibility of receiving a rental allowance and supports would be a difficult offer for someone who is homeless and experiencing serious mental health issues to refuse, it should be noted that a City of Toronto survey found that about 1 in 10 homeless people do not want permanent housing [1]. Of those who did not want housing, 20% said they preferred being homeless, 14% said they did not want help finding housing and 20% said they did not want to live in Toronto or were just traveling through [1]. (Note: our study is only able to offer people
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housing in the City of Toronto). It is also likely that some homeless people will not want the
particular type of housing being offered through our study – i.e. primarily independent, self-
contained units where the support services are not directly attached to the housing. Some
individuals will prefer a congregate living situation with on-site supports. Many may also prefer
an alternative and less intensive form of mental health support services. As explained in the study
consent process, participants must be willing to have contact with a study service provider at least
once per week. This will not appeal to everyone who is eligible for the study as many potential
participants will prefer less frequent or less structured models of case management support.

Withdrawal from Intervention
We do not envision any premature withdrawal of subjects from the study for safety
concerns. Participation in this study is completely voluntary and participants may
withdraw from the study at any time. Participants in the intervention group will not lose
their housing or support services should they decide to withdraw from the research
activities at any point. Given the pragmatic nature and the population of this study, we feel
it is ethically perilous to consider withdrawing the rent allowance and supports if a
participant refuses to continue with the research activities of the project, especially since a
return to a non-research situation would mostly likely be a return to homelessness.
Moreover, if participants are told that their housing and supports will be removed if they do
not comply with the research activities then this may be viewed as undue influence on the
part of the research team.

It should also be noted that we do not anticipate that many participants in the intervention
group will wish to withdraw from the research activities exclusively. The research
activities themselves (monthly 5-minute check-ins by phone, one 80-minute survey
interview at baseline followed by periodic interviews over two years ranging from 10 to 80
minutes) do not represent a significant additional burden for participants who are housed
and receiving support services. Participants in the intervention group will have likely
formed positive relationships with the study service providers and we anticipate that they
will be willing to participate in periodic interviews for which they will receive an
honorarium. With direction from the participant’s ACT team or ICM case manager,
research staff will periodically approach these individual’s to see if they might be willing to
re-join the study. Permission to maintain contact with participants who have withdrawn
from research activities during the 2-year participant enrollment period will be discussed as
part of the consent process.

Sustainability & Transition
The potential for evictions of participants in the intervention group at the end of the project
(March 31, 2013) is a risk and concern. The project team has a responsibility to ensure that
participants do no become homeless and without case management supports again at
completion of the research project. Everyone in the intervention group will be helped to
either stay where they are or move to other long term housing. Participants will not be
transitioned back to shelters or the street, or to potentially unstable pilot projects. In the
absence of funding from sources other than the Mental Health Commission of Canada
beyond the duration of the study, we will instruct service providers in year 3 to access rent-
geared-to-income housing and to ensure access to alternate appropriate support services.
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Everyone in the intervention group will be put on the social housing wait list (average wait is approximately 1 year for a bachelor apartment) and study service providers will partner with other support agencies in the community where participants can then be referred in the absence of extended funding after study completion. Participants will be updated about the sustainability of the project on an ongoing basis through their service provider and service providers will include participants as decision makers in their individual transition plans.

Planning for post-study system integration and sustainability has been part of this project from the outset. Program sustainability objectives include identifying appropriate strategies for scaling up successful elements of the demonstration project to be inclusive of all eligible clients in the Greater Toronto Area. Planning for and championing program transition and sustainability has begun with the establishment of a Local Advisory Committee for the project. This committee is made up of experts with extensive knowledge of health and social policy frameworks in Ontario, including service providers and people with lived experience of mental illness and homelessness. This committee is responsible for identifying feasible options for integrating successful demonstration project elements into the core funding portfolios of the relevant administrative agencies and championing program adoption with relevant stakeholders and agencies.

Ideally, if funding is extended, we would offer the effective services to the control group participants as well, but this is not necessarily feasible. Given limited resources, our first obligations are to those in the intervention group with whom we have entered into a fiduciary relationship as a service and support provider.

Safety of Research Personnel

Research assistants will be hired based on their experience with research and working with individuals who have mental illness and addiction. All research staff will undergo training in how to conduct research interviews with individuals who are homeless and have mental illness. Specific training will be provided around non-violent crisis management, and personal safety. Although the likelihood of violence against staff is low, safety precautions such as having two researchers present in a participant’s home if she/he has a violent history will be taken. Please see Appendix S: Safety Protocol.

5. Community Stakeholder Involvement

This research project has been developed collaboratively with the study service providers and the Toronto community. Broad and meaningful community participation has been sought to shape the content of this protocol, and we have aimed to conduct our work in line with core principles of equitable decision-making, particularly transparency and defensibility.

Since the beginning of the study development process, people with lived experience of mental health issues and/or homelessness have participated in planning meetings concerning governance, research approaches, and strategic implementation. Structures and guiding principles have since been established to ensure that people with lived experience are able to contribute to and communicate with the project and to ensure that their experience and perspective informs (a) appropriate and ethical implementation of services; (b) appropriate and
Appendix B: Study Protocol

ethical research practices; (c) governance of this project; (d) development of local research
questions and local methods for gathering and interpreting data; (e) approaches for informing
local and national stakeholder communities (including consumers, policy-makers, and the media)
about the project; (f) approaches for disseminating the policy implications of the study and
information about homelessness and mental health; (g) approaches for sustaining the
interventions after the research project is over. A caucus of approximately 20 people with lived
experience of mental health and/or homelessness meets monthly to discuss the study and provide
direct input and feedback to this stakeholder group through caucus membership on the study
work groups (described below).

A project ‘Site Operations Team’ meets every other week and is responsible for the
implementation and day-to-day operations of the project. The Site Operations Team includes
project leads from CRICH and the City of Toronto’s Shelter, Support and Housing
Administration Division, the community-based ACT and ICM service providers, two people
with lived experience of mental health issues and/or homelessness and a representative from the
Mental Health Commission of Canada. In addition, a series of Site Operations Team work
groups focused on specific aspects of the study (Research, Housing, Referrals, Services, Ethno-
Specific Services) meet on a monthly basis to inform and guide the project. These work groups
include additional community stakeholders including people with lived experience and external
service providers. As mentioned in Section 5 (Sustainability & Transition), a Local Advisory
Committee also allows for community input into the study.

6. Data Management & Security

The Mental Health Commission of Canada, through a competitive process, selected a vendor to
provide data collection software and information systems equipment and services for the study.
The chosen vendor is HealthDiary, a Canadian-owned company based in Toronto. HealthDiary
has a strong track record in providing similar systems for other multi-site health research studies
across Canada which have been submitted to and received ethics approvals from relevant
academic ethics review boards. These studies include: the Canadian Healthy Infant Longitudinal
Development Study (CHILD), the Christmas Epidemic of Exacerbations of COPD.

Specific details of HealthDiary’s compliance with industry standards are provided in Appendix P.

System Design
The system is designed as a secure web-based application that will provide the data collection and
storage services required for the project. It includes features for secure access control, secure data
management, data encryption, network security and privacy. The system will be assessed by an
information systems security expert external to the company at the design stage, and security
testing will be completed and documented by the core development team (which includes Health
Diary staff, information systems staff of the Mental Health Commission of Canada and National
Research team staff) prior to initiating data collection.

The research database application will run on a cluster of dedicated servers that provide database,
application and web services only for HealthDiary’s clients. These servers are located in a Tier 3+
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A commercial data centre in Toronto provided by Bell Canada. The data centre environment provides high levels of physical and network security, redundant Internet connections, redundant power supply, fire suppression systems and heating and ventilation systems. This environment provides the robust, resilient and secure environment required for hosting the application.

Physical access to the hardware that comprises the system will be restricted to authorised personnel only. The servers reside behind a dedicated hardware firewall and all network access to the application and servers is protected by security policies that include role based access controls, strong password and authentication, anti virus / anti-malware filtering and encryption of all traffic using Secure Sockets Layer (SSL). All hardware and operating systems are monitored and maintained on a regular basis for security and availability purposes.

All data within the application will be encrypted and protected with strong passwords and authentication. All identifiers in the data will be removed once the data has been collected and verified. The master list linking data with identifiers will be segregated and stored secured from the data. The application data is backed up daily to a secure storage location in the data centre. Physical access to these backups is highly restricted and the backups are password protected. Data backups are also taken offsite from the data centre by a secure transport service to a secure storage location provided by Iron Mountain. Physical access to the data backups at Iron Mountain is restricted to authorised personnel only.

Data Collection
In the field, quantitative data will be collected from participants by trained Research Assistants via interviews through a Computerized Assisted Personal Interviewing (CAPI) system. To access the HealthDiary application only an Internet browser is required and the application does not store any study data on the laptop’s local hard drive. Microsoft’s ReadyState technology will be used to prevent users from installing software, restricting access to features such as Control Panel, or storing data on local hard drives. A computer reboot will automatically restore the computer to the original configuration. The laptops will connect via the internet using Broadband Wireless technology and communication between the laptop computers and servers will be encrypted using SSL technology.

If for any specific interview in the field a Research Assistant is unable to connect to the central database (the frequency of this circumstance is expected to be rare), the information will be collected on hard copy, carried directly back to the research office by the Research Assistant, entered and then shredded. Research Assistants will be trained on security procedures around paper records, i.e. the records will be kept on their person at all times and returned to the research office the same day. Storage at home or in a car will not be permitted.

Personal information, for the purposes of scheduling and attending interview appointments with participants, may be printed from the central database via office-based desktop computers and will be similarly protected while in the field, and filed in a locked, limited access file cabinet in the research office, which will also have limited keyed access with no public access. Interviews that are conducted in the field office will be conducted in a separate space.
Connection under strict access controls will also be permitted via existing desktop computers, but only by authorized staff using specified desktop computers in allowable research sites and governed by specific security and confidentiality procedures for the study and the sites.

Qualitative data will be collected using digital recorders, transcribed and uploaded to a separate directory of the database. Study identifiers will be used to allow for connection of quantitative variables (e.g. demographics) to the qualitative data at the time of analysis; this will be done outside the central database, in other software, by the lead researchers for the qualitative components of the national study (Dr. Geoff Nelson and Dr. Myra Piat).

**Access**

Access to the application and data will be limited to authorised users only, using a multi-level, permissions protocol that will specify roles and types of data access permitted, using the need to know principle. A small group of national research team members (Dr. Jayne Barker, Dr. Paula Goering, Dr. Carol Adair and Dr. David Streiner) will have access to the full dataset from all sites. Because the profile data (i.e. identifying information) is kept separate in the database, access can be restricted centrally and within sites to those with a specific need for it only. When the data are exported for analysis, only study numbers will be present in the file. Co-Principal Investigators, Research Coordinators and Research Assistants in Toronto with specific roles such as participant follow-up or data review and management will have access to data for such specified purposes; but not to any data collected by other sites. Toronto Co-Investigators will have access to data for the purposes of data analysis but will not have access to personal identifiers.

All users will have unique usernames and will be required to use strong passwords. The system has protection against brute force attacks on the authentication pages. In addition, the system will automatically record the details of system security in the form of user access logs, data access logs and system logs. User access logs will be reviewed at least weekly and the other logs will be preserved for the duration of the study for special audits if needed.

All investigators and research personnel that have access privileges will receive specific orientation to the system procedures and sign a Confidentiality and Security declaration outlining their duties and responsibilities in accessing the system.

Data from other sources (e.g. provincial or regional administrative databases) at each site will not be linked with participants' records in the central database; the subset of data for each site will be output from the central database in SAS format and linked in local databases for analysis, in compliance with the ethics and organizational regulations governing each site.

**7. Knowledge Translation**

An integrated knowledge translation approach oriented toward sustainability planning is an important component of the project. In collaboration with the study’s Local Advisory Committee (made up of provincial government representatives, service providers and individuals who have experienced homelessness and mental illness) a communications plan
Appendix B: Study Protocol

will be developed and key partners and stakeholders will be identified to ensure the engagement of key target audiences in knowledge production and dissemination activities to ensure adoption of evidence and use of knowledge to inform policies.
References

Appendix B: Study Protocol

Montreal Research Demonstration Project
in Mental Health and Homelessness

CSSS Jeanne-Mance
Douglas Institute

January 31, 2009
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1. Introduction

The Montreal project is designed to comply with the core requirements outlined by the Commission in its request for applications; however, we have also added a number of elements which we feel will enhance the project’s relevance for Montreal, as well as its scientific interest. Specifically:

(1) We propose to add a fifth group comprising 100 persons with moderate needs; this will enable us to compare the effectiveness of social housing combined with intensive care management (ICM) with the Streets to Homes approach. We feel that it is essential to make such a comparison in order to generate study results that can actually influence homelessness policy in Montreal even if, in the end, the Housing First approach proves to be superior to care as usual.

(2) We have broadened and made more specific several questions which the Commission has asked us to address through qualitative approaches. Specifically, the analysis of the implementation process takes into account the context of programs and examines that context using a variety of complementary approaches.

(3) Additional qualitative analyses designed to directly compare how service users perceive different types of independent apartments and different types of social housing have been added.

(4) We propose to invite the 200 persons assigned to the two groups receiving ICM support to take part in a random assignment study of the IPS (Individual Placement and Support) employment support model. This kind of study, which has never before been attempted, would help to determine the extent to which it is possible to help a homeless population enter the regular labour market in the context of the Housing First or social housing approaches.

(5) We have proposed an innovative mechanism to ensure that the participation of service users (persons with lived experience) will significantly influence the conduct of the project. We will evaluate the impact of this mechanism on the decisions made throughout the course of the study. This sub-project will seek to permanently strengthen the capacity of service users to contribute to the development of services, as well as to studies that concern them.

(6) Our proposals for the dissemination of project results includes a theatrical intervention project and, possibly (if additional funding can be secured), a documentary that will examine the experience of service users who participated in the project.

Our project is the product of numerous consultations involving: (1) representatives of organizations that provide housing services for the homeless and for persons with mental health problems; (2) representatives of associations that provide social housing to low-income persons; (3) representatives of the City of Montreal (which is not a project sponsor, at least not for the time being, as explained below); (4) representatives of community organizations that provide community support to the mentally ill and/or homeless; (5) service users; (6) community organizers; (7) institutional program managers; (8) on one occasion, the directors of psychiatry departments in Montreal; (9) several psychiatrists, including those who will work with the Assertive Community Treatment (ACT) team; and (10) researchers. More than forty persons, including several service users, participated in one or more of over thirty meetings, not to mention project-related telephone discussions.

2. Lead co-applicants

2.1 Services component

The lead applicant/service provider is the Centre de Santé et Services sociaux (CSSS) Jeanne-Mance. The CSSS Jeanne-Mance is part of Quebec’s network of health and social service institutions; it reports directly to the Agence de Santé et Services sociaux (ASSS) de Montréal, which, in turn, reports to the Ministère de la Santé et des Services

1 Ms. Suzanne Carrière, director of specific services and public health, is currently the manager directly responsible for homeless programs at the CSSS Jeanne-Mance.
Montreal Project in Mental Health and Homelessness: January 31, 2009

The catchment area of the CSSS (Montreal Island has 12 such Centres) encompasses the largest number of homeless persons in the City of Montreal. Accordingly, it is the area in which services for the homeless are the most highly developed and the area that has been given a mandate by the ASSS de Montréal to coordinate homeless services over the entire territory of Montreal Island. Consequently, it is the most appropriate CSSS to coordinate services under the MHCC research demonstration project. The CSSS Jeanne Mance currently manages a budget of approximately $166 million.

The CSSS will directly administer: (1) ACT services; (2) one of two ICM support services; (3) the three workers assigned to locate apartments or other housing for clients and to manage rent supplements; (4) the supported employment team (3 workers, including a worker from the ACT team); and, finally, (5) the community organizer responsible for managing the service users hired to work on the project. However, the CSSS will not manage the social housing units in which project participants (particularly those in the fifth group) may choose to reside.

Furthermore, the CSSS Jeanne-Mance cannot, on its own, assume direct responsibility for providing ICM support to 200 persons. Therefore, we have established an agreement in principle with a community organization called Diogène. The CSSS will act as the trustee for the funds transferred to Diogène. The details of the agreement between the CSSS and Diogène have not yet been finalized.

2.2 Research component

The lead applicant/researcher is Dr. Eric Latimer, a researcher with the Douglas Mental Health University Institute and an associate professor with the Department of Psychiatry at McGill University. The Douglas Institute, where most of the research funds will be administered, is authorized to manage research grants.

The lead co-applicant/co-researcher is Dr. Christopher McAll, the scientific director of the Centre affilié universitaire, CSSS Jeanne-Mance, and director of the Centre de recherche de Montréal sur les inégalités sociales, les discriminations, et les pratiques alternatives de citoyenneté (CREMIS – the research centre of the CSSS). Dr. McAll is a full professor with the Department of Sociology at the Université de Montréal. Part of the research funds will be paid directly to the CSSS Jeanne-Mance, which, in its capacity as an affiliated university centre, is authorized to manage research grants.

3. Consortium members and affiliations

3.1 Services component (including housing)

As stated in the introduction, several organizations other than the CSSS Jeanne-Mance and Diogène have participated in developing this application. These organizations represent shelters, service user groups, psychiatric and rehabilitation service providers, and others:

- Action Autonomie
- Centre d’activités de Montréal pour l’équilibre émotionnel (C.A.M.É.É.)
- Centre Dollard-Cormier
- Centre Hospitalier Universitaire de Montréal (CHUM)
- Centre Le Havre de Trois-Rivières
- Collectif de recherche sur l’itinérance (CRI)
- Hôpital Louis-H. Lafontaine
- Impact, a mental health support group
- Douglas Institute
- Institut national de santé publique du Québec
- Old Brewery Mission
- Projet régional sur la représentation de Montréal
- Le RACOR en santé mentale
- RAPSIM
- Réseau d’aide aux personnes itinérantes de Montréal

We intend to meet every six months with these partners. We also hope to broaden the membership in our consortium, particularly by bringing in representatives of government agencies that have a role to play in housing (Office Municipal d’Habitation de Montréal, Société d’Habitation du Québec) and health (Agence de santé et services
3.2 Research component

The research team is composed of researchers from five universities that have campuses in Montreal (Concordia: Nielsen; McGill: Crocker, Fleury, Latimer; Montréal: Bonin, Lesage, McAll; Sherbrooke: Vasiliadis; UQAM: Dorvil, Dupuis, Gagné, Hurtubise, Morin, Roy), as well as two American universities: Dartmouth (Becker, Drake) and Indiana University-Purdue University Indianapolis (Bond). Most of these researchers are affiliated with five research centres: Centre de recherche Fernand Séguin (Bonin, Lesage), Centre de recherche de Montréal sur les inégalités sociales (CREMIS) (Gagné, Hurtubise, McAll); Centre de recherche sur l’itinérance (CRI) (Roy); Dartmouth Psychiatric Research Center (Becker, Drake), and the Douglas Mental Health University Institute (Crocker, Fleury, Latimer).

4. Establishments that will administer the funds

4.1 Services component

All funds related to clinical services will be administered by the CSSS Jeanne-Mance:

Ginette Léonard
Director of financial resources
Centre de santé et de services sociaux Jeanne-Mance
155 St-Joseph Blvd East
Montreal, Quebec H2T 1H4

We hope that the City of Montreal, which currently administers a rent supplement program, will be able to administer rent supplements under our project, the amounts of which will be in keeping with its standards. However, an agreement to this effect has yet to be concluded.

4.2 Research component

We propose that the amount requested for the research component be distributed immediately to the facilities of the lead researcher and lead co-researcher, namely:

<table>
<thead>
<tr>
<th>Research Centre</th>
<th>Centre affilié universitaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Douglas Mental Health University Institute</td>
<td>CSSS Jeanne-Mance, CLSC des Faubourgs</td>
</tr>
<tr>
<td>6875 LaSalle Boulevard</td>
<td>1250 Sanguinet Street</td>
</tr>
<tr>
<td>Verdun, Quebec H4H 1R3</td>
<td>Montreal, Quebec H2X 3E7</td>
</tr>
</tbody>
</table>

The amounts to be provided will be established once the final project agreement has been concluded; this agreement is likely to have an impact on the research budget and its distribution among the sub-projects. From there, a portion of the funds will be distributed to the institutions of affiliation of co-researchers associated with other centres responsible for conducting certain projects.

5. Local context and current service models

The most recent survey on homeless/mentally ill persons in Montreal and the services used by these persons dates back to 1998. That survey found that 12,666 of the 28,314 persons who used homeless resources during the year had in fact had no fixed address at some point in the year. Furthermore, 70% of homeless persons in Montreal had experienced mental health problems that same year. The persons belonging to this group were primarily male (84%) and 48% of them were between the ages of 30 and 44 [1]. More recently (2005), federal estimates have set the
number of homeless persons in Montreal at approximately 30,000. This population is concentrated in the city core but is also found in boroughs such as Hochelaga-Maisonneuve, Plateau Mont-Royal or the South-West (RAPSIM, April 2008). Assuming that the percentage of persons who are both homeless and mentally ill is still approximately 70%, we may also assume that some 20,000 homeless persons with mental health problems currently live in the city centre.

The network of service organizations in Montreal is vast and difficult to circumscribe. In order to identify organizations and facilities that provide outreach and assistance to homeless persons (which is to say the users of shelter services, soup kitchens, or day centres, not all of whom are necessarily homeless) who also have mental health problems, we must target all the resources that are dedicated to either of these problems. It may be relatively easy to identify mental health resources because this designation directly corresponds to a program of the Ministère de la santé et des services sociaux, but the same cannot be said of resources for the homeless. Resources for homeless persons in Montreal were developed on the margins of the public system until the late 1980s: at the time, these resources were primarily community organizations, often with a religious vocation. In the wake of the International year of Shelter for the Homeless (1987), the City of Montreal and the health system began to get involved in a more significant way.

There are two major groupings of community organizations, one active in the field of mental health (the Réseau alternatif et communautaire des organismes en santé mentale de l'île de Montréal or RACOR), the other working on behalf of the homeless (the Réseau d’aide aux personnes seules et itinérantes de Montréal or RAPSIM). Each of these encompasses over eighty organizations, some of which are members of both associations. The RAPSIM directory (Répertoire des ressources du RAPSIM actives en hébergement communautaire et en logement social avec soutien communautaire (2007)) lists 43 organizations, while the RACOR website lists 17 different groups. For its part, the ASSS de Montréal funds 52 community organizations that provide shelter services for youth, battered women, and men and women in crisis (ASSSM, 2008). We must also take into account public agencies and their stock of residential mental health facilities which can also take in the homeless and those at risk of homelessness (3,488 places according to the ASSSM, 2008). We should also include the specialized services of the public system, particularly those of the CSSS Jeanne-Mance and its homelessness teams (Jeunes de la rue and Urgence psychosociale-justice), which provide services to more than 4,000 persons a year, many of whom are homeless. We should also mention resources such as Programmes itinérance/sans domicile fixe (homelessness) and Cormier Lafontaine (mental health) administered by the Centre de réadaptation Dollard-Cormier. Every week, hospital emergency departments in Montreal take turns providing services for the homeless and most CLSCs also provide services to this population from time to time.

Among the organizations that provide services to the homeless and mentally ill in Montreal, the Équipe Itinérance, created in 1990, merits special mention, both for its mission to serve the homeless and the fact that it is based at the CSSS Jeanne-Mance and will surely be providing services to persons in the control group. The team is composed of nurses, social workers, a community organizer, a part-time physician, a part-type psychiatrist, a coordinator and a secretary. This team essentially operates as an intensive case management team and is specialized in working with the homeless: its members work in the community, providing outreach to the homeless; as such, they rely greatly on community resources. However, given the number of persons the team seeks to assist, it is not able to offer interventions as intensive as those provided by a true intensive case management team. Moreover, it does not have the ability to provide housing, as the experimental programs in the study will do.

Earlier, we mentioned Diogène, a community organization that provides ICM services to homeless persons and others. Since Diogène is located near the CSSS Jeanne-Mance, it will likely provide services to some of the individuals assigned to the control group.

The objectives of the Ministère de la Santé et des Services sociaux du Québec (which have been taken up by the ASSS de Montréal) are to significantly increase access to ICM services, as well as to assertive community treatment (ACT) for persons with mental health problems. While progress has been made in recent years, these targets are far from being achieved. At best, only a small minority of the persons assigned to the control group will benefit from these types of services.
The following section provides a more detailed description of housing services for the homeless in Montreal.

6. Service plan

6.1 General approach: Addition of a fifth group

Through our numerous discussions with organizations that provide housing for the homeless, as well as with representatives of the City of Montreal, it became clear that most view rent supplements for independent apartments as an approach that is destined to play a limited role. The City of Montreal and the Montreal Metropolitan community, both of which fund social housing, view social housing as an approach that is more likely to bring about structural and durable change in urban dynamics, particularly in sectors in need of revitalization. The funding of social housing through not-for-profit organizations also provides a means of developing forms of housing that the private sector does not produce.

The Office municipal d’habitation de Montréal currently manages some 7,000 units for which tenants receive rent supplements. This mechanism provides a means of offering affordable housing in neighbourhoods that lack subsidized buildings, as well as to accommodate homeless or displaced families. However, this stock of housing units has been either stable or declining for several years and no new units are expected to be created.

Given what was said earlier about limited access to intensive case management (ICM) services, as well as to social housing, we feel that even a convincing demonstration of the superiority of the Housing First approach over care as usual will not be enough to persuade our community to adopt this approach. There will be no evidence of its superiority over social housing, because too few clients will have had access to the latter. However, if we succeed in demonstrating that: (1) most clients prefer to live in independent apartments and are able to hold on to their apartments with appropriate external supports; (2) these clients are housed more stably and make better progress on a clinical level when housed in independent apartments; and (3) the Pathways/Streets to Home approach ultimately costs less, we will have made, at the very least, a substantial argument in favour of reorienting housing development in this direction.

Accordingly, we propose to create a fifth group, in keeping with an option described in the request for applications. In order to be able to directly compare the impact of social housing with that of housing in subsidized independent apartments, we firmly believe that the clinical management approach must be the same for both groups. Since it was not logistically possible to have the CSSS Jeanne-Mance organize two ICM groups and since there is reason to believe that a team organized by a CSSS and another organized by a community organization like Diogène may well have a different impact on their respective clienteles, we propose to randomly assign the clients in the housing groups to either team.

The table provided below summarizes the services we propose to offer.

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2 The term social housing is used here to mean subsidized housing where rents are made more affordable for persons with limited means. Many such buildings in Montreal are not dedicated to a mental health clientele. In many cases, community support (in the sense of a community of persons living in the same building) is also provided. This support can be fairly intensive: as many as three full-time workers for 32 apartments for example. In order to make up for the lack of ICM services (person-centered support), the support provided sometimes includes accompanying individuals in activities that go beyond the activities of every day life within their building.

3 Based on an e-mail from Suzanne LaFerrière, development consultant, Direction de l'habitation, Service de la mise en valeur du territoire et du patrimoine, City of Montreal, December 15, 2008.
<table>
<thead>
<tr>
<th>Persons with high needs</th>
<th>Experimental group (Housing First) ( (N=100 + 100) )</th>
<th>Comparison group (care as usual, enhanced, in Montreal) ( (N=100) )</th>
<th>Control group (care as usual) ( (N=100+100) )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A</td>
<td>Assertive community treatment (ACT model)</td>
<td></td>
<td>Group B</td>
</tr>
<tr>
<td></td>
<td>Choice of independent apartments, with rent</td>
<td></td>
<td>• No particular intervention; the individual</td>
</tr>
<tr>
<td></td>
<td>supplements and guaranteed bus/subway pass</td>
<td></td>
<td>goes on as though he or she were not part of</td>
</tr>
<tr>
<td></td>
<td>Social housing that is not reserved for</td>
<td></td>
<td>the study, aside from participating in</td>
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<tr>
<td></td>
<td>persons with mental health problems is also</td>
<td></td>
<td>interviews</td>
</tr>
<tr>
<td></td>
<td>offered(^1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group C</td>
<td>Streets to Homes type case management</td>
<td>Group D</td>
<td>Group E</td>
</tr>
<tr>
<td></td>
<td>(institutional or community-based team</td>
<td>• Streets to Homes type case management</td>
<td>• No particular intervention; the individual</td>
</tr>
<tr>
<td></td>
<td>(Diogène), clients randomly assigned)</td>
<td>(institutional or community-based team (Diogène), clients randomly assigned)</td>
<td>goes on as though he or she were not part of</td>
</tr>
<tr>
<td></td>
<td>• Choice of independent apartments, with rent</td>
<td>• Privileged access to apartments in buildings</td>
<td>the study, aside from participating in</td>
</tr>
<tr>
<td></td>
<td>supplements and guaranteed bus/subway pass</td>
<td>reserved for social housing(^2)</td>
<td>interviews</td>
</tr>
<tr>
<td></td>
<td>• Social housing that is not reserved for</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>persons with mental health problems is also</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>offered(^1)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) In the case of clients assigned to groups A and C, the project offers no subsidies for social housing providers (beyond the government subsidies already provided). Again, this housing is not reserved for persons with mental health problems (such dedicated housing is perceived as limiting social integration). We anticipate that the housing team will have difficulty identifying social housing resources that are prepared to accept this clientele.

\(^2\) We will strive to offer clients a choice of different types of social housing. Given that this group is offered ICM support services, we will attempt to find formulas in which community support (in this instance housing-related support) is minor and largely focused on the person’s life within the building. Those who leave their social housing units or who refuse to accept a housing unit, will be free to do as they choose, including finding an independent apartment; however, clients in this group will not receive rent supplements if they move into independent apartments.

### 6.2 Assertive community treatment (ACT) team - Group A

Our intention is to demonstrate a program that is consistent with the *Pathways to Housing* model, as described in the request for applications and the documents that were subsequently provided. This program will seek to offer the complete range of clinical services to homeless persons with major mental health problems. These clinical services will be combined with a *Housing First* program, as described in section 6.5.
The program will comprise 10 professional workers, including nurses, social workers, ergonomists and any other clinically appropriate professions (e.g., educators, psychotherapists), depending on recruitment opportunities, along with a team leader (the 11th team member, who will also provide clinical services) and a psychiatrist who will be available on a full-time basis. (The team leader will also be responsible for coordinating the institutional Streets to Home team.) In keeping with the ACT model, the team will also include an alcohol and drug addiction specialist, a job placement specialist trained in the Individual Placement and Support (IPS) approach, and a peer support worker. The professional/patient ratio will be 1:10, which is the standard for assertive community treatment teams; this ratio allows for highly intensive services (up to 2 meetings a day, 6 days out of seven, 12 hours a day, as well as 24/7 availability through a custodian system for crises and emergencies.

Program clients who require emergency visits or hospitalization will continue to be followed by the team and the team psychiatrist will become the attending physician while the patient is in hospital or work closely with the hospital care team in order to coordinate treatment and prepare the patient’s return into the community. Once it has reached maturity (in 18 months according to our plans), this team should be able to manage 100 patients. Over 70% of all contacts with clients will take place in their living environment.

The team will offer a complete range of services, including treatment of psychiatric and medical conditions, rehabilitation, crisis intervention, integrated addiction treatment (harm reduction approach), supported housing and employment (or education as the case may be – see below the sub-study on supported employment based on the IPS model), as well as any other needs identified by the patient (in accordance with the Pathways to Housing model). The clinical approach will be informed by the recovery movement and will emphasize client choice, the reduction of stigmatization, the resumption of normal adult roles, and integration into the community. The team will work closely with its partners in the Montreal homeless services system, including the homeless program of the CLSC des Faubourgs, other resources for the homeless, the Diogène program, and other partners offering services to homeless/mentally ill persons, to ensure that clients can access the entire range of support services they need in order to maintain their housing and pursue their recovery. However, the team will remain entirely responsible for its clients and will provide most of the psychiatric treatment and support services they require.

Eligible persons (namely the chronically homeless and those with serious mental health problems) will be identified by the outreach team and randomly assigned to the ACT team by the research group; they will meet with the team in their own living environment. An initial intervention plan, based on the client’s own priorities, will be established at the first meeting. The ACT team will work closely with clients and the housing team to help clients quickly find an apartment of their own choice (usually the first priority of homeless persons). Clients will have no obligations related to follow-up, treatment or substance abstinence; the only condition that will apply will be the standard Pathways condition of agreeing to a minimum of one visit per week from the team. Moreover, there will be no time limits on the services provided by the team; services will continue as long as they are deemed to be useful and appropriate by both the client and the team. Conceivably, some clients will reach a point in their recovery where they will have achieved a high level of stability and confidence, as well as the ability to independently manage their own housing arrangements, as well as their physical and psychiatric conditions, and other aspects of their lives (socialization, work, etc.); such clients will no longer require the same level of support and will be transferred to less intensive services (such as ICM or other types of ambulatory care services). Clinical services will be organized around an individual intervention plan developed with the client on the basis of the latter’s priorities and interests, the ultimate goal being the client’s recovery. Intervention plans will initially be established for 30-day periods until such time as the most immediate and urgent objectives have been achieved (securing and maintaining housing, stability, income and an initial budget, management of acute medical/physical conditions, initial organization of housing, etc.).

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4 It is unlikely that a client initially assigned to group A (Pathways) would be ready for such a transfer while the study is still underway (i.e., within two years of admission). However, if this should occur, we will try to keep the client in the Pathways program until the end of the two-year period, while reducing the intensity of the intervention provided.
Intervention plans will then be established for three-month periods and will seek to achieve longer-term objectives (occupation, employment, socialization, management of the risks and consequences associated with substances, etc.).

The ACT team will work closely with the research team to ensure that data is collected for the purposes of the overarching research project.

The CSSS Jeanne-Mance will be responsible for recruiting the team, managing human resources, paying salaries, verifying the quality of services (provided by non-medical personnel), securing necessary office space and equipment (computers, cell phones, transportation, etc.), as well as administering the clinical records of the team’s clients. The program will be located at one of the service points of CSSS Jeanne-Mance, preferably the office on Sanguinet Street, which is optimal in terms of its proximity to the target population, as well as to its natural partners, most notably the homeless program administered by the CLSC des Faubourgs. The physical spaces developed for the program will reflect the ACT team plans described in the reference work by Allness and Knoedler (2003) [2]. The CSSS Jeanne-Mance will oversee the recruitment and training of team members, as well as the administrative support and funding of current activities (with funds from the Mental Health Commission of Canada).

The CHUM (Centre Hospitalier Universitaire de Montréal) has made a commitment to provide medical/psychiatric support to the ACT-homelessness team. Several psychiatrists have expressed an interest in the project (including Drs. Marie-Carmen Plante, Olivier Farmer and Adolfo Segura), and it is understood that the CHUM is committed to providing sufficient psychiatrist time to ensure that the team is able to fulfill its mission (it is anticipated that the team will require the services of a qualified psychiatrist three days a week). The CHUM is also committed to making psychiatric emergency and hospitalization services available to the team to ensure that patients in the program will enjoy optimal, continuous follow-up (the same psychiatrist and the same team for community-based care, emergency interventions and hospitalizations), until a psychiatry department can be created for the CSSS Jeanne-Mance within Notre-Dame Hospital, at which time the hospital beds allocated to the CSSS will be transferred to the new department. Should this come to pass, the new department will assume these responsibilities and the CHUM will withdraw.

### 6.3 Institutional intensive case management – Groups C and D (moderate need experimental group and comparison group)

A team of five workers will be established to offer ICM support services along the lines of the Streets to Home model to half of the clients in groups B and C. These workers could be social workers, psychoeducators, or persons with other related training. Having a variety of experts is desirable since it will enrich the team’s discussions. Given the caseload that will be assumed by each worker, we do not anticipate including peer support workers. The team will offer its services 7 days a week, 12 hours a day, as described in the request for applications. The five-member team will be supervised by the ACT team coordinator, who will be supported by a part-time secretary.

The team will work closely with the members of the housing team (whose activities are described below). Approximately half of its clients will be from group C and will live primarily in independent apartments, while the other half will live primarily in social housing. The ICM team will also work closely with a worker from the IPS team (see IPS study below).

The team’s offices will be located at the CSSS Jeanne-Mance, in the same building as those of the ACT team.5

### 6.4 Intensive case management by a community organization - groups C and D

As indicated above, the creation of a fifth group will require the formation of a third clinical team, which will be supported by the community organization Diogène. The latter has been given two regional mandates by the ASSS de Montréal: (1) to offer services that constitute an alternative to incarceration and prevent problems with the justice

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5 As indicated in the budget, a number of refits and renovations will be required to accommodate this clientele.
system for the target clientele; and (2) (directly relevant to our project) to provide support to organizations that work with the homeless, as well as direct services to the clients of these organizations (http://www.rosac.ca/membres/diogene.htm). Of the various organizations providing community support to persons with mental health problems, Diogène is the one whose experience is most relevant to our project. There is also a facilitating logistical factor: its offices are located not far from where the other workers and interviewers in the study will be based.

With its vast experience working with the homeless, Diogène will be able to adopt a mode of operation along the lines of Streets to Homes. Like the institutional ICM team, Diogène will work closely with a member of the housing team and a member of the IPS team.

6.5 Choice of independent apartments – groups A and C (experimental groups)

The persons assigned to groups A and C will have access to the services of the housing team (which will be composed of three members). Two members in this team will identify independent apartments that correspond to the preferences of clients in groups A and C and are made affordable as a result of rent supplements. In order to maximize clients’ chances of holding on to their apartments, rent supplement amounts will be based on the standards established by the City of Montreal in its own rent supplement program (see budget – the supplements are approximately $400 a month). In order to increase the number of options offered to clients, the housing team will also offer social housing units – in buildings reserved for low-income persons who do not necessarily have mental health problems. (Units in buildings dedicated to persons with mental health problems will not be offered to groups A and C). However, no subsidies from the Commission will be granted for social housing for persons in groups A and C. Under these circumstances, it is highly unlikely that social housing providers would be interested in setting aside some of their units for our clients. Accordingly—and also because most clients prefer to have their own apartment—we anticipate that the vast majority of our clients will be housed in independent apartments, at least initially.

Housing team. We have made numerous references to the housing team. This team will be composed of four workers, all funded through the project. Two of these workers will be associated with groups A and C and will be given the following mission: (1) identify independent apartments (or, on occasion, social housing, as indicated above) that meet the needs of the two experimental groups (affordable, good quality-price ratio, close to a subway station or the city centre if possible, variety), based on the personal preferences expressed by clients when they entered the project; (2) working with the clinical team, have clients visit available apartments; (3) help clients furnish and set up their apartments; (4) if time permits, provide additional support to clients once they have moved into their apartments to facilitate their integration into their new living environment. The third worker on the housing team will identify subsidized social housing for the comparison group. The fourth worker will be responsible for administering rent supplements for independent apartments (experimental groups A and C) and social housing (comparison group D). In order to facilitate its dealings with the clinical teams, the housing team will also be based at the CLSC des Faubourgs.

6.6 Choice of social housing – group D (comparison group)

The comparison group for persons with moderate needs (group D) will enjoy privileged access to social housing (secured for them by the third member of the housing team). In order to make such units available to group D members, significant subsidies will be offered to building owners or managers (see budget). Based on the discussions that were held while we were preparing this application, subsidies on the order specified in our budget would secure a sufficient number of places to accommodate the 100 persons in group D. The designated worker from the housing team will seek to offer clients as many options as possible. Comparisons between groups C and D will essentially relate to the types of housing they respectively occupy.

Clients from group D will also be free to opt for an independent apartment; however, since they belong to group D, they will be required to forgo any rent supplement if they choose to live in an independent apartment. Accordingly, we anticipate that most clients in this group will opt to live in social housing.
6.7 Groups B and E (high need and moderate need control groups)

The two control groups will receive care as usual. We feel that the construction of groups A, C and D (experimental groups and comparison group) should not affect the housing options made available to the control groups, for two reasons: (1) clients in groups A and C, who might normally have gone into social housing, will be steered toward the apartment market, thereby freeing up “natural” spaces (not subsidized through the research project) in the social housing market; (2) social housing spaces occupied by group D will have been made available to this group through subsidies and would not have been offered (at least for the most part) to clients in the control group—particularly since most members of the latter group do not have access to the kind of community support needed to facilitate access to housing.

6.8 Training

Our intention is to have workers from the ACT/Pathways and ICM/Streets to Homes teams participate in the training provided for by the MHCC. We also propose to involve two trainers from the Centre national d’excellence en santé mentale (CNESM), Deborah Thomson and Sylvie Bouchard. The CNESM has a mandate to support the development of assertive community treatment (ACT) and intensive case management (ICM) teams across the province. The creation of the CNESM indicates that the Ministère de la Santé et des Services sociaux understands that training a clinical team requires far more than initial basic training: coaching from a experienced consultant/trainer over a period of one year or more is also required. [3] Both Deborah Thomson, who will support the ACT teams in part of the province, including Montreal, and Sylvie Bouchard, who will work with the ICM teams, will support the three clinical teams in their efforts to conform with the model.

The Douglas Institute IPS team, which was trained in Dartmouth to train other IPS teams in the province, will train the IPS workers. This will include both initial training, as well as follow up training throughout the project. 6

7. Research plan

7.1 Overview

Our intention is to cooperate fully with the MHCC project and to provide data that is comparable to that provided by other sites for the purpose of aggregate analyses. Consequently, we will not reiterate all of the research questions contained in the MHCC research design, as set out in the request for applications.

However, as we indicated in the introduction, we wish to take advantage of the opportunity offered by the MHCC project to address a number of additional questions. These questions have been selected on the basis of the following criteria:

(1) Will the information contribute to a better understanding of the effects of the intervention as it applies to Montreal?

(2) Will the information help us understand the differences observed between the two Housing First groups and the two control groups?

(3) Will the information have local policy relevance?

(4) Will the information contribute to the improvement of Housing First services?

(5) Will the information be relevant for service users?

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6 An agreement to this effect has not yet been reached with the Douglas Institute, but past experience suggests that it should be relatively easy to secure such an agreement.
In this section, we will begin by detailing the data collection procedures that we plan to put in place, including the administration of a questionnaire to the entire cohort. We will then describe the proposed research sub-projects, which have been grouped according to the criteria listed in the preceding paragraph.

**7.2 Data collection procedures – administration of a questionnaire to the entire cohort**

**7.2.1 Identification of potential study participants**

A three-person, mixed-gender outreach team with street outreach experience with the homeless will be recruited by the research team to help identify persons who meet the study’s eligibility criteria (homelessness and mental health problems). Our plan is to have the team in place three months before the start of the recruitment process, that is by early June 2009. These workers will spend time in different areas frequented by homeless persons. Our strategy for ensuring an appropriate recruitment rate for the project is to take the time to establish a relationship of trust between the outreach team and homeless persons. The outreach team will be in a position to identify persons who appear to meet the criteria of the research project in terms of their housing arrangements and mental health status. Our hope is that the relationship of trust established over weeks or months will make potential participants sufficiently comfortable to agree to meet with an interviewer and, ultimately, to participate in the study. (We will not reiterate the criteria set out in the request for applications, but we will respect them). The initial contact between interviewer and homeless person will take place in the presence of the outreach team member with whom the homeless person has established a relationship of trust.

Outreach team members will be available to intervene anew, at least initially, if an interviewer has difficulty maintaining contact with a client (for example, if the client does not present for the second interview for admission into the study). They will also collaborate with the regular interviewers on the brief intermediate interviews carried out on months 1, 2, 4, 5, 7, 8, ..., 23, the purpose of which is to maintain contact with clients, as well as to ensure that they will be available to participate in the longer interviews (months 3, 6, 9, 12, ..., 24.).

The three members of this team will be hired by the research team, which will discriminate in favour of candidates who have themselves experienced homelessness.

*Interviewer team.* The number of interviewers on the team will vary according to the stage of the study, but may rise to seven during months in which approximately 500 persons are followed. The interviewer team will be responsible for collecting data. We will strive to ensure that the team includes at least two service users.

*Eligibility verification.* At the outset, the interviewers will be responsible for verifying clients’ eligibility. They will use the information provided by the outreach team to confirm the person’s homeless status and determine whether their mental health status justifies placing them at the very least in the moderate need group.

**7.2.2 Client consent and assignment to a group**

Clients whose eligibility has been established will receive detailed explanations concerning the conduct of the study, including: the nature of the groups to which they may be assigned (based on their level of need, which will be determined once they agree to participate in the study), the nature, duration and frequency of interviews, and the chances that the advantages associated with their participation in the study will come to an end once the study is completed. The confidentiality of client information will be stressed. Clients will be asked to answer a number of questions designed to ensure that they have fully understood the information imparted to them. Clients who show a clear interest in participating and a sound understanding of the implications of such participation will be asked to sign a consent form. Those who agree to sign the consent form will then be asked to complete the first portion of the intake assessment. (The intake interview may take up to four hours in total.) Clients will receive $25 upon completion of the first portion; a second meeting will then be scheduled, ideally for the following day.

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7 Our concern is that obtaining information from third parties to establish a person’s level of need, which, in any case, would require the person’s consent, might intimidate potential participants and deter them from participating in the study.
End of intake interview and assignment to an experimental or control group. At the following meeting, the second portion of the interview will be completed. Based on this interview, the interviewer will determine whether the person has a high or moderate level of need. Depending on the outcome of that decision, the interviewer will then open one of two envelopes that will reveal the group to which the client has been assigned.

Random assignment procedure: In our view, it would be preferable that all the sites use the same procedure to assign clients to groups. In an earlier study carried out by the lead researcher [4], we used a block randomization approach, with stratification based on two criteria, to ensure that certain important variables would be balanced among the different groups. In the present study, we could stratify participants according to gender and age – two variables that are commonly thought to influence homelessness.

7.2.3 Verification of questionnaires
Our plan is to have the questionnaires administered by computer so that the validity of the data can be established automatically. For instruments specific to Montreal (see next section), it may be necessary to computerize certain questionnaires.

7.2.4 Subsequent interviews
The interviewers will be responsible for conducting follow-up interviews at 6, 12, 18 and 24 months, as well as shorter interviews every three months. They will work with the outreach team to ensure that the short intermediate interviews are also carried out. Our plan is to have the outreach team gradually withdraw from the project as our interviewers gain enough experience to maintain contact with participants (we naturally anticipate that the control group will be the group with which it is most difficult to maintain contact).

7.3 Gaining a better understanding of the Housing First intervention in Montreal
The Canadian research team intends to aggregate data obtained in Montreal that is common to the five sites with the data from the other sites; this will endow this study with a remarkable degree of statistical power and allow for more a detailed analysis of sub-groups than is possible with a sample taken from a single site.

However, we can only propose to carry out comparative analyses between the experimental groups and control groups in Montreal. (Later, we will return to the matter of comparing groups C and D). Our partners would no doubt be interested in the results, although, in our view, the comparison between groups C and D is the one most likely to influence housing policy.

Due to lack of space, we will not provide detailed descriptions of the analytical methods we propose to use to compare clinical results; these methods are in fact typical of those normally used in random assignment studies. A good example would be the analyses that were carried out by the lead researcher and a number of colleagues as part of a random assignment trial dealing with an IPS-style employment support program. [4]. We will remain in touch with the Canadian research team while these analyses are being carried out.

It seems likely, however, that the instruments that are common to the five sites will not cover all the areas that interest us or will cover them in a less complete fashion than we would like. Given that discussions concerning the exact nature of these common instruments have yet to be concluded, we are unable to be more specific on this score for the time being. However, we can mention three areas that may ultimately be measured with less accuracy that we would like or that may not be evaluated at all: (1) services rendered and related costs; (2) criminality and victimization; and (3) families.

7.3.1 Effect on services rendered and costs
In order to achieve an accurate economic evaluation (see section 7.5), we will need to know, with a degree of certainty, exactly which services people have used: a generic instrument for the five cities cannot possibly account for the services that are specific to each city. For example, the unit cost of social housing will not be the same (although this is primarily relevant to the comparison between groups C and D).
It will also be important to be able to describe the service trajectories of homeless persons in the control groups, something which also requires a certain degree of specificity.

Finally, the ability to identify the specific resources which the control group used, as well as those they found to be most useful, will enable us to study a sample of these resources in depth (and thereby gain a better understanding of the differences observed between the groups – see section 7.4.2).

7.3.2 Effect of the intervention on criminality and victimization and effect of personality traits on housing success

Deinstitutionalization has increased the presence and visibility of persons with mental health problems, while inappropriate community care has relegated these persons to the physical and social margins of society. As a result, the likelihood of criminal justice involvement has also increased for these individuals. Canadian studies have shown that persons with serious mental health problems have more frequent dealings with the police, either for being suspected or accused of committing offences. They also commit more offences and are more likely to re-offend. [5]

Furthermore, persons with mental health problems, (particularly those with serious problems), are more likely to have issues of comorbidity, such as substance abuse and antisocial personality disorders. According to Belcher [6], persons with serious mental health problems who become homeless upon being discharged from hospital are more likely to have problems with the criminal justice system. Not only do homeless persons have higher rates of criminality than the general population, but homeless persons with serious mental health problems have rates that are higher still. [7]. In most cases, the offences are minor ones [8], but a far from negligible proportion of persons with serious mental health problems are arrested for violent crimes. [5]. Alcohol abuse and antisocial personality disorders constitute significant associated factors in these cases. [9]

1) Criminal trajectories

The objective here is to evaluate the extent of the impact of the project intervention on the participant’s criminal trajectory. To describe this trajectory, we will include with the battery of questionnaires a detailed chronological assessment of contacts with the law in the year preceding the initial assessment as well as for the entire duration of the project: calendars will be used for this purpose (timeline follow-back method). The information will include: number and types of contacts with the police, contacts with the Montreal mental health court, number of arrests and types of offences, number and duration of incarcerations, etc.

We will also examine criminal records. The criminal history as well as self-reported information will be added to the official data from the criminal records obtained from the Fingerprinting Service of the Royal Canadian Mounted Police (RCMP). In addition, since criminal acts leading to a verdict of not criminally responsible on account of mental disorder as well as orders for assessment of fitness to stand trial are not systematically compiled by the RCMP, this information will be collected from the records of the Commission d’examen des troubles mentaux du Québec.

These data will then be combined with the information on mental health services in order to draw up a comparative history profile for individuals with and without criminal records. For each participant, the dates and locations of convictions (RCMP), Commission d’examen hearings and health services received (RAMQ–Med-Echo) during the two-year study follow-up period as well as during the year preceding their inclusion in the project will be recorded. Using these data, we will identify and group similar trajectories based on similarities in type of institutional contact, for example health services only vs. justice system and health care system.

2) Victimization

It is plausible that a Housing First type intervention may reduce the level of victimization by removing homeless persons from dangerous environments. Individuals with mental health problems are at much greater risk of being victims of criminal acts and violence. The reported prevalence rates for exposure to interpersonal violence range from 48% to 98% among individuals with a serious mental disorder [10-12]. In a recent survey of the scientific literature, Choe et al. showed that approximately 35% of individuals with a serious mental disorder had been victimized in the
year preceding the survey [13]. Teplin et al. also report that nearly one quarter of individuals with a serious mental health problem interviewed had been victims of an act of violence in the year preceding the interview, i.e. 11 times more than the general population, after accounting for sociodemographic variables [14].

Instrument: The criminal victimization module of Statistics Canada’s General Social Survey (GSS) will be used for comparison with the Canadian data for the entire participant follow-up period (administration time = 10 minutes).

3) Impulsiveness, violence, aggressiveness and antisocial personality disorders
We are also considering collecting data on impulsiveness, violence and aggressiveness, as well as antisocial personality disorders (due to space constraints, we will not go into detail here). These measurements could affect the individual’s behaviour in housing and jeopardize his success in a Housing First type program (or in social housing). However, we will have to see whether it is feasible to incorporate these measurements in a battery of instruments that is likely to be relatively long.

4) Multiple correspondence analyses
This type of analysis involves grouping together individuals with similar characteristics, i.e. disruptive behaviour patterns, that are likely to jeopardize their success in housing. (The rest of this section has been written in English due to the very technical language involved.) Challenging behavior profiles will be generated using multiple correspondence analyses, an extension of simple correspondence analysis for more than two variables represented in a multi-way frequency crosstabulation [15, 16]. The results of correspondence analyses, whether simple or multiple, provide information which is similar in nature to those produced by principal component analysis, but it is oriented toward categorical data. Multiple correspondence analysis will first be used to explore relationships between the aggression variables from the SOS in order to find and understand aggression profiles as well as an input for clustering analysis. In order to determine the number of dimensions to retain in the analysis, the “Scree Test” will be applied [17]. Although multiple correspondence analysis provides a good picture of the data, hierarchical clustering analysis is needed in order to group individuals of similar challenging behavior into respective classes. The complementary nature of the two methods lies both in the basic understanding of the data structure as well as its amenability to the interpretation of results [18]. Ward’s criterion will then be applied given that it has been shown to yield a minimum loss of inertia [19]. In order to determine the number of clusters to be retained, the dendrogram (aggregation tree) yielded from the hierarchical analysis will be used. Both multiple correspondence and hierarchical analyses will be performed using SAS for Windows version 9.1 (SAS Institute Inc, 2006 #8626).

7.3.3 Intervention’s effects on families
Families frequently play an important role in the mental health services of their family member. One of the objectives of the Quebec Department of Health and Social Services (MSSS) is to encourage the participation of service users and their families in decision structures. However, families also want to have some input in discussions on the principles and practices governing the mental health field (MSSS 2005). The experience of past reforms has shown that these changes can have a negative impact on the burden and, consequently, the health of natural caregivers, who frequently turn to community organizations for support. However, studies have shown that individuals’ prior family history plays a role in their current lives, as a result of abandonment at a young age or a history of abuse or neglect (Reilly, 1993). It is also reported that a homeless person may decide that he no longer wants to see his family, or the family may no longer want to see the homeless person. Studies also report that persons with concurrent mental and addiction disorders are homeless longer and have less contact with their families. Finally, there is some reason to believe that in a program such as Housing First, some individuals who improve their quality of life will become closer to their families.

The main objective of the proposed analysis is to understand the role of families of homeless persons suffering from mental disorders, in a context of changes in mental health and addiction services, and how this role can be affected by the participation of their family member in a Housing First type program (or in the comparison group).
During the baseline interview for all project participants, we will ask the participants to authorize access to various data, such as data from the Régie d’assurance maladie du Québec (RAMQ) [Quebec health insurance plan] (medical services and drugs), MED-ECHO (hospitalizations), and the RCMP for criminal records. At that time, we will ask the participants whether they also agree to allow us to meet with a family member they feel closest to or to whom they would like to be closer. Participants will have to complete a consent form for this meeting, with the names and telephone numbers of these family members. We will then create a theoretical sampling of 15 individuals, preferably with the following distribution: approximately five from the Housing First group – groups A and C; five from the comparison group – group D; and five from the control group. We will meet with these natural caregivers twice: at the start of the project and 18 months later; the interviews will last approximately 90 minutes. The first interview will deal with a retrospective of their ties with their family member participating in the project and the help that they have provided or continue to provide. The second will examine whether any changes have occurred between the two meetings and will explore the nature of these changes. We will also examine the natural caregivers’ perceptions about the future of their family member and what improvements may be necessary in order to more effectively help that person.

The qualitative data generated by the group and individual interviews will be analyzed using the method proposed by Miles and Huberman with the assistance of the Nvivo software program. According to Miles and Huberman, analysis of the data collected consists of three simultaneous flows of activities: data reduction, data display and conclusion drawing/verification [20].

**7.4 Analyses aimed at gaining a better understanding of the underlying reasons for the differences observed between the experimental and control groups**

**7.4.1 Context and implementation analyses**

In order to understand the effects of the services that both the experimental groups and control groups receive, it is necessary to understand: (1) the nature of the services that clients in the control groups receive; and (2) the extent to which the experimental services have been implemented as planned.

The implementation analysis described in this section aims to clarify these two questions. At the same time, it will answer the questions posed by the MHCC concerning the project development phase. In the next section (7.4.2), we will describe a complementary analysis which aims to examine in depth certain key services received by clients in the control group.

This description of the implementation component will be divided into two sections: 1) implementation context (i.e. organization of services for the homeless) and 2) implementation of the intervention (experimental groups).

The implementation studies will evaluate the degree of operationalization of an intervention, i.e. the difference between the actions planned and implemented. This exercise contributes to a better understanding of the factors that facilitate or hinder an intervention, and thus weight the impact of an intervention as implemented in practice. By providing a detailed description of the intervention implementation process, this type of study also facilitates the generalization of similar interventions in other contexts and their likelihood of being successfully implemented. Hence, if the implementation of an intervention is suboptimal, it is unlikely to have much impact, although this should not be interpreted as an “inadequate intervention.” An implementation study will therefore identify the strengths and weaknesses of the intervention models (i.e. experimental groups) as a function of various aspects or dimensions (e.g. leadership, competence, conflicting culture, inadequate availability of housing) and, ultimately, help devise solutions for facilitating their optimal implementation.

The literature on implementation, and specifically in the health care field, emphasizes the difficulty of implementing interventions with complex systems. In a review of the literature on implementation, O'Toole [21] identifies more than 300 key variables critical to the successful implementation of an intervention: goal clarity, the human, financial and managerial resources mobilized, consensus concerning the planned change, leadership, costs of
the reform, etc. The variables that characterize the successful implementation of an intervention fall into two categories, those associated with the intervention per se, and contextual variables, i.e. the suitability of the intervention to the structure, to the organizational culture and in meeting client needs [22-26]. In fact, both the implementation and the effects of an intervention depend on a thorough understanding of the system in which this intervention is carried out. In the case under study, a better understanding of the system and of the services normally provided to the homeless will help more accurately weight the outcomes between the experimental and control groups. The proposed implementation study should also lead to a better understanding of the differences between the outcomes associated with implementation of the experiment in Quebec versus other Canadian sites.

1) First component: Implementation context or current organization of services for the homeless

In order to more clearly identify the context, issues and effects of implementation of the intervention, this section aims to describe the organization of services provided to homeless people in Montreal (i.e. structure, practice, dynamic and internal and external issues). The organization of services involves public institutions (health and social services network), community organizations (COs – or not-for-profit organizations: NPOs) and the housing sector. Aspects considered will include the service lines (levels of specialization) and the governance structures mobilized (i.e. types of programs, administered by the regional agency, institutions or the municipality; integration with local services networks (LSNs): 12 in Montreal, etc.). Although the main objective here is to identify the organization and current issues relevant to the services provided to the homeless in Montreal, the study will also attempt a brief reconstruction of the key periods in the evolution of the organization of services in recent years. The information sources, aspects examined and data-processing methods are described below.

Data collection

A variety of information sources will be used and data will be collected in two phases, which are planned based on the type of data to be retrieved and in order to optimize the information. The first phase of data collection includes: 1) a review of the literature on homelessness in Montreal (and in Quebec to a lesser extent – secondary sources, including the interviews conducted during development of the protocol); 2) the activity reports and financial reports of the organizations providing services to the homeless for the year 2007/2008 that can be completed by the organizations’ websites (especially: COs or NPOs – primary sources); and 3) a brief questionnaire to be completed by key types of organizations (i.e. public and COs based on their respective missions). The second phase, which complements the first, includes: 1) interviews with key actors in the homelessness sector (regardless of their organizational affiliation and 2) questionnaires to be completed by organizations in the homelessness sector. The key actors will represent the service-providing organizations in the public health and social services network (including various institutions and programs), COs (or NPOs) and the Montreal housing community, but will also include representatives of the government, the Agence de Montréal-Centre and the municipality. In the public sector, the main sources contacted will be downtown institutions (e.g. hospitals – mainly emergency and psychiatry; CSSS [health and social services centres]–homelessness component; substance use). In the case of COs and NPOs, the main sources contacted will be: 1) shelters, 2) hostels, 3) social housing units with community support, 4) day and evening centres, 5) street and/or community services and support, 6) employment assistance and/or social and job integration services, and 7) others or various social service agencies serving a wide range of clients. Approximately 50 questionnaires will be distributed to typical organizations, and approximately 30 interviews of approximately 90

8 None of the programs offered by COs funded by the MSSS (CO support program) are specifically designated as “homelessness” programs. The programs examined will include: disadvantaged persons, mental health, substance abuse/alcoholism and mixed housing. The Réseau d’aide aux personnes seules et itinérantes de Montréal (RAPSIM) includes 82 organizations that work directly with the homeless or persons at risk of becoming homeless.

9 This component is coordinated by Dr. Dorvil, but certain aspects will be incorporated in the implementation study.

10 There is no specific program in the MSSS structure relating to homelessness. The most relevant programs are: mental health, dependency and general services (including emergency).
minutes are planned in order to complete this component. Group interviews could be arranged in some cases. A questionnaire on sampling of the resources most frequently used by clients will also be carried out in order to gain a better understanding of the services provided and practices for the homeless in Montreal (component coordinated by Dr. McAll). In addition, the “service use component” (questionnaire incorporated and adapted from the main project) will help improve our understanding of the organization of services for the homeless in Montreal.

**Data processing**

For completion of the first phase of the research project, a coding key will be developed for retrieving data from written information sources. The questionnaire will complete the aspects not covered by written sources, and that are less essential to cover during interviews. In the second phase, an interview guide will be developed, adapted to the type of interview (e.g. experts or organizations; public, COs or housing). The coding key for handwritten sources, the short questionnaire and the interview guide will be organized according to the following criteria: 1) year, location and context in which the organization was founded;* 2) mission;* 3) financial profile (including funding sources);* 4) coverage area;* 5) service hours;* 6) governance (internal operations and role of users);* 7) number of employees and volunteers (types of jobs, training, staff retention and user involvement);* 8) types and number of services provided (or programs, including: types of practice and oversight – scale of activities...);* 9) profile of the clients served (e.g. gender, age, education, ethnicity, length of time homeless, diagnosis or types of problems, utilization of services, number of persons);* 10) clinical tools used (e.g. intervention guide, training);* 11) associations with which the organization is affiliated;* 12) participation in consultation and coordination committees, other committees, etc.;* 13) partnership relations (number of partners and their importance, references, type of relations...);* 14) organization’s main problems and strengths; 15) organizations’ perceptions about the main problems and needs of the homeless and the “system’s” response to these problems (shortcomings and strengths; 16) main issues and challenges (specific to the organization and to the homelessness field); 17) evolution of the organization of services (various key periods); and 18) impact of the intervention (i.e. experimental groups) on the homelessness network.

All the information will be classified into major categories using the N*Vivo data-processing software: 1) structure of the organization of the homelessness network, 2) internal operations of the organizations, 3) client profiles, 4) clinical practices, 5) inter-organizational relations, and 6) issues and challenges. Various graphic representations of the organization of services may be used in order to synthesize the information.

**2) Second component: Implementation of the intervention – the three experimental groups**

This component, which directly meets the expectations of the MHCC while being supported by the preceding component, aims to evaluate the degree of implementation of the intervention, i.e. the difference between actions planned and implemented during the experimental project. The implementation study is divided into two data-processing phases: 1) the project start-up phase, and 2) the implementation phase, which will nevertheless take into account the entire project (i.e. including the start-up phase). The first phase (1) covers the initial investments from project commencement to the delivery of services to the first users of the experimental project. The second phase (2) covers the period of delivery of services to users of the experimental project; however, data collection will be maximized insofar as possible during the final year of the project (in order to maximize optimal implementation of the intervention). Various data collection sources will be used: documentation, questionnaires, participant observation and interviews (individual or group).

Documentation pertaining to the intervention (i.e. produced during the project) will be reviewed. This will include the results drawn from the “organization of services in the homelessness sector” component, conducted concurrently. Two types of questionnaires will be used: 1) an initial questionnaire to monitor compliance of the interventions and practices with the models, aimed at the personnel mobilized in the three experimental groups; 2) a second questionnaire aimed at all users (“utilization” questionnaire: main experimental design), with the addition of specific

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11 Data on the aspects marked with an asterisk will be collected mainly during the first phase of the study. The aspects marked with an asterisk in brackets fall mainly under the second phase, associated with the interviews.
questions on the intervention for the three experimental groups. The participant observations will enable us to examine the intervention governance structures\(^\text{12}\) and a typical day's activities during an intervention with the three experimental models. The interviews will supplement the information already obtained from these other data collection sources. The key persons interviewed here will be: intervention governance teams, personnel working with the experimental groups and housing resource persons\(^\text{13}\) or project resource persons, although not directly involved in the intervention, as well as users of the three experimental models.

The questionnaire on the personnel will be completed by three clinicians representative of the teams and will include two types of measurements: a compilation of activity reports, prepared every three months, and more general questions on the intervention every six months (total: 72 activity reports and 36 questionnaires). The participant observations will be systematically carried out at all project governance meetings (i.e. consortium, steering committee, etc.). With the clinical teams, three half-day observations will be carried out for each team (monitoring of the various personnel) at the start and at the end of the experiment (total: 18 observations of the work of the clinical teams). Interviews with housing managers, personnel and owners, whether individual or group depending on the interviewee, will be conducted at the start and at the end of the implementation of the intervention. For this group, we are planning about 20 interviews of approximately 90 minutes in total. The interviews of users will essentially be conducted in the final year of implementation, as a group. In this case, three group interviews will be organized, based on the user profile (results of the utilization questionnaire (e.g. patients satisfied or not satisfied with the intervention – for a total of nine group interviews – style: three-hour focus groups, including a 20-minute break – approximately eight persons per group).

The questionnaires and interview or observation guides, developed at the start of the research process (incorporating the aspects that will be covered in the main project), will consider the following aspects:

A) For the intervention start-up phase: 1) structure and process instituted for development of the project, which will be divided into two periods: a) pre-start-up of the governance structure for the Montreal site: organization of the federal project \(\rightarrow\) local, organization of the local leadership and project governance committees; b) more formal start-up of the process: types and number of governance structures and meetings, process for encouraging participation of the actors, search for partnerships outside the intervention governance structures, preparation, meeting dynamics, degree of autonomy of the actors – particularly local vs. federal...) ; 2) involvement of the actors in the intervention governance process based on the various committees established (number of actors involved, types of actors involved (or not involved), degree of involvement of the actors, specific leadership provided by certain actors, including the principal investigators and project coordinators; degree of organization of the work and processes, conflicts and consensus concerning the intervention (shared/conflicting vision of the intervention), degree of participation in the intervention, issues and challenges surrounding the intervention...); 3) process for organizing the clinical intervention (models: Streets to Homes, Pathways and fifth group): team building approach and associated issues and challenges, etc.; 4) housing organization process (component coordinated by Dorvil): process for encouraging participation of actors and structures, stakeholders: governance structure instituted, types of project participation and associated processes, conditions for project development/involvement, sharing of the vision and dynamics (conflicts...), etc.

B) For the experimental implementation phase: 1) organizations and actors involved in the intervention: participation in the project, sharing of the intervention philosophy, leadership mobilized around development of the intervention, establishment of the teams (recruitment, strengths and weaknesses of the teams, training process, tools developed), relations with affiliated organizations, relations with project partners – the various existing public, CO and housing networks; mental health and substance use, homelessness network...; 2) the intervention teams: number of professionals, types of professions (complementarity of the group), experience (homelessness, mental health, substance use), group dynamics, inter-team relations, team governance structure, types and number of interventions

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\(^\text{12}\) The user participation component will be coordinated by Dr. Gagné and colleagues, but will also be considered in the overall implementation analysis.

\(^\text{13}\) Component coordinated by Dr. Dorvil.
(by case and in a typical day – in this instance, participant observation), degree of use of the tools developed for the intervention, issues and challenges...; 3) housing (component coordinated by Dorvil): types of stakeholders included in the project (housing and actors / for housing including: typology (i.e. private housing – room and board, type of building – NPOs, social housing, supervised housing...), location and quality of the housing units (number of housing units/for one unit, space, noise, location, security, ease of access to services and public transit, availability of common areas, cost...), availability of supervision, and type of services provided if applicable / ease with which social service workers can contact the user (housing and intervention link) / links with site management (owners., regional agency...), etc.

All this information will be coded according to the project start-up and implementation period, taking into consideration the general themes mentioned above: 1) governance structures, 2) clinical intervention models, and 3) housing. An advisory committee, composed of the research team and decision-makers, project personnel and key users, will be established to oversee the research process. A brief interim report on the project start-up period and a final report including all the results of the implementation study will be produced.

7.4.2 Qualitative analysis of intervention practices developed by community organizations identified by control group participants as having a positive impact on their trajectory

The analysis of the implementation context will provide exhaustive but relatively general information on the services provided to the homeless. As a complement to this overview, we are proposing an in-depth examination of the organizations identified by at least two control group participants as having a positive impact on their trajectory during the first 18 months of the project. This sample will be stratified according to the different types of organizations identified through the work carried out as part of the “organization of services” component as well as from data obtained from the survey of 30 Montreal organizations conducted in preparation for this application. The project aims to gain a better understanding of the role of each of these organizations and their impact on the individuals who use their services. Interviews will be conducted with two representatives from each organization selected as well as with a random selection of recipients of their services (five persons per organization).

The comprehensive analysis will examine the factors contributing to the attainment or non-attainment of the organization’s goals as they relate to the attainment or non-attainment of the users’ goals. The analysis criteria will permit in particular a cross-sectional analysis concerning the intervention’s impact on the individual’s “well-being” and quality of life – by examining both parties’ perceptions of well-being and quality of life. The contribution of these various types of intervention to the individual’s recovery will also be examined, using standardized criteria that will permit a cross-cutting analysis of the interventions. In the case of users, the interviews will focus on reconstructing the individual’s life trajectory in order to identify the impact of the organization’s intervention on the trajectory, while giving the concept of “recovery” a meaning that is more grounded in the individual’s experience. Concurrent interviews conducted with representatives of the organization in question (through the reconstruction of three or four cases selected at random from among the interventions immediately preceding the interview) will help us understand the general parameters of the intervention as experienced by each party, its impact on the individual’s (user’s) trajectory and the degree of convergence or divergence in their perceptions of well-being, goals and methods.

If the differences between the outcomes for the Housing First groups and the control groups prove are found to be less significant than in the other cities, this component, combined with the implementation analysis, will help us understand why.

7.4.3 Case histories

The MHCC requires that qualitative interviews be conducted with a random sample of 10 individuals per group (therefore, in our case, 50 individuals) at baseline and after 18 months. These interviews will focus on their personal stories. It is proposed (in the request for applications) that the focus be placed at the start of the baseline interview on “events, memories, or episodes in their lives (one high point, one low point and one turning point)” and that they then be asked to incorporate these events into their life stories. During the second interview (after 18 months), the focus will once again be on “one high point, one low point, and one turning point [...] in their lives” but, this time,
since the baseline qualitative interview. The second interview “will focus on specific experiences related to their housing and clinical services” and “participation in other community services” in the case of the usual care groups. It is planned that “the specific focus, questions and approach will be developed collaboratively by qualitative site researchers, participants of local advisory committees and qualitative researchers on the national research team.”

While focusing on the high points, low points and turning points, in the case of the baseline interview, we consider that the housing history can provide a useful starting point to the individual’s life history (and trajectory) by allowing him to tell his life (over a relatively long period) and recount the various material, relational and health conditions associated with each stage. We will also favor an approach that will help identify the significant actors who, in the individual’s opinion, played a positive, negative or neutral role during the various “events” comprising the trajectory. This type of approach will help to more effectively determine the impact of the current demonstration project (and its “actors”) on these trajectories.

Comparing these stories, particularly at 18 months, will help us understand how the individuals progressed as a function of the groups to which they were assigned.

7.5 Analyses aimed at making the study more relevant for local decision-makers

7.5.1 Quantitative comparisons between groups C and D (moderate needs, housed in a private apartment vs. social housing)

In section 6, we described the local circumstances and reasoning that prompted our decision to propose a comparison between a group preferring social housing and a group housed in private apartments. By using an experimental design, we will be able to compare outcomes at 24 months between these two groups (groups C and D) on the basis of various quantitative measurements that will help identify the effects of being housed in social housing vs. a private apartment. The same methods mentioned earlier in the discussion on the planned comparative analyses between the Housing First groups and the control groups will also be used to compare groups C and D. We believe that this comparison, including a costs comparison, will be very relevant for local decision-makers.

We will also include an economic assessment, conducted from the perspectives of the health care system, the government and society. The economic assessment of the intervention groups will be presented as an incremental cost-utility ratio (ICUR), based on an incremental analysis, which will take into account the quality-adjusted life year (QALY) measured for clients using the measurement instrument to be selected (HUI, EQ-5D, or, based on our earlier proposal to the Canadian team, SF-6D). In order to take into account the sampling uncertainty in these ratios, we will also use the net health benefit framework to produce cost-effectiveness acceptability curves. The total costs (medical and non-medical) will be based on the unit costs of services and resources used, which we will have to calculate from local data. This will permit a generalization and a more accurate conclusion concerning the ICURs obtained for our health care system and our province (unit costs in Quebec are considerably lower than in most other provinces, reflecting our lower salaries). The services and resources used will include housing and/or residential services, hospitalizations, emergencies, outpatient medical care, rehabilitation and substance abuse services, and medications. Information on the utilization of services by clients will be obtained by compiling the data from the study questionnaires with the data from the RAMQ and Med-Echo administrative databases. Finally, we will perform regression analyses to determine the sociodemographic and clinical factors that have the greatest impact on service utilization and associated costs.

7.5.2 Comparison between the outcomes of clients in groups C and D as a function of the intensive case management service (CSSS Jeanne-Mance or Diogène) to which they were assigned

Since participants in groups C and D will be randomly assigned to receive the Streets to Homes service from either an institutional team (CSSS Jeanne-Mance) or a community team (Diogène) and because these two groups will otherwise receive similar services (assigned randomly in equal proportions to private apartments or social housing),
the experimental design described in section 6 will enable us to compare the effects of the services provided by the two types of organizations.

Although politically sensitive, this type of comparison is relevant in the Quebec context because the provision of VIS services is currently divided between institutional and community programs, in different ways depending on the region. The principal investigator is currently heading a study, funded by the Canadian Institutes of Health Research program Partnerships for Health System Improvement, one of the aims of which is precisely to shed some light on this issue. The many complementary qualitative analyses planned for the project will help us understand the reasons why differences could emerge between the groups and therefore, potentially, help identify avenues for improving the services provided by the programs offered by each type of organization.

For a small additional cost, the proposed randomized crossover design will enable us to provide some answers to very different, but equally relevant, questions in our context.

7.5.3 Complement for comparing social housing and private apartments

A comparison between a treatment centred on social housing and a treatment centred primarily on a subsidized private apartment encourages us to examine in greater depth the living conditions of the individuals in these two types of living environments.

To this end, we propose the following approach. Our semi-structured interviews (15 per sector, approximately 90 minutes long) with residents in the different housing models will cover the following five major aspects: 1-What are the characteristics of the current housing unit? Comparison with their accommodations in the last few years. 2-What are the tenants’ perceptions of their impact on their living environment, expectations, needs and aspirations? Daily activities. 3-What is the level of social functioning of these residents? Consequences of their condition (mental illness, homelessness...) on their integration into society 4-What is the residents’ relationship with the organized and informal social support? 5-How satisfied are they with their quality of life? The grounded theory method [27, 28] is well suited to studying a still relatively unknown phenomenon such as housing in a private apartment vs. social housing, since it is in keeping with a perspective of innovation and remains open to any new avenues for research suggested by experience in the field. Instead of verifying existing data in the field (deductive method), this method starts from the field in order to develop scientific knowledge about the subject under study. By taking as the starting point the perceptions of the individuals living in these environment, the grounded theory method encourages attainment of another objective of this research project, to bring to the fore the tenants’ opinions and experiential knowledge. Representativeness will be ensured by the diversity of types encountered in the research project, with the number determined once theoretical saturation has been reached. The interviews are based on open-ended questions that contain neither right nor wrong answers, allowing the respondents to emphasize the elements they consider most important. Each interview will be analyzed individually using a conceptual, dynamic and comparative thematic model according to the five aspects mentioned earlier. We will also conduct the same type of interviews with the managers of the various types of housing (five per sector) according to the following themes: 1- How does the resident occupy his time on a daily basis?; how is the space allocated?; what is the day program?. 2- The role of the owners (or manager), their past experience and future plans, their philosophy of action, their views on homelessness and mental illness, and their relations with the services network. 3-The authority of housing managers to enforce rules and regulations, regulation and decision process. The analyses will be carried out following the same process described earlier. Using these analyses, we will establish a typology of accommodations, residents and owners, as we did for institutional housing [29].

Finally, we will conduct a standard documentary analysis using the annual reports, regulations manuals, etc. in order to become familiar with these types of housing both from the “outside”, i.e. officially, and also unofficially, i.e. from the “inside”, using the “day book” method, by examining logbooks and comments in the handwritten notes of health care personnel and security personnel.
7.6 Toward improving the Housing First approach

7.6.1 IPS employment support

Individual placement and support (IPS) type employment support is now recognized as an effective approach in helping individuals with serious mental disorders to work [30, 31], and its effectiveness has also been demonstrated in the Montreal context [4]. Although in some experimental studies part of the sample may have been initially homeless and although the IPS approach appears to have been effective for this sub-group as well (Bond and Drake, manuscript submitted), no experimental studies have yet been conducted specifically on the homeless. It would be useful to know the extent to which: (1) homeless people with mental disorders are interested in finding a job in the short term; and (2) how effective the IPS approach is with this population as well.

As mentioned in section 6, the ACT/Pathways team is supposed to include an employment counsellor (in accordance with current standards for this type of program and with the request for applications). This counsellor should be trained in the IPS model and thus able to help clients who want to work to do so, and insofar as possible, in a regular work environment.

However, there are currently very few IPS programs in Montreal. The Douglas Institute, in southwest Montreal, has one, which serves approximately 100 individuals in its coverage area. Louis-Hippolyte Lafontaine Hospital, in east Montreal, also recently established this type of program. However, there is still no ISP program in central Montreal. The labour force integration programs available all operate differently, but none include all the features of an IPS program recognized as effective, particularly integration of employment counsellors in the clinical team and long-term follow-up of clients.

Consequently, under current circumstances, virtually none of the clients assigned to the groups other than the ACT/Pathways group will have access to an IPS program.

We are therefore proposing to superimpose on the experimental study an additional experimental sub-study, which will be conducted as follows.

Beginning immediately after the baseline interview and in all subsequent meetings with the interviewer up to the 12th month inclusive, we will ask the participants in groups C and D whether they would also like to participate in an additional study concerning job integration programs. During their first year of participation, they will also be able to meet with employment counsellors, who will talk to them about work so that they have a better idea about the opportunities available to them. Client participation will remain optional: we want to enrol in this sub-study only individuals who are genuinely interested in working in a regular work environment. Because we believe that many homeless people will not be ready to consider a return to employment at the outset of the study, but may be willing to do so relatively soon after being housed and stabilized, we are proposing that clients be able to join the experimental IPS sub-study over a one-year timeframe, leaving a minimum of one year of follow-up for each client (since the total duration of follow-up in the main study is two years).

Clients who agree to participate in the study will either be referred to existing job integration resources (by their case manager, but also with the assistance of the employment counsellor, who will be familiar with the services available) or be enrolled in the IPS program.

Because the common protocol already includes follow-up of all clients participating in the sub-study, since they are also participating in the main study, there will be no additional interview costs: the marginal cost of conducting this experimental study is therefore minimal.

It is planned that the common protocol will include detailed questions on work experience, including start and end dates of any employment, hourly wage, etc. However, we will add a few additional questions, which remain to be determined specifically, but which will include an evaluation of satisfaction with the employment-related services. To compensate the participants, we will offer them an additional payment of $10 per interview (excluding the intervening interviews at months 1, 2, 4, 5, etc.).

Clients who agree to participate in this sub-study will be assigned randomly, once again using stratified block randomization. The stratification will be determined based on work experience in the last five years (yes or no) and on the service and type of housing to which the individual has been assigned, with blocks of four in order to ensure...
that the experimental and control groups are balanced in terms of these variables. The individual will be informed by the interviewer of the group to which he has been assigned once consent has been obtained and after administration of the common interviews. This information may also be disclosed will also be made by opening an opaque envelope.

Each IPS worker shall follow up a maximum of 20 clients at a time; two IPS workers can therefore follow up 40 clients at a time. This would yield an initial sample of 2x40 = 80. However, some attrition of the IPS groups can be expected, since recruitment may extend over 30 months (18 months for recruitment into the main study plus 12 additional months to allow participants the opportunity to join the IPS sub-study). A simulation exercise, assuming an attrition rate of 0.015% per month (which works out to approximately 20% per year, as observed with the study at the Douglas Institute), indicates that, allowing for attrition, we would be able to recruit approximately 90 subjects (45 in each group). The difference in effectiveness in terms of finding a regular job between IPS and the standard services is generally so great that a sample of this size should be sufficient. If, for example, the relative effectiveness is the same as in the Montreal IPS study (47% vs. 18% found a regular job within a year) [4], which is a relatively low rate of effectiveness in comparison with most other studies [31], for a sample of 90, this would result in a value of p=0.001. This calculation does not take into account the longitudinal nature of the data, which further increases the statistical power.[32].

The statistical analyses would be similar to those previously performed by members of our team for the Montreal IPS study [4].

The MHCC study therefore affords an opportunity to test the effectiveness of IPS with homeless people suffering from mental disorders – which would represent a significant contribution to research on services for this population – at minimal cost, since the data collection already planned for the main study could be used.

7.6.2 Cluster analysis of study participants

In order to improve Housing First type services, it is important to gain a better understanding of how they operate, as a function of the characteristics of individuals. One approach frequently used to characterize different individuals is cluster analysis. Earlier, we proposed using this approach relying on multiple correspondence analysis in this case) to characterize profiles of subjects who have difficulty finding and remaining in housing due to aggressive or antisocial personality traits. In this case, the goal of the proposed analysis is more general: it involves using the data collected at the five sites to identify the profiles of participants (assigned to one of the five groups) who were fairly successful in terms of remaining housed.

Research from the 1980s showed that homeless people constitute a heterogeneous population [6]. However, previous studies used regression analysis in an effort to determine the factors associated with the utilization of mental health services or with the success of programs for the homeless. If used exclusively, these techniques can prove to be reductive or even erroneous when employed to measure complex phenomena (Rapkin & Luke, 1993). In addition, a number of researchers have instead proposed creating typologies of homeless persons suffering from mental illness using cluster analysis. Recently, Bonin, Fournier and Blais (2009) identified a typology of homeless persons with mental disorders from among the clients of resources for the homeless in Montreal and Quebec City by considering their utilization of services. Six groups of homeless persons were identified: 1) formerly depressed individuals and former alcoholics; 2) those with current depressive disorders; 3) those presenting with comorbidity; 4) formerly homeless people; 5) homeless women, and 6) schizophrenics.

These cluster analyses were performed with the help of the service utilization model developed by Pescosolido (1991, 1992), which will be used for the present study. Pescosolido presents a model called the Network-Episode Model (NEM), which offers a broader view than previous models of the mentally ill and their contacts with the health care system. Pescosolido proposes a “career” approach which takes events into account in a dynamic manner, while respecting the sequences of those events and the multiple options available. Action strategies are conceptualized as emerging from an affective and rational process intrinsically linked to the social dimension, rather than to personal choice (Pescosolido, 1992). This model will be used for the selection of variables and also for its methodological approach, which involves the use of quantitative and qualitative methods.
Method

This project is a mixed methods research project, i.e. it includes qualitative and quantitative elements, as advocated by Pescosolido (1991, 1998). The sample will be comprised of all project participants, whether they are part of the control or experimental groups, and the inclusion and exclusion criteria are the same as for the main project. Most of the variables to be included in this analysis come directly from the data collected as part of the basic study. The choice of variables will be determined, on the one hand, from concepts developed by Pescosolido and, on the other, from the preliminary analyses that will be carried out. The main blocks of variables obtained from the model are: (1) sociodemographic characteristics; (2) utilization of mental health services; (3) improvement in living conditions (this improvement will be a composite of the participants’ perceptions relative to the changes perceived during the project period lasting several months; this will therefore involve, in relation to the method developed by Pescosolido (1998), creating a numerical variable that will represent the participants’ view of the progress made in the project); (4) disease characteristics, including “illness career”; and (5) social network.

We have considered a number of measurements for these concepts, not all of which appear to be necessary to cover in the common core of instruments for the five sites. We will retain some based on the length of administration of the instruments chosen for the common core.

Analysis

Preliminary analyses will be used to identify the links between the variables in order to avoid redundancies. Gower’s method will be employed as a distance measure, since it permits the simultaneous use of variables from different measurement levels, i.e. dichotomous variables, nominal variables and continuous variables in order to extract the distance between them (Aldenderfer & Blasfield, 1984). Ward’s method is a method frequently used to analyze clusters (Lorr, 1983). This method was developed in order to optimize the minimum variance within clusters. We will also explore the possibility of using the multiple correspondence analysis mentioned earlier.

7.7 Relevant Studies for Service Users: Assessing the Impact of User Participation on the Project

As described below, we have developed, in cooperation with service users and their representatives, an elaborate mechanism, based on the results of recent research, to facilitate active, significant participation by service users in the project as a whole.

Our current understanding suggests that their involvement will empower them, enabling them to acquire useful skills and knowledge [33-36]. Yet will it have an impact beyond those individuals? The few existing studies on participation in a comprehensive service organization tend to focus on effects at the individual level (i.e., on the user himself) rather than the systems level [36].

Since an experimental design is impracticable in this context, we propose a qualitative approach to assess both the extent to which the 12 users associated with the project (see below), according to the perceptions of various observer groups, appear to have had an impact on their decision and the extent to which an analysis of objective documents (minutes of meetings, in particular) suggests that their participation in meetings has actually influenced decisions.

To a large extent, knowledge will be transferred and results disseminated using original methods borrowed from forum theatre and direct cinema to reach a lay audience. We will also use traditional methods, such as conferences and peer-reviewed articles, to communicate results.
Methodology and Information Sources

Given the research conditions, the methodology chosen is based on established ethnography. Since our aim is to understand a new social practice from the perspective of exploration rather than verification, we will construct an open observation and analysis grid intended to produce a description of progress in the experiment’s components: (1) The participation or support activity according to the physical characteristics of its locations, its function and hierarchical position in the project; (2) the players involved, their institutional, social and other roles, status and memberships, etc.; (3) representations of their formal and informal objectives, expectations and misgivings concerning user participation; and (4) concrete actions expressing the impact of such participation, i.e., speeches, publications, internal and external interactions, etc.

Data will be collected via (1) silent observation notes taken during Committees, meetings and peer resourcing activities conducted throughout the project; (2) documentary analysis of all written material produced as part of the project: reports, minutes, announcements and advertising, written contracts and agreements, and various publications; (3) analysis of verbatim records of interviews of a sampling of volunteer project participants consisting of three persons per group, be they users, managers, workers or researchers. The interviews will be held at the beginning of the process, after 18 months of activity and at the beginning of the final year of the project.

An initial analysis of data from the various sources will be produced after the first round of interviews is held to validate/modify the analysis grid. Three members of the project “implementation” team will conduct the analysis. Disagreement between members will be resolved by consensus. The purpose of the analysis will be to establish/stabilize the analysis categories for, and relate appropriate subjects to, the grid. Initially, the typologies of, and relations among, players will be identified on a provisional basis, for the purpose of comparison with those that will be identified later in the data collection process.

8. Ethical Approval

Approval procedures for research projects in Québec, particularly those involving multicentric research, have changed significantly over the last 18 months. To establish whether the regulations in force are applicable to our project, we consulted with Ms. Johane de Champlain, ethics consultant to the Fonds de la recherche en santé du Québec and vice-president of the Comité central d’éthique de la recherche of the MSSS. It is probably advisable to go through the approval process for multicentric projects, in case it becomes necessary at some point in the project to obtain data from more than four Centres de santé et services sociaux. Without going into details about the procedure here, approval would only require going through the Douglas and CSSS Jeanne-Mance ethics committees. Since the new regulations set strict timeframes for the various approval stages, the project could probably be approved by June 1 if it was submitted by March 1 (once details of the memorandum have been finalized).

9. Results Dissemination Plan

9.1 Traditional Methods

Our dissemination plan includes traditional results dissemination mechanisms, such as writing scientific reports and articles, and presenting papers at local and international conferences. Our collaboration site, http://projetrdsmimtl.ning.com/, which is already up and running and moderated by the assistant project coordinator, will be expanded and will help keep all parties involved in the project and their partners informed of developments. However, we also plan to use more innovative dissemination methods.

9.2 Forum Theatre

The forum theatre created as part of this project (in collaboration with the Mise au jeu theatre company) is a form of street theatre intended to present the results of different research components to mixed publics (users, workers, researchers, managers) for purposes of dissemination, validation and reflection. In particular, street theatre encourages the participation of marginalized individuals (in this case, those having experienced homelessness and using mental health services). Key events based on the first-hand accounts of interviewees will be “staged” to illustrate the problems confronting them, particularly with respect to living and housing conditions, as well as social relationships characterized by discrimination and stigmatization, along with their more positive experiences (e.g., in
various types of intervention). These scenes will focus on the period prior to the project (as reconstructed in the life stories) and experiences from the project itself. The theatrical event then becomes a forum for discussion and reflection based on the results previously staged. In this case, the “public” becomes the central player of the event, with the goal being to formulate recommendations to consolidate or transform existing action strategies. We are proposing a street theatre tour of the province (in collaboration with agencies active in the areas of homelessness and mental health and the health and social services network) to provide additional forums for dissemination/validation/reflection and maximize the number of proposals prepared for presentation in both documentary and theatrical format at a final event in Montreal.

9.3 Video Documentation Project

This component would use digital videography to show how service users can influence the research process. The first objective (funded by the grant) would be to provide a digital video recording of life stories, evaluative and participative action research and street theatre. The second objective would be to integrate talks with project heads, researchers, health workers and activists. The last objective would be to publish an ethnographic documentary (with outside support if possible) serving to: (i) explore users as a political group, (ii) provide an understanding of how users maintain their “community” and (iii) give a unique view of the role of intermediaries, professionals and activist groups in mobilizing users.

Although discussions on this subject are still in progress, we are already considering (with the agreement of the CSMC, of course) using part of the funding, in collaboration with a professional documentary filmmaker, to prepare a project for which most of the funding would come from another source. This movie-quality film would focus on the viewpoint of the homeless as a group and their views on this project in particular. The film could be aired on television and excerpts would be permanently available on the web.

10. Research Team

In our view, we have assembled for this project a first-rate multidisciplinary team that combines expertise in a large number of relevant fields, from homelessness, through employment support and economic assessment, to the justice-mental health interface. Each team member is described briefly below; the governance structure will be described in the next subsequent section.

Deborah R. Becker is Assistant Research Professor of Community and Family Medicine and member of the Dartmouth Psychiatric Research Center. She is the principal originator of the IPS model and internationally renowned for her expertise on the model’s application. She has helped train the Douglas Institute’s IPS team and will serve as a consultant on the IPS project, limiting her involvement to monthly or occasional participation.

Gary R. Bond is Chancellor’s Professor, Professor of Psychology at University Purdue University Indianapolis. As his résumé attests, he is one of the most prolific, most influential authors in the field of psychiatric rehabilitation. He has published numerous articles and works on intensive follow-up (ACT) and the IPS approach to employment support. He will collaborate specifically on the IPS study conducted by the principal investigator. As with Debbie Becker and Professor Drake, his involvement will be limited to monthly or occasional participation via conference call with the principal investigator concerning the IPS substudy.

Jean-Pierre Bonin is associate professor at the Faculté des sciences infirmières, Université de Montréal and researcher at the Centre de recherche Fernand Seguin affiliated with the Hôpital Louis-H. Lafontaine. His research interests lie in mental health services, particularly for homeless persons afflicted with mental illness and attendant drug addiction and mental health disorders. He has worked with Louise Fournier on the Enquête sur la santé de la clientèle des ressources pour personnes itinérantes (2001, 2003). He will be responsible for analysing aggregates (7.6.2) and assessing the impact of intervention on families. He plans to devote at least five hours a week to the project.

Anne Crocker, Ph.D., CIHR-New Investigator, specializes in legal psychiatry. She is Director, Services, Policy and Population Health Axis at the Douglas Institute Research Centre. Her work (supported by the CIHR, FQRSC, FRSQ and
Mental Health Commission of Canada) bridges two important aspects of legal psychiatry: (1) identification of psychosocial factors associated with violence and criminality in vulnerable populations such as individuals suffering from serious mental illness or intellectual disability, risk assessment and management; (2) the mental health-justice interface and the analysis of criminal justice mechanisms (e.g. criminal responsibility, Tribunal de la santé mentale). She will be responsible for analyses concerning judicial trajectories and victimization. She plans to devote an average of three hours a week to the project.

Henri Dorvil is a social worker and holds a Ph.D. in sociology. He is full professor at the École de travail social, Université du Québec à Montréal. A regular of the Groupe de recherche sur les aspects sociaux de la santé et de la prévention (GRASP/FAS), Université de Montréal, he is also a researcher associated with the Axe de psychiatrie sociale, Centre de recherche Fernand-Séguin, Hôpital Louis-H Lafontaine. His work focuses particularly on the stigmatization associated with mental illness, particularly in the areas of housing, employment and mass media. He will be responsible for comparison of public housing with private rental apartments.

Robert E. Drake is Professor of Psychiatry and of Community and Family Medicine and Director of the Dartmouth Psychiatric Research Center. Like Professor Bond, he is one of the most prolific and influential writers on psychiatric rehabilitation. He has collaborated closely with Deborah Becker on the development and study of the IPS model. His involvement will be limited to conference calls with the principal investigator concerning the IPS substudy, on a monthly or occasional basis, depending on the stage of the project.

Gilles Dupuis, Ph.D., psychology, has taught quantitative methods at the Département de psychologie, Université du Québec à Montréal. He has worked in the field of quality of life (QL) for 20 years and has set up a QL measurement website (http://qualitédevie.ca). He is a researcher in the Département de médecine psychosomatique, Montreal Heart Institute (MHI). He is scientific director of the Centre de liaison sur l’intervention et la prévention psychosociales (CLIPP), which provides expertise in knowledge transfer. He will collaborate with Henri Dorvil on the comparison of public housing with private rental apartments.

Marie-Josée Fleury has a Ph.D. in public health with specialization in health services organization. She is assistant professor in the Department of Psychiatry, McGill University (associate professor appointment anticipated for 2009 spring). She is also associate professor in the Département d’administration de la santé, Université de Montréal, and researcher at the Douglas Research Centre and holds a CIHR New Investigator Award. Dr. Fleury’s areas of interest include health services organization, health service use and assessment of health service adequacy for the needs of patients suffering from mental health disorders. She is in charge of a number of research projects relating to frontline service organization, current mental health system reform with specific analysis of determinants of patient recovery, and mental health service usage profiles. Dr. Fleury’s research is focused on achieving a better understanding of the most efficient models for improving the mental health system’s performance. She will coordinate the implementation analyses and plans to devote seven hours per week to the project.

Jean Gagné holds a Ph.D. in sociology. He is currently a community organizer with the community services team of CSSS Jeanne-Mance and a practitioner/researcher with the Collectif de recherche de Montréal sur les inégalités sociales, les discriminations et les pratiques alternatives de citoyenneté (CRÉMIS) in the university centre affiliated with CSSS Jeanne-Mance. His primary areas of interest include community action, citizen participation in public service organization, mental health and the homelessness phenomenon. Jean Gagné has been involved in community organization as coordinator of the Regroupement des ressources alternatives en santé mentale. He was previously a worker and director of the Maison St-Jacques, an alternative mental health treatment resource in Montreal. He has also been involved in different community associations and resources as an administrator. He will be responsible for ensuring that service user participation in the project runs smoothly, working closely with the community worker that we plan to hire and with the service user team associated with the project (section 9). He will also be responsible for the service user impact evaluation project.

Roch Hurtubise is full professor in the Département de service social, Université de Sherbrooke. He graduated from Université de Montréal in sociology and pursued postdoctoral studies at Aix-Marseille in France. His research
areas and interests include family issues, poverty, food aid, street youth and homelessness. He is a director of the Collectif de recherche sur l’itinérance (CRI), one of Canada’s best-known teams working on homelessness. His collaboration will be primarily with Christopher McAll on the participative evaluation of 10 agencies.

Eric Latimer is associate professor in the Department of Psychiatry, McGill University, and associate member, Department of Epidemiology, Biostatistics and Occupational Health. As a health economist, he teaches a course on economic evaluation of health programs there and is also a researcher at the Douglas Institute. He has collaborated with a number of researchers, including Deborah Becker and Robert Drake, and recently directed a random distribution study of the Douglas Institute’s IPS program. He is lead author of the Guide de pratique pour les équipes de suivi intensif dans la communauté by the Association des Hôpitaux du Québec (2004). He is treasurer of the Canadian Association for Health Services and Policy Research and a member of the Canadian Institute of Health Services and Policy Research Advisory Board. He will be responsible for comparative analyses between groups C and D, the IPS substudy, and economic evaluation. As principal investigator, he will be responsible for ensuring that the entire research component runs smoothly. He plans to devote 12 hours per week to the project.

Alain Lesage is assistant director of the Centre de recherche Fernand-Seguin affiliated with the Université de Montréal, and responsible for the social psychiatry and service research section. He is a member of the science committee of the Mental Health Commission of Canada. For over two decades, he has worked to increase awareness of the clinical and social needs of persons with serious mental disorders. For over a decade, he has worked to develop a research capability on the services pertaining to, and social dimensions of, mental health and drug addiction in Quebec and Canada, collaborating with Drs. E. Goldner (British Columbia), Paula Goering (Ontario) and Eric Latimer (Quebec) through the Canadian Academy of Psychiatric Epidemiology and a CHRI-funded strategic training program. He was the driving force behind the Montreal and Quebec consortium formed upon the announcement of the MHCC project and will continue as an intermediary with the governance authorities of the MHCC and the Province of Quebec, which, along with the consortium, has provided assurances that Montreal will remain a site for the demonstration project. He will collaborate on projects by Jean-Pierre Bonin and Marie-Josée Fleury, and on the economic evaluation with Eric Latimer and Helen-Maria Vasiadis. He plans to devote three hours per week to the project.

Christopher McAll is full professor of sociology at the Université de Montréal. A specialist in social inequality, he studies the dimensions of social inequality and discrimination, such as ethnolinguistic inequality, the life trajectories of different populations toward social assistance, populations in rent-controlled housing (“HLM”), etc. He has also experimented with new forms of dissemination, including forum theatre to create new public spaces for reflection. His research activities have included collaborations and partnerships with the community and participation in the creation of the Centre de recherche et de formation de CLSC Côte-des-Neiges (with Robert Sévigny), in which he served as assistant director of research from 1993 to 2003. He has been scientific director of the affiliated university centre CAU CSSS-Jeanne-Mance since January 2004 (supported by the FQRSC and MSSS), where he founded the Centre de recherche de Montréal sur les inégalités sociales, les discriminations et les pratiques alternatives de citoyenneté (CREMIS) and, in 2008, the Revue du CREMIS of which he is director. He was also director of the Programme de recherche sur le racisme et la discrimination at the Université de Montréal from 1995 to 2003 and director of graduate studies in the Département de sociologie of the same university. He will be responsible for the MHCC-commissioned qualitative analyses relating to the life histories, participative evaluation of the 10 agencies and street theatre project. As the project’s co-principal investigator, he will sit on the project steering committee.

Paul Morin holds a Ph.D. in sociology and is associate professor in the Département de service social, Université de Sherbrooke. He is also director of research at the university centre affiliated with the Centre de santé et de services sociaux, Institut universitaire de gériatrie de Sherbrooke (CSSS-IUGS). A pioneer in the promotion and defence of mental health rights, Paul Morin worked for many years in this activity sector and the theme of housing as a factor in social relations was the product of his practices and research. He will collaborate with Henri Dorvil on comparing housing types.
**Greg Nielsen**, Ph.D. Sociology (Université de Montréal), Professor and Director of the Concordia Centre for Broadcasting Studies: Public Culture After Modernity. His recent work has been on contemporary critical theory and a series of comparative studies of mediated forms of urban citizenship. His main project includes a study of how contemporary journalism is confronted daily with a growing list of citizenship controversies concerned with inner city poverty, undocumented migrants, and “reasonable accommodation” of cultural diversity in the Montreal and New York City contexts. At the CCBS Dr. Nielsen is executive co-investigator and leader of the group studying Citizenship with the MCRI Culture of Cities Project; Coordinator of the Diniacopoulos BBC Radio World News project and scholarship program, and Curator for the legal depository of the CBC radio drama archive. His publications include numerous articles and co-edited journals in the area of the sociology of culture and in political and social thought. He will be responsible for the cinematographic recording and knowledge translation component of the project.

**Shirley Roy** is a professor in the Département de sociologie, Université du Québec à Montréal. Her work focuses on homelessness, poverty and social exclusion, drug addiction, mental health and other issues. She is co-director of the Collectif de recherche sur l’itinérance (CRI), one of Canada’s best-known teams working on homelessness. She will collaborate on Christopher McAll’s projects.

**Catherine Vallée** is currently completing postdoctoral studies in public health at the Université de Montréal and in the Direction des systèmes de soins et services, Institut national de santé publique du Québec. With a solid clinical background as an occupational therapist, consultant, trainer and manager, she has dedicated the last few years of practice to serving the study’s clientele, in the context of community follow-up and housing support. She will contribute to the overall qualitative aspects of the study.

**Helen-Maria Vasiliadis**, Ph.D., holds a Master’s degree in pharmacology from the Université de Montréal and a Ph.D. in epidemiology and biostatistics from McGill University. She has also trained in health economics. She has completed two years of postdoctoral research on mental health and drug addiction policies and services and a one-year fellowship at the Harvard School of Public Health in psychiatric epidemiology. She is currently FRSQ Chercheur Boursier - Junior 1. Her research interests include the following: determinants associated with the use of population mental health services, utility of administrative databases for population studies, cost-effectiveness analysis of health services to different psychiatric clients, quality of life and program evaluation. She will focus on economic evaluation and plans to devote four hours per week to the project.

### 11. Governance Structure

In light of the project’s complexity, we have settled on a governance structure that includes several committees and levels of decision-making, as illustrated in the diagram on the following page.

First, a **steering committee**, composed of a limited number of key players, will make it possible to make more sensitive or central decisions, to guide the project and ensure that it is coherent. The committee will be chaired by Sonia Côté, coordinator of the Montreal project, and will include Suzanne Carrière, Bertrand Gagné (director of Diogène), Eric Latimer, Christopher McAll, and two service users. (The participation by service users is described in section 10.) The steering committee will normally meet once a month but may meet more frequently in the early stages or at key moments in the project.

The steering committee will be supported by semi-annual meetings of the **consortium**, described at the beginning of this document, in addition to the full research team and three service users. The consortium will play an advisory, rather than decision-making, role. Allowing all the partners in the project to sit at the same table will enable continuous information exchange among partners and persons most directly involved in the project. A collaboration website, which is already up and running at [http://projetrdsmimtl.ning.com/](http://projetrdsmimtl.ning.com/), will continue to facilitate this information exchange between the project and its partners.

Two other committees - the general research committee and the clinical committee - will report to the steering committee. The **general research committee** will be composed of all the researchers from Montreal, as well as two service users, and will meet at key moments or at least once per quarter. As the principal investigator, Eric Latimer will chair the committee. The committee will be responsible for ensuring compliance with the various research
protocols and for coordinating specific projects, particularly those using both quantitative and qualitative data from the questionnaires.

To allow for more detailed work on integration between related research areas, two work teams will divide up the research work related to their respective issues. The first group will form the services, housing and trajectories committee, which will be chaired by Marie-Josée Fleury and include Henri Dorvil, Jean Gagné, Eric Latimer, Alain Lesage, Christopher McAll, Greg Nielsen and Catherine Vallée. A second committee, called the client follow-up committee and chaired by Eric Latimer, will include Jean-Pierre Bonin, Anne Crocker, Alain Lesage and Helen-Maria Vasiliadis. As may be seen, the first committee will coordinate the predominantly qualitative projects and the second will be responsible for the predominantly quantitative projects, while carrying out the major task of ensuring follow-up of 500 homeless people in the context of a research project. We anticipate that two service users will participate in each of the meetings, which will initially be held once a month, and subsequently as required. Finally, a number of specific research committees will be established, based on the various projects described in section 7. The committees will be chaired by each project leader. Two service users will also attend each committee meeting.

In parallel with the general research committee, a clinical committee will be established, consisting of key players in the clinical intervention: Jason Champagne (responsible for several clinical services including the Streets to Homes team from CSSS Jeanne-Mance), Bertrand Gagné, the intensive follow-up coordinator (to be determined) and Sonia Côté. This committee will ensure that the various institutional and community intensive follow-up and intensive case management teams run smoothly and are properly coordinated. Two service users will sit on this committee as well.

12. Service User Participation

When setting up the project, we invited the self-help group, Action Autonomie, which was commissioned by the Agence de Montréal to develop participation mechanisms for service users, to participate in our discussions and identify service users who could inform our decisions. Our contacts subsequently led to development of a mechanism in which we suggest that service users can play an effective role in the project’s overall orientation and direction.

14 While Gilles Dupuis, Roch Hurtubise, Paul Morin and Shirley Roy are also expected to serve on this committee and the general research committee, this has not yet been confirmed.
This mechanism was informed by findings in the literature concerning the preconditions necessary for significant participation by service users. The literature indicates, first, that the language used must be accessible and comprehensible to all, which implies investment in the production of consequent training activities. The work atmosphere must facilitate communication and listening by providing a friendly environment and a program and schedule adapted to users’ specific needs. As well, since relations between users and managers, researchers and workers are customarily unequal, it is essential to avoid making the former feel isolated and even marginalized in the process. The project proponents must therefore facilitate relations with local user groups. Throughout the process, they will be accompanied by an experienced peer or support person and will attend multipartite work sessions together. Finally, a policy on remuneration and reimbursement will assign equivalent value to their contribution and that of the professional participants. Agendas should be capable of amendment on request and should contain a rule of order allowing users to address any topic of their choice. Users should be able to play key roles in meetings and to participate in any official representations by the proceeding in which they are participants [36, 37].

The organization agreed on with the service user participation project funded by the Agence, in the context of discussions in which Action autonomie and a service user (Jean-Nicolas Ouellet of CAMÉÉ- Montréal-Nord) were also involved, is based on the following principles: (1) at least two users should attend each meeting; (2) given the number of meetings planned (section 12), the work should be divided among several users; (3) users should be compensated fairly for their contribution; (4) users should be provided with support and accompanied by a support person; and (5) other service users should be made available to them as resource persons.

In the previous section, we referred to the numerous meetings of the different committees that will be established to manage the project and to the fact that we expect that two service users (or three, in the case of the consortium, owing to the larger number of participants) will attend each meeting. The steering committee will meet at key moments in the project and service users will have an opportunity in those meetings to provide feedback and brief the team on progress achieved in the project and its various components. This “consultation/power-to-influence form of participation is considered essential if the project is to run smoothly. The same type of process will be applied for the three research committees, the clinical committee and the specific research committees. The meetings will vary in frequency, depending on work progress. Finally, service users will be invited to attend the large meetings of the consortium, held twice a year.

Because so many meetings will be held, we plan to hire 12 service users to divide up the job of ensuring a presence at each meeting. We will be looking for people with significant experience in mental health/homelessness who are highly motivated and available to commit to the participative process for a long time, ideally, for the full four years of the project. We expect that all 12 users will have to devote one day per month for the duration of the project.

In order to ensure effective participation by those persons in the process, we are planning the following measures:

i. Hiring of a part-time (20 hours/week) animator to support the participative process. He/she will be responsible for recruiting service users, organizing training and meetings, preparing users for participation and subsequently debriefing them, and offering the necessary support during meetings. He/she will also provide liaison with social assistance and support the requisite administrative procedures. He/she may be called on to perform other duties and be available at other times, as required.

ii. Remuneration on an hourly basis for participant involvement in various activities. Remuneration will average $50 per half-day, in accordance with Agence de la santé et des services sociaux de Montréal policy. Additional participation expenses, such as the cost of transportation or meals when activities are based away from the usual place of work, will also be covered.

iii. Meetings between the service users themselves, organized and led by the community worker, allowing all service users attending the meetings to share their experiences, discuss the project’s progress and review their contributions. This will also provide an opportunity for problem solving, as required.

iv. Periodic (i.e., quarterly) participation in different forms of focus groups/consultations with peers. To facilitate their participation in meetings, users will be allocated a participation budget covering snack or meal expenses, transportation assistance, equipment, stationery audio-visual rental, etc.
Moreover, we hope that users will participate in other aspects of the project, such as street theatre, videography to document participation by service users, writing up of final reports and dissemination of results. We have also indicated that we would like to hire users to sit on the interview and outreach teams.

13. Protection of Personal Information

We will take the necessary precautions to ensure that personal information is protected. All electronic files will be stored securely. To the extent possible, data will be identified by code rather than by individual names and a master list will be stored especially securely. Excerpts from interviews, when quoted, will be modified if necessary to ensure that the interviewee cannot be identified. In preparation for the submission to ethics committees, and once procedures for transmitting data to the Canadian research team have been defined, we will establish more detailed procedures to ensure that personal information receives the highest security.
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Statistical Analysis Plan

The purpose of this study is to test the effectiveness of a Housing First with Intensive Case Management intervention for homeless individuals with mental illness and unmet mental health needs over a period of 12 months. To this end, our data analysis will use exploratory and explanatory approaches. Exploratory data analysis will include descriptive statistics and graphs to inform about the functional form of the 12-month trajectories of our outcomes of housing status, health status, quality of life, health service use, and justice system involvement. For example, graphs will describe the change in the CSI scores over time and will help to identify the appropriate time function (i.e., linear or quadratic), or may suggest interactions of intervention arm and time. Because we are interested in modeling how outcome trajectories change over time within individuals, as well as determining how outcome trajectories change between individuals, we will apply findings from the exploratory data analysis to develop random effects growth models (i.e., multilevel models for change). For CSI, for example, scores at each Month (Level 1) are nested within each individual (Level 2), and we will adapt the general strategies described in Singer [reference 2] to build several multilevel models. We will fit three models, starting with Model 1 that only considers random intercepts at each data level (the null model). This model provides information on symptoms variability before any predictor is included, and serves as the reference comparison for subsequent models. Model 2 considers the individual growth model of change with random intercepts and slopes. Assuming linear change, the sub-model at Level 1 defines that symptom scores $Y_{ti}$ for Month $t$, individual $i$ is represented as:

$$Y_{ti} = \pi_{0i} + \pi_{1i} \times \text{Month}_{ti} + \epsilon_{ti},$$

where $\epsilon_{ti}$ is the random error assumed to have normal distribution with mean 0 and variance $\sigma^{2}_e$ (i.e., $N(0, \sigma^{2}_e)$).

The sub-model at Level 2 defines that the intercept ($\pi_{0i}$) and slope ($\pi_{1i}$) of symptom scores’ trajectories for individual $i$ vary around a mean value as:

$$\pi_{0i} = \beta_{00} + r_{0i}$$
$$\pi_{1i} = \beta_{10} + r_{1i}$$

where $r_{0i}, r_{1i}$ are random errors around the means assumed to be $N(0, \sigma_{r0}^{2}), N(0, \sigma_{r1}^{2})$, respectively, with covariance $\sigma_{r0r1}$.

The composite Model 2 is then:

$$Y_{ti} = \beta_{00} + \beta_{10} \times \text{Month}_{ti} + r_{0i} + r_{1i} \times \text{Month}_{ti} + \epsilon_{ti},$$

In Model 3, we expand Model 3 by allowing individual intercepts to vary by Intervention arm and Site, and slopes to vary only by Intervention arm. Therefore the sub-model at the individual Level 2 is written as

$$\pi_{0i} = \beta_{00} + \beta_{01} \times \text{Intervention}_{i} + \beta_{02} \times \text{Site}_{i} + \beta_{03} \times (\text{Intervention} \times \text{Site})_{i} + r_{0i}$$
$$\pi_{1i} = \beta_{10} + \beta_{11} \times \text{Intervention}_{i} + r_{1i}$$

Substituting, we have the following composite Model 3:

$$Y_{ti} = \beta_{00} + \beta_{01} \times \text{Intervention}_{i} + \beta_{02} \times \text{Site}_{i} + \beta_{03} \times (\text{Intervention} \times \text{Site})_{i} + r_{0i} + \beta_{10} \times \text{Month}_{ti} + \beta_{11} \times \text{Intervention} \times \text{Month}_{ti} + r_{1i} \times \text{Month}_{ti} + \epsilon_{ti},$$

Finally, in Model 4, we expand Model 3 by allowing individual trajectories to vary by Intervention arm and Site, and potentially interact. Therefore the sub-model at the individual
Level 2 is written as
\[ \pi_{0i} = \beta_{00} + \beta_{01} \cdot \text{Intervention}_i + \beta_{02} \cdot \text{Site}_i + \beta_{03} \cdot (\text{Intervention} \cdot \text{Site})_i + r_{0i} \]
\[ \pi_{1i} = \beta_{10} + \beta_{11} \cdot \text{Intervention}_i + \beta_{12} \cdot \text{Site}_i + \beta_{13} \cdot (\text{Intervention} \cdot \text{Site})_i + r_{1i} \]

Substituting, we have the following **composite Model 4**:
\[ Y_{ti} = \beta_{00} + \beta_{01} \cdot \text{Intervention}_i + \beta_{02} \cdot \text{Site}_i + \beta_{03} \cdot (\text{Intervention} \cdot \text{Site})_i + r_{0i} + \]
\[ \beta_{10} \cdot \text{Month}_{ti} + \beta_{11} \cdot \text{Intervention}_i \cdot \text{Month}_{ti} + \beta_{12} \cdot \text{Site}_i \cdot \text{Month}_{ti} + \beta_{13} \cdot (\text{Intervention} \cdot \text{Site})_i \cdot \text{Month}_{ti} + r_{1i} \cdot \text{Month}_{ti} + e_{ti} \]

We will use maximum likelihood estimation so nested models can be compared by testing the difference in deviance (\(-2\log\text{-likelihood}\)). Non-nested models will be compared using the AIC or BIC criterion (Singer 2, Raudenbush reference 3).

For continuous outcomes that meet standards of normality of the distribution of errors, we will use the procedure MIXED in SAS version 9.3. In case the distribution of any of our outcomes is too skewed and we need to create categories or define counts, we will use either a logistic or Poisson generalized hierarchical linear model approach (Hox reference 4), implemented either in PROC NLMIXED or the new PROC GLIMMIX in SAS. We will apply multiple imputation methods to account for missing data (to be developed later).

To be further developed: comparing models when using non-linear mixed models.

**References**


