Please provide a short title for this study (256 characters or less):

* Addressing Postpartum Mood and Weight Concerns to Sustain Smoking Cessation

**T1.0 Does your proposed project constitute a "research" study, a "quality assurance" project, or "innovative practice" procedure?**

* Research study

**T2.0 Is the proposed research study limited to the inclusion of deceased individuals?**

* no

**T3.0 What is the anticipated risk to the research participants?**

* Minimal Risk

**T3.1 Why do you feel that this research study involves no more than minimal risk to the research subjects?**

* Risks involve those associated with participant completion of assessments as some of the questions administered may be upsetting. There is also a risk that the program will not help participants remain abstinent from cigarettes.

Subjects will be instructed that they are free not to answer any question they do not wish to answer and that they may withdraw from the study at any time. They will also be made aware in the informed consent document that the program will not guarantee their continued smoking cessation.

All assessors involved in the study will be master's level clinicians with appropriate training on the specific pre and post partum counseling that is part of study protocol. Overall, we believe that the risks to the subjects are reasonable given the potential knowledge to be gained from the study. We also believe that the potential risks are no more probable or of higher magnitude than those encountered in ordinary, daily life.

**T4.0 Does the proposed study qualify for "exempt" IRB review or for a determination of either "not research" or "no human subject" involvement?**

* no

**T5.0 Does the proposed research study qualify for "expedited" IRB review status?**
* yes

[reviewer notes~]  
**T5.1** Does this research involve the collection and storage of biological specimens for future testing?  
* no

[reviewer notes~]  
**T5.2** Does this research involve prisoners, or is it anticipated that the research may involve prisoners?  
If your answer is [Yes], federal regulations require review by a convened IRB committee.  
* no

[reviewer notes~]  
**T5.3** Are you requesting a waiver of the requirement to obtain informed consent (from some or all potential subjects) for participation in this research study, or any procedures associated with the conduct of this research study?  
* yes
CS1.0 What is the reason for this submission?

* New Research Protocol Submission

CS1.1 Has this research study been approved previously by the University of Pittsburgh IRB?

* no

If Yes, provide the IRB # and append both the completed Research Study Renewal Report Form and the Data and Safety Monitoring Report.

If a Paper Conversion/Renewal submission: you are required to upload the Research Study Renewal Report Form, DSMP report, copy of the currently approved IRB protocol and consent form(s) or the application will be returned.

Study Documentation:
Name Modified Date
There are no items to display

Previous IRB #

CS1.1.1 Has this research study (or a substantially similar research study) been previously disapproved by the University of Pittsburgh IRB or, to your knowledge, by any other IRB?

* no

If Yes, identify the IRB and the primary reasons for disapproval:

CS2.0 Title of Research Study:

* Addressing Postpartum Mood and Weight Concerns to Sustain Smoking Cessation

CS2.1 Research Protocol Abstract:

* The majority of women who quit smoking during pregnancy will relapse during the first year postpartum, and postpartum smoking has deleterious effects on the health of both the mother and her children. For example, smoking increases the risk of certain cancers, respiratory symptoms and reproductive complications among women, and exposure to tobacco smoke has been linked to sudden infant death syndrome, ear infections, respiratory illness and asthma among children. Previous interventions designed to address postpartum smoking have not successfully increased rates of sustained abstinence postpartum. However, our research has documented that mood and weight concerns are associated with postpartum smoking relapse, and pilot data support the acceptability of strategies to address mood and weight concerns in the postpartum period. Thus, this application proposes a randomized controlled trial of a novel, cognitive behavioral postpartum relapse prevention program that addresses women’s mood and weight concerns delivered during the postpartum period when the risk of relapse is high. Pregnant women who have quit smoking and are interested in staying quit postpartum (N = 300) will be randomly assigned to: 1) a relapse prevention intervention that addresses mood and weight concerns, or 2) a nondirective, supportive condition designed to control for the effects of therapeutic time and
attention. We hypothesize that relapse will be less likely at 6 and 12 months postpartum for women in the intervention group than those in the supportive condition. We will also examine the mediators and moderators of treatment response. Results of this investigation will provide information on the efficacy of a cognitive behavioral relapse prevention intervention that incorporates strategies to address mood and weight concerns to prevent smoking relapse and inform future research on the prevention of smoking and other drug use postpartum.

CS3.0 Name of the Principal Investigator:
* MICHELE LEVINE

CS3.1 Affiliation of Principal Investigator:
* University faculty member

If your answer was Other, fill in the Principal Investigator's affiliation:

If you chose any of the Pitt options, please indicate the specific campus:
Main Campus - Pittsburgh

CS3.2 Address of Principal Investigator:
* 3811 O'Hara Street
Iroquois Building, Suite 606
Pittsburgh, PA 15213

CS3.3 Recorded Primary Affiliation of the Principal Investigator:
U of Pgh | School of Medicine | Psychiatry

CS3.4 Identify the School, Department, Division or Center which is responsible for oversight of this research study:
* U of Pgh | School of Medicine | Psychiatry

CS3.5 Telephone Number of Principal Investigator
* 412-647-0703

CS3.6 Recorded Current E-mail Address of Principal Investigator to which all notifications will be sent:
levinem@upmc.edu

CS3.7 Fax Number
412-647-2429

CS3.8 Are any of the personnel associated with this study from Carnegie Mellon University?
* no

CS4.0 Name(s) of Co-Investigator(s):

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CS5.0 Name of Primary Research Coordinator:

MEGHAN WISINSKI

CS5.1 University/UPMC Address of Primary Research Coordinator:

3811 O'Hara Street  
Iroquois Building, Suite 606  
Pittsburgh, PA 15213

CS5.2 Telephone Number of Primary Research Coordinator:

412-647-9230

CS6.0 Name of Secondary Research Coordinator:

CS6.1 University/UPMC Address of Secondary Research Coordinator:

CS6.2 Telephone Number of Secondary Research Coordinator:

CS6.3 Administrative Support Individual:

Cover Sheet Section

CS 8.1 Select the school, department or division which is responsible for scientific review of this submission.

* U of Pgh | Western Psychiatric Institute and Clinic
CS9.0 Does this research study involve the administration of an investigational or FDA-approved drug for research purposes?
* no

CS10.0 Is this research study being conducted under an investigator-sponsored Investigational New Drug (IND) application or investigator-sponsored Investigational Device Exemption (IDE) elements?
* no

[reviewer notes~]

CS11.0 Use the "Add" button to upload one or more of the following:
- the sponsor protocol (including investigator initiated studies) and/or other brochures
- the multi-center protocol and consent form template, if applicable

Is this research study industry sponsored?
* no

Is this a multi-centered study?
* 

[reviewer notes~]

CS12.0 Do any of the proposed experimental interventions (i.e., the drugs or procedures being evaluated under this research study) involve exposure to ionizing radiation and/or do any of the research procedures (i.e., excluding screening or follow-up procedures that are consistent with standard care of the respective patient-subject population) involve exposure to ionizing radiation (e.g., experimental interventions or applicable research procedures involving x-ray [including CT] procedures, radioactive drugs or radiation therapy)?
* no

Upload Radiation Forms:
Name Modified Date Version
There are no items to display

CS13.0 Does this research study involve the deliberate transfer of recombinant DNA (rDNA) or DNA or RNA derived from rDNA into human subjects?
* no

Upload Appendix M of NIH Guidelines:
Name Modified Date Version
There are no items to display

CS14.0 Will research subjects undergo any of the following that could potentially be billed by UPMC: diagnostic and/or interventional procedures, administration of drugs, insertion of
medical devices, collection of biological specimens, laboratory assays, and/or any other patient care services?

* yes

Upload Fiscal Forms:

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<td>3/26/2008 9:52 AM</td>
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[reviewer notes~]

CS14.1 Will this study be submitted to the UPMC Clinical Trials Office?

* no

CS14.2 If you have already submitted to the UPMC Clinical Trials Office, please include the 6 digit identification number.

[reviewer notes~]

CS15.0 Indicate the sites where research activities will be performed and/or private information will be obtained.

* Choose all sites that apply and/or use Other to include sites not listed:

Sites:

UPMC

List other sites, as required:

For non Pitt or UPMC entities, upload documents granting permission to conduct research at that site:

Name Modified Date Version

There are no items to display

[reviewer notes~]

CS15.1 Indicate each of the UPMC institutions (e.g., hospitals, clinics) where research will be performed and/or private information will be obtained:

* Check all that apply:

Sites

UPMC Magee Women's Hospital
UPMC Presbyterian
UPMC Western Psychiatric Institute & Clinic

List others UPMC institutions, if applicable:

15.1.1 Have you, MICHELE LEVINE, verified that all members of the research team have the appropriate expertise and credentials to perform those research procedures that are their responsibility as outlined in the IRB protocol?

* yes
CS16.0 Special Research Subject Populations: Check the categories that apply to this research study.

* Categories
   - Children (age < 18 years old)
   - Pregnant women, fetuses and/or neonates

CS 17.0 Does your research involve the use of ANY human stem cells?

* no
1.1 Objective: What is the overall purpose of this research study? (Limit response to 1-2 sentences.)

The goal of the proposed investigation is to determine whether a cognitive behavioral relapse prevention intervention designed to address mood and weight concerns during the postpartum period will decrease the rate of postpartum relapse to smoking. The study design will be a two-group, randomized controlled trial.

1.2 Specific Aims: List the goals of the proposed study (e.g., describe the relevant hypotheses or the specific problems or issues that will be addressed by the study).*

The specific aims of this application are to:

1) Evaluate the relative efficacy of a postpartum smoking relapse prevention program using cognitive behavioral therapy, CBT (pink), and a supportive, nondirective comparison condition SBT (blue) to increase the proportion of women who remain abstinent through 12 months postpartum. We hypothesize that women randomized to CBT (pink) will maintain higher rates of smoking abstinence at 6 and 12 months postpartum, and expect SBT (blue) to increase the length of time abstinence is sustained relative to CBT (pink).

2) Examine the impact of the CBT (pink) intervention on mood, weight concerns and smoking self-efficacy. We predict that women randomized to CBT (pink) will have greater improvements in mood (i.e., decreases in depressive symptoms and perceived stress), weight concerns (i.e., increases in self-efficacy for weight management) and self-efficacy to abstain from smoking than will those in SBT (blue).

A secondary aim is to:

3) Explore factors associated with abstinence postpartum. Previous studies suggest that nicotine dependence, socioeconomic factors (e.g., lower SES, less education), partner smoking, age and race may moderate abstinence rates postpartum. We will also evaluate mood, weight concerns and self-efficacy to abstain from smoking as predictors or mediators of abstinence.

The work done as part of this study will lead to the development of an efficacious treatment for the prevention of smoking among postpartum women and an improved understanding of the factors associated with postpartum relapse. Results from this randomized clinical trial also will provide information on the effects of therapeutic time and attention on postpartum smoking relapse. If the SBT (blue) condition is efficacious, it will provide an intervention that may be readily disseminated among postpartum women. Thus, this work will provide clear direction for the prevention of relapse to smoking postpartum and may inform postpartum care for women substance users in general.

1.3 Background: Briefly describe previous findings or observations that provide the background leading to this proposal.

Women are more likely to quit smoking during pregnancy than at any other time of life (Ebrahim et al., 2000; Williamson et al., 1989). Maternal smoking during pregnancy is associated with low birth weight, premature delivery, infant mortality, spontaneous abortion, decreased infant arousal, poor lung functioning, and sudden infant death syndrome (Franco et al., 1999; Gilliland et al., 2000; Ness et al., 1999; Pollack et al., 2000; Pollack, 2001; Wang et al., 1997). The effectiveness of prenatal smoking cessation programs is well established (Ershoff et al., 1989; Floyd et al., 1993). Currently, only 12% of women smoke during pregnancy (Ebrahim et al., 2000), and the prevalence of smoking during pregnancy has decreased significantly over time (Ebrahim et al., 2000; Mathews, 2001).

However, the majority of women who quit during pregnancy will resume smoking during the year following childbirth (Fingerhut et al., 1990; McBride et al., 1990; Mullen et al., 1990). An estimated 25% of women will relapse to smoking within one month of delivery, and between 60% and 70% of women will return to smoking by six months postpartum (Fingerhut et al., 1990; McBride et al., 1990; Mullen et al., 1990; Ratner et al., 2000). Thus, addressing women’s smoking during pregnancy alone is...
insufficient, and efforts to prevent relapse to smoking in the postpartum period are of critical public health importance. Below, we review literature relating to postpartum smoking relapse and its prevention to document the need for novel approaches to intervention. We then review previous work suggesting the salience of mood and weight concerns in smoking relapse, and document that these factors are critical targets for treatment.

Postpartum Smoking
Given the prevalence of smoking relapse during the postpartum period, interventions designed to prevent postpartum smoking are important to public health for several reasons. First, women who resume smoking after childbirth expose their young children to tobacco smoke, which has been linked to sudden infant death syndrome, ear infections, respiratory illness and asthma (Dybing et al., 1999; Ey et al., 1995). Exposure to environmental tobacco smoke also has been related to deficits in cognitive and behavioral performance among children (Cornelius et al., 2000; Kahn, Zuckerman et al., 2002; Maughan et al., 2001).

Second, smoking during the postpartum period has deleterious effects on the mother's health. Although smoking is associated with numerous health consequences for individuals of both genders, it presents greater health risks for women than for men. After controlling for other risk factors, women smokers are at increased risk for lung cancer (Kure et al., 1996; Zang et al., 1996), bladder cancer (Castelao et al., 2001), respiratory symptoms (Langhammer et al., 2000) and myocardial infarction (Prescott et al., 1998) relative to men. Women smokers also are at risk for cervical cancer (Castle et al., 2002), reproductive complications and menstrual dysfunction (Baron et al., 1990).

There also are unique aspects of the postpartum period that may increase the likelihood that efforts to encourage women to maintain smoking abstinence at this time will be effective. Women who quit during pregnancy spend up to eight months smoke-free (Dolan-Mullen et al., 1994). These women, presumably, have overcome the acute nicotine withdrawal symptoms, broken many habitual associations to smoking and developed some successful strategies for coping with urges to smoke by the end of pregnancy. Moreover, the adoption of the role as caretaker for a newborn may itself increase a woman's motivation to stay quit.

In summary, because of the high rates of smoking relapse and consequent negative health impact on women and children, the postpartum period is an important target for smoking relapse prevention efforts. Interventions designed to prevent women from resuming smoking during this period may decrease the overall smoking rate among women and the exposure of infants and young children to environmental tobacco smoke.

Correlates of Postpartum Smoking Relapse
Several factors have been related to smoking relapse in the postpartum period. The use of alcohol (Severson et al., 1995), membership in a minority group (Carmichael et al., 2000), higher levels of nicotine dependence (Carmichael et al., 2000; McBride et al., 1992; Ratner et al., 2000), younger age (Valanis et al., 2001) and a lack of intention (Mullen et al., 1997) or confidence (Van't Hof et al., 2000) to remain abstinent have been associated with a resumption of smoking after pregnancy. Having a partner who smokes also has received consistent support as a factor related to postpartum relapse (Kahn et al., 2002; McBride et al., 1990, 1992; Ratner et al., 2000; Severson et al, 1995,1997; Stotts, et al., 2000; Wall et al., 1995).

In contrast, findings regarding the relationship between breast feeding and postpartum relapse have been inconsistent. Some studies have found a protective effect of breast feeding on relapse (McBride et al., 1990; Ratner et al., 1999, 2000), while others have found no effect (Kahn, et al., 2002; Severson et al., 1997; Stotts et al., 2000). Thus, nicotine dependence, socioeconomic status and other factors related to the postpartum period appear to moderate the risk of smoking relapse postpartum. Nevertheless, as described below, efforts to diminish postpartum relapse have yielded only modest effects. Consequently, our work has focused on identifying modifiable correlates of smoking relapse.

Weight Concerns and Mood Relate to Postpartum Smoking
There are two theoretically relevant factors that may affect postpartum smoking, concerns about weight and changes in mood. The association between smoking cessation and weight gain has been well documented (Hudmon et al., 1999; Killen et al., 1996; McBride et al., 1996; Perkins et al., 2001), and weight concerns are common postpartum. There also is a well-established association between mood and smoking (Hall et al., 1993). Mood changes, which include both increases in depressive symptoms
and perceived stress, are common postpartum. Mood and weight concerns also co-occur and together may affect the likelihood of a woman's relapse to smoking postpartum.

Weight concerns and postpartum smoking
Smoking cessation is associated with weight gain (Hudmon et al., 1999; Klesges et al., 1997; Streater et al., 1989), and many women (Klesges et al., 1988), particularly those concerned about postcessation weight gain (Pomerleau et al., 2001), endorse the use of smoking as a weight control strategy. Concern about potential weight gain following a quit attempt is more common among women than men (Meyers, et al., 1997; Pomerleau, 1996; Sorensen et al., 1987) and has been associated with treatment attrition (Mizes et al., 1998) and poor cessation outcomes (Meyers, et al., 1997). The issue of cessation-related weight gain may be particularly troublesome for weight concerned women smokers who are expressly unwilling to tolerate even modest weight gains associated with quitting (Levine et al., 2001).

Many women retain a portion of the weight gained during pregnancy in the year after delivery (Gore et al., 2003), and pregnancy has been related to the development of weight problems among women (Walker, 1995; Williamson et al., 1994). Retention of pregnancy-related weight gain is associated with the amount of weight gained during pregnancy (Rooney et al., 2002) and appears to disproportionately affect minority women (Gore et al., 2003). In addition, maladaptive eating attitudes, dieting behaviors and concerns about shape or weight increase during the postpartum period (Baker et al., 1999; Stein et al., 1996).

Concerns about weight gain or the use of smoking as a weight control strategy may increase a woman's vulnerability to smoking during the postpartum period. Successful smoking abstinence during the postpartum period has been associated with increased confidence in preventing weight gain (McBride et al., 1996), and women with greater concerns about shape and weight are more likely than those with fewer weight concerns to endorse the use of smoking as a postpartum weight control strategy (Pomerleau et al., 2000). Additionally, concerns about weight (McBride et al., 1990, 1992), the use of snacking as a strategy to cope with smoking urges during pregnancy (McBride et al., 1992) and having gained more than an average amount of weight during pregnancy (Carmichael et al., 2000) are associated with postpartum smoking relapse. Weight concerns during pregnancy also are related to a woman's motivation to sustain abstinence postpartum (Levine et al., 2006).

In summary, theoretical and empirical evidence suggests that weight concerns increase the likelihood of smoking relapse during the postpartum period. Importantly, smoking-related weight concerns are modifiable (Levine et al., 2003; Perkins et al., 2001). A cognitive behavioral intervention designed to ameliorate women's concerns about smoking-related weight gain has been shown to be an efficacious smoking cessation treatment (Perkins et al., 2001). Thus, the ability of women to sustain smoking abstinence postpartum can be enhanced by an intervention designed to address postpartum weight concerns, a key feature of the intervention proposed in this application.

Mood and postpartum smoking
There also is a strong relationship between smoking and mood. Problems with mood, conceptualized as the experience of depressive symptoms, depressive disorders, negative affect or perceived stress, are common during the postpartum period and have been related to women's smoking. Negative mood is associated with smoking relapse (Ginsberg et al., 1995; Killen et al., 1996; Pomerleau et al., 2001; Shiffman et al., 1996), and many smokers attribute their cigarette use to a perceived anxiolytic effect of smoking (Parrott, 1999). Depressive symptomatology also predicts a return to smoking, regardless of level of nicotine dependence (Niaura et al., 2001). Not surprisingly, women with higher levels of depressive symptoms are more likely to smoke during pregnancy than are those with less depressive symptomatology (Hoffman et al., 2000; Zhu et al., 2002).

Depressive symptoms are a common experience postpartum. The prevalence of clinically significant major depressive disorder during the postpartum period is as high as 14.5% in the three months after birth (Gaynes et al., 2005; O'Hara et al., 1996). Many more women experience elevated depressive symptoms or minor depression (Hopkins et al., 1984; Whiffen, 1992). New mothers also face numerous stressors, and stress both during pregnancy (Ritter et al., 2000) and in the postpartum period (Harlow et al., 2004; Swendsen et al., 2000), increases a woman's risk for postpartum depressive symptoms.

Stress also modestly increases a woman's risk of relapsing to smoking in the postpartum period (Carmichael et al., 2000). For example, higher levels of perceived stress are associated with decreased
motivation to remain abstinent postpartum (Levine et al., in press). Smoking cessation interventions
that address changes in mood are effective among smokers who are vulnerable to negative mood
(Brown et al., 2001; Hall et al., 1994, 1996). Thus, the intervention proposed in this application is
designed to address postpartum mood, including perceived stress and depressive symptoms, to improve
rates of sustained smoking abstinence after delivery.

Co-occurrence of postpartum mood and weight concerns
The co-occurrence of mood and weight concerns may further increase the likelihood of postpartum
smoking relapse. There is considerable evidence that mood is associated with overeating and eating
disorder symptoms (Greeno et al., 1994; Joiner et al., 1995; Killen et al., 1994; Poulakis et al., 1993),
and overeating or concerns about weight can increase negative moods. For example, higher pregnancy-
related weight gains are associated with depressive symptoms among pregnant women (Cameron et al.,
1996), and postpartum weight retention may contribute to negative mood, a trigger for smoking
relapse. Thus, negative mood or stress may stimulate overeating in vulnerable individuals, and
overeating may contribute to weight gain or a failure to lose pregnancy-related weight, either of which
might further contribute to negative mood and ultimately to smoking relapse.

Although several studies have tested postpartum relapse prevention interventions, none of the
interventions have been designed to address the mood and weight concerns that specifically relate to
the postpartum period. Therefore, our aim is to incorporate strategies to address mood and weight
concerns in a postpartum smoking relapse prevention intervention and thereby improve the rates of
sustained smoking abstinence postpartum.

Previous Postpartum Smoking Relapse Prevention Interventions
Several studies have tested the efficacy of interventions designed to prevent smoking relapse among
postpartum women (Mullen, 2004). Initially, interventions were designed to prevent pregnant women
who had quit from relapsing during their pregnancy (Petersen et al., 1992; Secker-Walker et al., 1995,
1998; Valanis et al., 2001). More recently, interventions have been designed to increase cessation rates
during pregnancy and improve rates of sustained abstinence postpartum (Higgins et al., 2004; McBride
et al., 2004). Postpartum relapse prevention interventions have been provided in a number of ways,
such as during obstetrical visits (Gielen et al., 1997; McBride et al., 1999; Pbert et al., 2004; Secker-
Walker et al., 1995, 1998; Valanis et al., 2001), in the hospital following delivery (Johnson et al., 2000)
and during pediatrician visits (Pbert et al., 2004; Severson et al., 1997; Van't Hof et al., 2000; Wall et
al., 1995). Treatment components have included self-help materials McBride et al., 1999; Severson et
al., 1997; Van't Hof et al., 2000), advice during routine prenatal visits (Pbert et al., 2004; Secker-
Walker et al., 1995,1998; Valanis et al., 2001), counseling by a nurse (Johnson et al., 2000; Ratner et
al., 2000; Van't Hof et al., 2000) and combinations of these approaches. For example, two studies
(Pbert et al., 2004; Valanis et al., 2001) evaluated the combination of training for providers in both
obstetrics and pediatrics. In both, provider training significantly decreased rates of smoking relapse
during pregnancy relative to usual care, but increased rates of sustained abstinence postpartum were
shown in only one investigation (Valanis et

Although some postpartum relapse prevention interventions have been successful in increasing the
amount of time women remain abstinent after delivery (McBride et al., 1999, 2004; Pbert et al., 2004;
Ratner et al., 2000), the overall efficacy of these interventions has been equivocal. McBride and
colleagues (1999) compared the efficacy of a relapse prevention program delivered during the prenatal
period to a prenatal intervention coupled with postnatal phone calls and mailings. At six months
postpartum, women who received both the pre- and postpartum intervention were less likely to have
relapsed than were those who received only the prenatal intervention. Although the difference in relapse
rates between these groups was only marginally significant, survival analyses indicated that women
receiving the postpartum contact maintained abstinence for a longer period.

More recently, McBride and colleagues (2004) examined the efficacy of training a woman’s partner to
provide support for smoking cessation during pregnancy and the maintenance of abstinence
postpartum. Partner support was no better than usual care in preventing smoking relapse postpartum,
with 33% and 37% of women who were quit by the end of pregnancy sustaining abstinence at six
months postpartum in the usual care and partner assisted groups, respectively. Another recent
approach involves the use of contingency management. Based on its efficacy among pregnant women
(Donatelle et al., 2000), Higgins and colleagues (2004) tested the use of contingent vouchers to
establish abstinence during pregnancy and prevent relapse postpartum. Pregnant women smokers
completed either a contingent or noncontingent voucher program during the first 12 weeks postpartum. In the contingent group, vouchers that were redeemable for retail items were awarded contingent upon provision of an expired-air carbon monoxide (CO) level indicative of not smoking. The noncontingent group received vouchers independently of smoking status. No additional intervention was offered to either group. Point prevalence abstinence rates at the end of treatment were significantly higher in the contingent (33%) than in the noncontingent group (0%).

Thus, previous postpartum relapse prevention interventions have been modestly successful in delaying relapse to smoking. However, with few exceptions (Higgins et al., 2004; Valanis et al., 2001), these interventions have not substantially decreased the overall rate of relapse. Moreover, with the possible exception of pilot data supporting the use of contingent vouchers to reinforce abstinence (Higgins et al., 2004), no specific intervention component has been found to significantly reduce rates of postpartum smoking relapse. Novel approaches to improving rates of sustained abstinence postpartum are needed to address limitations of previous work and improve abstinence rates.

1.4 Significance: Why is it important that this research be conducted? What gaps in existing information or knowledge is this research intended to fill?

The majority of women who quit smoking during pregnancy will resume smoking within six months postpartum. Because of the serious health consequences of smoking for women and their infants and children, postpartum smoking relapse is a critical public health concern, and efficacious interventions to prevent postpartum smoking are needed. We therefore propose to test the efficacy of a postpartum relapse prevention intervention that addresses several gaps in the literature on postpartum smoking.

First, the proposed intervention is novel, conceptually driven and informed by our pilot data. We will target women’s mood and weight concerns, which are relevant to smoking relapse postpartum. Second, the proposed intervention will be delivered at the time when the risk of relapse is greatest (i.e., during the first six months of the postpartum period) and when mood and weight concerns are particularly salient. The intervention also is of adequate intensity and will be delivered in a format appropriate for and acceptable to new mothers. An intervention provided at the right time, of the right intensity and in the right format is likely to increase rates of sustained abstinence postpartum. Third, the proposed intervention will be tested among an ethnically diverse sample of women. Thus, results of this randomized trial will provide clear information on the efficacy of a novel approach to the prevention of postpartum smoking relapse among women of diverse backgrounds.
2.1 Does this research study involve the use or evaluation of a drug, biological, or nutritional (e.g., herbal) supplement?

* no  

2.2 Will this research evaluate the safety and/or effectiveness of one or more devices?

* no  

2.3 Summarize the general classification (e.g., descriptive, experimental) and methodological design (e.g., observational, cross-sectional, longitudinal, randomized, open-label single-blind, double-blind, placebo-controlled, active treatment controlled, parallel arm, cross-over arm) of the proposed research study, as applicable.

* The present study will be a randomized, controlled trial of behavioral intervention during the postpartum period (N=300). Women who quit smoking as a result of pregnancy and are motivated to remain abstinent postpartum will complete a baseline assessment and be randomized during the third trimester of pregnancy to either a cognitive behavioral relapse prevention intervention specifically designed for women who quit smoking during pregnancy, or a nonspecific, supportive condition. Women will be treated for six months following delivery and will be followed for assessment at 3, 6, and 12 months postpartum.

2.3.1 Does this research study involve a placebo-controlled arm?

* no  

2.4 Will any research subjects be withdrawn from known effective therapy for the purpose of participating in this research study?

* no  

2.5 Will screening procedures (i.e., procedures to determine research subject eligibility) be performed specifically for the purpose of this research study?

* yes  

2.5.1 List the screening procedures that will be performed for the purpose of this research study.

* The procedures are listed below.

Append the study flow chart:
Name Modified Date Version
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Describe in detail the screening procedures:
Potential participants who respond to advertisements or who have been referred from an existing prenatal smoking cessation program (STOP) or physicians will be contacted by telephone for further screening. In addition, we are requesting a waiver of the HIPAA authorization requirement for the sharing of contact information for the purpose of recruiting potential research subjects. This waiver will facilitate our efforts to recruit eligible participants, as those who will be referred from the STOP program, a smoking cessation program for pregnant mothers, will be pregnant ex-smokers.

By asking for the HIPAA waiver, we are requesting permission to make the first contact with potential participants who have agreed to hear about research from the STOP Program, local physicians, or other programs. Please see the attached form that patients who have been introduced to STARTS will fill out to indicate they agree to have research staff contact them. Signing this form will also indicate that they are aware that the contact information they provide and their estimated due date, obtained through medical records, will be sent directly to the STARTS staff.

We will also be contacting women who have signed up for the Magee-Womens Hospital research registry, indicating that they would like to be contacted about research opportunities. Women who agree to hear about research through the Magee research registry will be called by study staff and screened by phone using the approved screening script to determine eligibility.

Judith Balk, MD, will be overseeing and facilitating our utilization of the registry. She will serve as the Magee-Womens Hospital representative and recruitment liaison and has agreed to sponsor our study. She is a consultant on the study and will contribute to recruitment strategies and methods associated with the Magee research registry. She will not have scientific involvement in the study or clinical involvement with participants.

Screening for all women will occur between 34 and 38 weeks of pregnancy. Women who call earlier will be tracked and eligibility will be documented again at the end of pregnancy.

We will screen participants initially over the phone. During this telephone screening call, study staff will explain the purpose of the study, answer questions about the study, and obtain verbal consent to ask screening questions. Women then will be asked several questions to determine their preliminary eligibility to participate including prepregnancy smoking rate, current smoking rate, age, and motivation to remain abstinent postpartum. Motivation will be assessed on a 4-point scale ranging from "not at all" motivated [0] to "a lot" (extremely) motivated [3], and women with a score of at least 2 will be eligible. Women who meet these preliminary eligibility requirements will be scheduled to meet with project staff at a prenatal appointment prior to delivery (i.e., between 34 and 38 weeks of pregnancy).

The purpose of this prenatal assessment session will be to document screening information, provide complete information about the program and obtain informed consent. All participants will sign a consent form approved by the University of Pittsburgh Institutional Review Board. Potential participants will be informed via consent form that there is still a chance they will be unable to participate after completing screening procedures.

If they are ineligible after completing these procedures, study staff will explain the reason for ineligibility and answer any questions they might have. If upon completion of these screening procedures they are found eligible, study staff will immediately continue on to the first study assessment, the prenatal assessment, during the same visit.

At this visit, women who agree to participate will provide an expired-air carbon monoxide (CO) sample, provide detailed information on medication usage, and complete the PRIME MD. CO will be used to document current nonsmoking, and the PRIME MD will be used to screen for psychiatric disorders. The PRIME MD is an assessment of current psychiatric disorders designed for use in primary care. Women will complete the 26-item self-report questionnaire and those who receive a positive score will complete further screening with an assessor to verify diagnoses.

Participants will be asked to provide a list of medications they are currently taking and have taken in the past year. This will help study staff identify a potential acute psychiatric disorder or suicidal ideation, both of which are exclusion criteria. Certain medications or conditions will make patients ineligible, as well, and those will be identified this way.
The assessment of CO, the PRIME MD, and a medication list will provide the final verification of eligibility.

2.5.2 What steps will be taken in the event that a clinically significant, unexpected disease or condition is identified during the conduct of the screening procedures?

* Choose from the options below: Addressed below:

Steps to be taken if unexpected condition identified: In the event that a clinically significant, unexpected disease or condition is identified during the conduct of the screening procedures, potential participants will be referred to the appropriate medical follow-up.

2.6 Provide a detailed description of all research activities (e.g., all drugs or devices; psychosocial interventions or measures) that will be performed for the purpose of this research study.

This description of activities should be complete and of sufficient detail to permit an adequate assessment of associated risks. At a minimum this should include:

- personnel performing the procedures
- location of procedures
- duration of procedures
- timeline of study procedures

* The goal of this investigation is to determine whether a cognitive behavioral relapse prevention intervention designed to address mood and weight concerns during the postpartum period will decrease the rate of postpartum relapse to smoking. We will conduct a two-group, randomized controlled trial. Women who quit smoking as a result of pregnancy, have been quit for at least one month prior to delivery and are motivated to remain abstinent postpartum will complete baseline assessments and be randomly assigned during the third trimester of pregnancy to either a cognitive behavioral relapse prevention intervention specifically designed for women who quit smoking during pregnancy (CBT (pink)) or a nonspecific, supportive condition (SBT (blue)). Both conditions will receive written information on the dangers of postpartum smoking and an equivalent number and amount of sessions immediately prior to delivery and during the first six months postpartum. Women will be treated for the first six months postpartum because substantial evidence has shown the risk of relapse to be greatest during the six months immediately following delivery (McBride et al., 1990; Mullen et al., 1990). All participants will receive face-to-face sessions, calls and groups throughout the first six months postpartum. There will be no additional intervention after six months, although women will complete a follow-up assessment at 12 months postpartum. All women will complete assessments at baseline (during pregnancy) and 3, 6 and 12 months postpartum.

Assessments

Assessment of smoking. Smoking status will be assessed using expired-air CO, self-report, and analysis of cotinine which is collected with a saliva sample. Samples will be frozen and stored for later analysis. Saliva will be tested for cotinine, a metabolite of nicotine, which will give us data to determine whether or not participants have had any nicotine in approximately the last week.

Definition of abstinence. Women will be queried about any smoking using a time line follow-back format we have used in previous studies (Perkins et al., 2001).

Assessment of smoking history. At baseline, women will answer questions about their past smoking behavior (e.g., cigarettes/day, onset of regular smoking, date of last cigarette), and previous attempts to quit. Finally, all women will be asked about their prepregnancy level of nicotine dependence using the Fagerstrom Test of Nicotine Dependence (Heatherton et al., 1991), a commonly used, validated assessment tool. Women also will complete the Reasons for Quitting Scale (RQS; Curry et al., 1990), a measure of intrinsic and extrinsic motivation for smoking cessation that also incorporates items designed to assess pregnancy and parenting as motivations to stop smoking (Curry et al., 2001).
Assessment of smoking self-efficacy. Women will complete the Smoking Self-Efficacy Questionnaire (SEQ; Etter et al., 2000) at each assessment. The SEQ is a 12-item scale that reflects confidence to abstain from smoking in various high-risk situations. The SEQ has been shown to discriminate between current and former smokers (Etter et al., 2000) and has high internal consistency (Etter et al.; Webb et al., 2005).

Assessment of demographics, pregnancy and postpartum behaviors. Demographic information (e.g., age, race, ethnicity, income), parity and information about the pregnancy (e.g., whether pregnancy was intentional) will be collected at baseline. Variables that have been related to postpartum smoking relapse, including confidence in remaining abstinent, smoking status of others in the home and alcohol use will be assessed. In addition, women's intention to breastfeed will be measured at baseline, and actual breastfeeding will be documented at follow-up assessments.

Assessment of general weight concerns. A number of questionnaires will be used to capture the different aspects of women's concerns about shape and weight. To assess general issues related to weight and shape, participants will complete the Body Esteem Scale for Adolescents and Adults (Mendelson et al., 2001). This 23-item self-report measure has been shown to be a valid and reliable measure of attitudes about weight and appearance among community samples. Women also will complete the Three Factor Eating Questionnaire, which contains three empirically derived factors with good internal consistency in nonclinical samples (Stunkard et al., 1985). The restraint factor reflects conscious thoughts and purposeful behaviors to control food intake. Disinhibition reflects a tendency to relinquish control over food intake in response to environmental or emotional stimuli, and the hunger factor reflects the behavioral consequences of subjective hunger.

At the baseline assessment, women will be asked to estimate their body weight prior to pregnancy. The difference between this self-reported weight and actual weight at the baseline assessment will provide an indication of late pregnancy-related weight gain. Height will be measured using a portable height board, and used to calculate Body Mass Index (weight in kilograms divided by height in meters squared).

Assessment of smoking-specific weight concerns. Women will complete questionnaires assessing the use of smoking as a weight control strategy (Pomerleau et al., 1993), self-efficacy about weight management after quitting smoking (Borrelli et al., 1998) and cessation-specific weight concerns (Borrelli et al., 1998; Perkins et al., 2001).

Assessment of mood. Depressive symptoms will be assessed with two measures. Women will complete the Center for Epidemiological Studies-Depression Scale (Radloff, 1977) to assess current depressive symptomatology. The CES-D was selected because it appears to be less sensitive than other depression scales to somatic symptoms that may be common during the postpartum period (Coyle et al., 1992). In addition, women will complete the Edinburgh Postnatal Depression Scale (Cox et al., 1987), a widely used 10-item assessment specific to postpartum depression. Responses on the CES-D and EPDS will be carefully reviewed, and women who endorse extreme scores or suicidality will be contacted for further evaluation and referral if necessary. The Perceived Stress Scale (Cohen et al., 1983), designed to assess the degree to which an individual appraises situations as stressful, also will be administered. The PSS is a 14-item scale with adequate reliability that has been used in other smoking cessation studies (Cohen, 1986). Women will also complete a 24-item investigator designed stress scale specific to postpartum stress, the Postpartum Stress Scale (PPSS). This scale was selected because it has the potential to uniquely capture stressors associated specifically with the postpartum period, which other stress scales will not necessarily detect.

Women will complete the assessments described above first at a prenatal appointment which will happen immediately after they are screened and eligible at the screening appointment. Women will then be randomized to either CBT (pink) or SBT (blue). Randomization schedules, generated at the start of the project, will determine women's assignment to either CBT (pink) or SBT (blue). Upon completion of assessments, participants will be informed of their group assignment. Project staff, unaware of treatment assignment, will reveal the participant's random assignment and provide instructions about follow-up procedures. All women will receive the brochure containing information about the importance of not smoking around infants and young children.

Intervention: CBT (pink)
The intervention, CBT (pink), is a cognitive behavioral approach to relapse prevention and has been designed using theory and techniques from the cognitive behavioral treatment of mood (Beck, 1995), eating and weight problems (Fairburn et al., 1993), smoking cessation (FreshStart; Shiffman et al., 1990) and general relapse prevention (Marlatt et al., 1985). The intervention is specifically based on our work concerning the relationship of mood and weight concerns to relapse, the acceptability of a postpartum relapse prevention intervention, and the approaches used successfully with women from diverse backgrounds in the STOP study.

The intervention will be delivered in multiple modalities, two individual counseling modalities: phone sessions and face-to-face sessions, and two general support modalities: postpartum group meetings and nonspecific messages of support and encouragement from the project. To maximize retention in the intervention, women will receive gift vouchers that can be redeemed at local grocery or baby stores to reinforce attendance at individual, face-to-face sessions. Women also will receive birthday cards, messages of congratulations and other personal correspondence during the trial. In addition, childcare will be provided at each face-to-face session and during support groups, and we will arrange free parking or provide bus fare for women.

Telephone and face-to-face sessions will target women’s mood and weight concerns. Phone sessions will last approximately 15 minutes and face-to-face sessions will be approximately 30 minutes. For the six planned, postpartum face-to-face sessions, study staff will arrange to either meet participants at a community location (e.g., supermarket, library) or in their homes to accommodate participants’ schedules. In addition to meeting in convenient locations, women will receive a gift voucher, redeemable at a local grocery or baby store, at the conclusion of each individual face-to-face session to assist with subject retention. Vouchers will be for $10 or $20, and women who attend all six postpartum face-to-face sessions will be eligible to receive a total of $100 worth of vouchers.

Group meetings are included to meet women’s reported desire for social support from other young mothers. The group will be held at fixed times monthly at our clinic, and women will be invited to attend the group after delivery. At each group, childcare and assistance with transportation (i.e., bus passes or passes for parking) will be provided. A member of the study staff will facilitate groups, and topics will be selected from the list of topics used in the manual. Finally, additional nonspecific phone calls (i.e., messages of encouragement and support) and information mailed to participants also are designed to decrease feelings of social and emotional isolation.

In addition, the interventionist will introduce herself and give a brief overview of the treatment that will be provided after delivery. This meeting will help establish a relationship between the interventionist and participant which will facilitate women’s receptivity to early phone calls and will not interfere with the many demands on mothers of young infants. The intervention begins with a session of psychoeducation immediately following a woman’s delivery. During this session, which will take place within days after delivery, the interventionist will present our model of postpartum smoking, discuss the rationale for addressing mood and weight concerns, and answer questions about the treatment.

Addressing mood and weight concerns
As in other manualized interventions (Malik et al, 2003; Wilson, 1998), the topics and skills of the CBT (pink) intervention are presented in a standardized fashion. However, treatment is individualized by focusing each session on the woman’s unique situation. Thus, the CBT (pink) intervention balances the presentation of information on a specific topic with the teaching and reinforcement of cognitive behavioral skills. The CBT (pink) Intervention will proceed in three phases. Phase 1 begins right after delivery and includes provision of psychoeducation about mood and weight concerns during the postpartum period and skills to enhance motivation for sustained abstinence. Participants will receive our model of postpartum relapse. For example, the interventionist will explain: "We have heard from women that concerns about returning to a prepregnancy weight, the stresses of having a new baby, and other changes in mood and lifestyle after childbirth can interfere with staying quit. We therefore want to talk about your concerns and share ideas for relaxation, healthy eating and stress management, even if you have not had any desire to smoke."

Phase 2 teaches specific cognitive behavioral strategies related to mood and weight concerns and includes strategies similar to those used in previous studies addressing mood (Hall et al., 1994, 1996) and weight concerns (Levine et al., 2003; Perkins et al., 1997) among smokers. We elected not to target partners for two reasons. First, in a recent, well-conducted study, targeting partner’s support was
not effective in preventing relapse (McBride et al., 2004). Second, the majority (89%) of the candidates for this trial are not married or living as married. To address the relationship between smoking and weight during the postpartum period, women will receive information about healthy rates of weight loss after pregnancy (Keppel et al., 1993; Walker, 1995), lessons on the dangers of strict calorie restriction and strategies for healthy eating. Participants interested in pursuing weight loss will be directed to consult with their physician before initiating a weight loss program. Sessions also will target women’s thoughts about their current body shape and weight, and women will work to moderate maladaptive cognitions and beliefs about the importance of shape and weight. For example, women’s thoughts about being unattractive at anything other than her pre pregnancy weight will be targeted for modification. Weight concerns specific to smoking also will be targeted by addressing common thoughts relating smoking to weight control.

Physical activity also will be addressed in the CBT (pink) intervention. Physical activity will be introduced as an alternative to smoking, and a tool to improve mood and assist with weight concerns. Women will be advised to participate in moderate activity in the form of walking and provided with a prescription for walking consistent with the current guidelines from the American College of Sports Medicine (Pate et al., 1995). Lessons targeting the link between smoking and mood during the postpartum period will address common adjustment issues. Maladaptive thoughts about the use of smoking to modulate mood will be challenged, and women will discuss strategies to increase social contacts and pleasant events. They also will learn relaxation techniques, talk about the importance of balancing their needs with those of their new baby and discuss other mood modulation strategies.

Phase 3 will allow participants to focus on the mood or weight concern issues most relevant to them. During this phase, the sessions will begin with a review of issues. To facilitate this review, interventionists will use a structured checklist at the start of each contact that will assess the various areas the intervention is designed to target. Specifically, the interventionist will ask about: recent urges to smoke, feelings of stress, depressive symptoms and concerns about weight. Finally, participants will discuss termination and plans for continued management of mood, weight concerns and smoking urges posttreatment.

Comparison Group: Nonspecific Supportive Relapse Prevention (SBT (blue))
Women randomized to SBT (blue) will be seen on the same schedule as those in CBT (pink). Women in SBT (blue) will receive seven phone (approximately 15 minutes each) and six face-to-face (approximately 30 minutes each) sessions as well as postpartum support group meetings, nonspecific messages of encouragement from the project and gift vouchers to reinforce attendance at face-to-face sessions. As in CBT (pink), study staff will arrange to meet participants at convenient locations and accommodate participants’ schedules.

In the SBT (blue) condition, like CBT (pink), treatment will include psychoeducation about the dangers of postpartum smoking and exposure to environmental tobacco and the development of a supportive, therapeutic relationship. SBT (blue), like CBT (pink), also will provide a treatment rationale. The rationale for the SBT (blue) intervention is that attention from a concerned interventionist provided in the context of a strong therapeutic relationship may help sustain smoking abstinence. However, in contrast to CBT (pink) which is a cognitive behavioral treatment, interventionists in SBT (blue) will use a flexible, nondirective, supportive approach. Thus, women in SBT (blue) will not receive cognitive behavioral treatment for relapse prevention, engage in contextual reviews of smoking urges, receive information about managing moods and addressing weight concerns or learn cognitive behavioral techniques to ameliorate these concerns. The SBT (blue) intervention has been derived from previous relapse prevention research (Schmitz et al., 2001; 2004), is consistent with focus group data indicating postpartum women’s need for enhanced support, the short-term efficacy of nondirective counseling in the treatment of postpartum depression (Cooper et al., 2003; Holden et al., 1989) and the principles of supportive psychotherapy (Dewald, 1994).

Audio tapes.
Tapes will be stored as any other data in the study is stored, in a locked file cabinet in an office of Western Psychiatric Institute and Clinic. A case number will indicate identity on these records. This information will be accessible only to the investigators and their research study staff listed on the first page of the consent document. The tapes will not include names or any other identifiable information and will be destroyed seven years after the study is over.
2.7 Will follow up procedures (e.g., tests to measure the efficacy and/or safety of the experimental intervention(s); to include monitoring procedures and/or outcome measures) be performed specifically for the purpose of this research study?

* yes

If your answer is Yes, list the follow up procedures that will be performed for the purpose of this research study.

Choose which option you will use to satisfy this statement: The procedures are listed below.

Study Flow Chart:

name version
There are no items to display

OR

List follow up procedures:

Women will complete follow-up assessments at 3-, 6-, and 12-months postpartum. Study staff will meet them at places convenient for them, such as local restaurants or postpartum follow-up appointments with their doctors, to conduct these follow-up assessments. They will complete the same measures as they did at the baseline prenatal assessment, with the following differences or exceptions:

Assessments

The 3-month assessment is necessary to document changes since birth that may mediate the effects of treatment, and the 6-month assessment corresponds to the end of treatment. All women also will be contacted for a follow-up assessment at 12 months postpartum. Women in both groups will receive incentives to complete each research assessment.

Definition of abstinence.

Women will be queried about any smoking since their last assessment using a time line follow-back format we have used in previous studies (Perkins et al., 2001). Relapse will be defined as seven consecutive days of smoking or a CO greater than 8 ppm (Hughes et al., 2003; Ossip-Klein et al., 1986). Days to a first lapse and a full relapse postpartum will be determined by counting the number of days between delivery and the first day of any smoking (i.e., a puff of more), and between delivery and seven consecutive days of smoking or a CO greater than 8 ppm, respectively.

All baseline saliva samples and follow-ups samples from women who reported abstinence will then be analyzed for cotinine, a major metabolite of nicotine. A cotinine level of less than 15 ng/ml (SRNT Subcommittee on Biochemical Verification, 2002) will be use to verify self-report of nonsmoking. Although continuous abstinence will be the primary outcome measure, seven-day point prevalence also will be reported.

Assessment of demographics, pregnancy and postpartum behaviors.

Method of infant feeding will be collected at each assessment.

Assessment of general weight concerns.

At each postpartum assessment, women will be weighed in street clothing without shoes on a portable electronic scale. The differences between self-reported, prepregnancy weight and actual weight will be used to determine the amount of weight retained postpartum.

2.8 Does this research study involve the use of any non-standard questionnaires or survey instruments for the purpose of subject screening, as an experimental intervention, or for follow-up assessments?

* yes
If **Yes**, append those questionnaires or survey instruments not currently listed in Appendix G:

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[reviewer notes¬]

2.9 Would any of the research procedures (i.e., screening procedures, experimental interventions, follow up procedures) performed specifically for the purpose of this research study be performed for the subject's routine medical care or surveillance if s/he were not a participant in this study?

* No

If **Yes**, address the research procedures below:

**2.10 Will blood samples be withdrawn for the purpose of this research study?**

* no

If **Yes**, address below:

[reviewer notes¬]

**2.11 What is the total duration of the subject's participation in this research study?**

* Fill in duration below (e.g., x months):
  approximately 14 months

[reviewer notes¬]

**2.12 Does this research study involve the planned deception, in any manner, of research subjects?**

* no

[reviewer notes¬]

**2.13 Does this research study involve the analysis of de-identified private (e.g., medical record) information collected using an "honest broker" system/process?**

* no

[reviewer notes¬]
2.14 Does this research study involve the collection of identifiable medical record information maintained by a HIPAA covered entity (i.e., health care provider [e.g., hospital, physician's office], health care plan, or health care clearinghouse) and/or the generation of information that will be placed into medical records maintained by a HIPAA covered entity?

* yes

2.14.1 Describe the specific nature of the medical record information that will be collected from a HIPAA covered entity and/or the specific nature of the research-derived information that will be placed in the medical records maintained by a HIPAA covered entity.

* The medical information that will be collected from participants' physicians and put into their research records for this study will be actual delivery dates. We need this information from physicians so that we have an accurate date from which to schedule follow-up sessions with participants. Our first postpartum session occurs immediately after delivery, so any delay in obtaining delivery dates can result in missed treatment sessions. Participants will be notified of this interaction with their physicians and asked to sign a release as part of the consent document.

Patients' physician or STOP Program interventionist may also share with us contact information of patients who they think might be eligible and who they then will approach for the STARTS study. In this situation, patients will fill out a form that includes name, contact information, estimated due date (given by physician/STOP interventionist), and their consent to their doctor/STOP interventionist sharing the information with us and our contacting them (form is attached). This form will also allow us to share with the STOP Program any information they need to collect on participants that we have in common. Participants may withdraw the consent for sharing information with the STOP Program at any time by writing a letter to inform study staff of their decision.

2.14.2 Are you requesting a waiver of the requirement to obtain written HIPAA authorization for the collection of the identifiable medical record information from a HIPAA covered entity?

* yes

2.14.2.1 To ensure that this research use of the identifiable medical record information involves no greater than minimal risk to privacy, describe your plan to protect patient-subject identifiers from improper use or disclosure [45 CFR 164.512 (l)(2)(ii)(A)(1)].

* Describe your plan:
We plan to store all files, including identifiable medical record information, in a secure, locked filing cabinet to which only the investigator and her research staff have access. Any information entered into a computer database will be password protected.

2.14.2.2 To ensure that this research use of the identifiable medical record information involves no greater than minimal risk to privacy, describe your plan to destroy patient-subject identifiers at the earliest opportunity consistent with the research. Indicate at what point in the research the patient-subject identifiers will be destroyed. If applicable, provide a health, research or legal justification for retaining the identifiers [45 CFR 164.512 (l)(2)(ii) (A)(2)].

* Indicate when identifiers will be destroyed or a rationale for retaining:
Patient-subject identifiers, that is, any medical or identifying information linked with participant data, will be destroyed seven years after the study is over.

2.14.2.3 To ensure that this research use of the identifiable medical record information involves no greater than minimal risk to privacy, provide your assurance that this information will not be reused or disclosed to any other person or entity (i.e., other than the listed investigators and their research staff), except as required by law, for authorized oversight of
the research study, or for other research for which the IRB has granted a waiver of the written HIPAA authorization [45 CFR 164.512 (i)(2)(ii)(A)(3)].

* Provide your assurance:
This information will not be reused or disclosed to any person or entity other than the listed investigators and their research staff except as required by law, for authorized oversight of the research study, or for other research for which the IRB has granted a waiver of the written HIPAA authorization.

2.14.2.4 Why could this research not practicably be conducted unless the waiver of written HIPAA authorization is granted [45 CFR 164.512 (i)(2)(ii)(B)]?

* Fill in information below:
We will need the contact information that physicians and the STOP Program provide in order to recruit participants into the study.

2.14.2.5 Why could this research not practicably be conducted without access to and use of the identifiable medical record information [45 CFR 164.512 (i)(2)(ii)(C)]?

* Fill in information below:
We need this information from physicians so that we have an accurate date from which to schedule follow-up sessions with participants. Our first postpartum session occurs immediately after delivery, so any delay in obtaining delivery dates can result in missed sessions.

2.14.2.6 Explain why the nature and amount of the medical record information that will be collected is felt to be the minimum necessary in order to conduct this research study [45 CFR 164.514 (d)].

* Fill in information below:
We are requesting a waiver of written HIPAA authorization so that we can obtain contact information from patients of physicians and clients of the STOP Program who have agreed to having their physician or the STOP Program pass this information along to us. We are only requesting information that is directly related to eligibility for our study.

We will obtain general contact information, including name, phone numbers, and address, from pregnant women. We will obtain estimated due dates from each woman's physician or STOP interventionist, with her permission. Once we have this information, we will contact and obtain verbal consent to conduct a telephone screen with interested women. Therefore, we are obtaining minimal information using the HIPAA waiver. We are not requesting permission to obtain any information that is not relevant to recruitment for our study.

2.15 Does this research study involve the collection and banking of tissue or biological specimens for genetic testing and/or future research use?

* no

2.16 Does this research study involve obtaining, from the research subject (i.e., the proband), information concerning family members or acquaintances of the research subject (i.e., a "third party")?

* yes

2.16.1 Describe the nature of the information about the third party that will be obtained from the research subject (i.e., the proband).
* Fill in information below:
Basic contact information (phone numbers, addresses, relation to participant) will be obtained from participant for family and friends who may be able to contact or relay a message to her in the event that the participant is unreachable but has not withdrawn from the study. Some information will also be collected about the participant’s baby in visits 2-4 (3, 6, and 12 months postpartum), such as birth weight and birth date.

2.16.2 If the information about the third party is of a private nature, will it be obtained in such a manner whereby the identity of the third party is or may readily be ascertained by the investigators or associated with this information?

* Select below: Not applicable - The information about the third party is not of a private nature

If you answered Yes or No above, please provide additional information regarding the collection and recording of the third party information below:

2.17 What are the criteria (i.e., endpoints) that will be utilized to address the specific questions and/or hypotheses being tested?

* 

H1a: Compared to women in SBT (blue), a greater proportion of women in the CBT (pink) condition will remain abstinent at 6 and 12 months postpartum.

H1b: The length of time abstinence is sustained will be longer for women in the CBT (pink) condition than those in SBT (blue).

H2: Women randomized to CBT (pink) will have greater improvements in mood (i.e., decreases in depressive symptoms and perceived stress), weight concerns (i.e., increases in weight self-efficacy and decreases in weight concerns) and self efficacy to abstain from smoking than will those in SBT (blue).

H3. Explore factors associated with abstinence postpartum.

2.18 What statistical approach(es) will be used to analyze the data with respect to the study endpoints?

* Addressed below:

The primary analysis (H1a) involves comparing the proportion of women remaining continuously abstinent, verified by cotinine, in the CBT (pink) and SBT (blue) condition at the end of treatment (6 months postpartum) and at 12 months postpartum. We also will evaluate point prevalence abstinence rates at both 6 and 12 months postpartum. Analysis for this aim will proceed in three steps. First, chi-square tests will be used to compare the proportion of women continuously abstinent in both CBT (pink) and SBT (blue). Second, logistic regression will be used to compare the main binary outcome, abstinent or relapsed, between the groups controlling for other variables that have been related to postpartum relapse (parity, breast feeding, age, alcohol use, race). Finally, models based on the generalized estimating equation (GEE) approach will be fit, so that all four assessment points (i.e., baseline, 3, 6 and 12 months postpartum) can be incorporated into this analysis (Diggle et al., 1994), and women can be included if they have not completed all assessment points.

For the second part of the primary hypothesis (H1b), we will use Kaplan-Meier survival curves to test differences in the number of days women remain abstinent in CBT (pink) relative to SBT (blue). In this analysis, "survival" will be defined as time to relapse, and the survival curves represent the probability of relapse over time. The survival curves will be computed and plotted, and the log-rank test will be used to evaluate differences in the time to relapse between the groups.

Next, a mixed model analysis will be used to evaluate mood, weight concerns and smoking self-efficacy as a function of group (CBT (pink) vs. SBT (blue)), time (baseline, 3, 6 and 12 months postpartum) and
the interaction term of group by time. Tests of treatment effect will be performed by evaluating the group and group by time interaction terms. Follow-up analyses will be used to evaluate differential changes between CBT (pink) and SBT (blue) from pretreatment to posttreatment and from posttreatment to follow-up.

Third (H3), we hypothesize that decreases in perceived stress and depressive symptoms, increases in ability to manage weight without smoking and increases in self-efficacy to abstain from smoking will mediate the ability to remain abstinent among all women. Differences in outcome between women with higher prepregnancy nicotine dependence, lower SES, less education and different racial backgrounds will be evaluated. To test the hypothesis that mood, weight concerns and smoking self-efficacy are predictors of postpartum smoking relapse, a series of separate logistic regression analyses will examine the relationship between the mood, weight concern and smoking self-efficacy variables and relapse at six months postpartum after controlling for treatment group. Because an exacerbation of mood or weight concerns or the absolute magnitude of symptoms postpartum may increase the risk of relapse, both changes in mood and weight concerns between baseline and postpartum time points as well as the magnitude of symptoms postpartum will be evaluated in separate models after controlling for treatment. Mood, weight concerns, smoking self-efficacy, demographic and pregnancy and postpartum behavior variables will be used to predict the binary outcome, abstinence vs. relapse at six months postpartum in univariate logistic regression analyses, after controlling for treatment group. Next, mood and weight concern variables will again be examined in hierarchical logistic regression analyses after controlling for other factors related to postpartum smoking. Specifically, we will control for race, age, prepregnancy nicotine dependence and current alcohol use. In these exploratory analyses, we also will examine interactions between mood and weight concerns variables.

We also will evaluate the mood, weight concern and smoking self-efficacy variables as potential mediators of outcome. We will use the following steps to determine if these variables mediate the relationship between treatment (CBT (pink) vs. SBT (blue)) and outcome (abstinence vs. relapse): (1) the effects of treatment on outcome will be estimated using GEE, with the coefficient (c) representing the total effect of the intervention on outcome without taking any mediators into account; (2) the simultaneous effects of both intervention and mediator will be estimated with the coefficient (c') representing the effect of the intervention after controlling for the effects of the mediator; and (3) the difference between (c) and (c') will be evaluated, as the estimate of the mediated effect. The difference between (c) and (c') measures the extent to which the mediator accounts for the relationship between treatment and outcome.

Each of the mood and weight concern variables will be evaluated individually as mediators. Next, variables with significant univariate relationships to treatment and outcome will be modeled together and interactions between mood and weight concerns will be tested. Also, as with categorical abstinence, we will model time to relapse using Cox proportional hazards and extensions of this approach (Cox, 1972). This approach is used to model the hazard rate, or instantaneous rate of relapse, as a function of the predictors of interest, such as treatment group, weight concerns or mood. This model allows for the inclusion of predictors that change over time so differences in weight concerns and mood at each time point can be included in the model. The underlying assumption of the model is that the ratio of the hazard rates of any two individuals in the data set is a constant. However, using time varying predictors and extensions of the Cox model that allow for the beta parameters to vary over time, this assumption can be relaxed. For this phase of the analysis, time varying predictors such as mood and weight concerns will be considered.

* 2.19 Will this research study be conducted in a foreign country or a site wherein the cultural background of the potential subject population is substantially different from that of Pittsburgh and its surrounding communities?

* no

* 2.20 Will investigators at sites other than the University of Pittsburgh and/or affiliate UPMC institutions be engaged in the conduct of this research study under the overall direction of the principal investigator named on this IRB application?
2.21 Will this research study be conducted within a nursing home located in Pennsylvania?

* no
Section 3 - Human Subjects

3.1 Indicate the age range of the subject population to be enrolled into this research study.

* 14 years and older

3.2 Indicate the gender of the subject population to be enrolled into this research study:

* Females only - Provide a justification for limiting enrollment to only one gender.

Provide justification for single gender, as appropriate:
Due to the nature of the research study, which focuses on pregnancy, only women will be recruited.

3.3 Will any racial or ethnic subgroups be specifically excluded from participation in this research study?

* no

Identify subgroup(s) and provide justification, if answer is Yes:

3.4 Will all individuals being recruited to participate in this research study be able to read and comprehend English?

* yes

If your answer is No, identify the languages that will be understood by the potential research subjects.

3.5 Participation of Children: Will children (i.e., age < 18 years) be included in this research study?

* yes

If No, provide a justification for excluding children:

3.5.1 Specify the age range(s) of the children to be included as participants in this research study.

(Check all that apply below:)

* Specify age ranges of children:
Choices
14-17 years of age

3.5.2 Provide a rationale for the specific age range(s) of the children to be included as participants in this research study.

* Pregnant females 14 years of age and older will be included in the proposed research. Based on our pilot data, we expect that some study participants will be under the age of 21, although we expect our mean age for participants to be higher. Children under the age of 14 will not be included because the postpartum concerns of females younger than age 14 are likely to differ from those of females 14 years
of age or older. For example, younger children require developmentally appropriate assessment and intervention. Moreover, it is important to note that in pilot work, we have not received any inquiries about participating in the study from females under the age of 14.

3.5.3 Describe the expertise of the investigative team for dealing with children of the specific age range(s) to be included as participants in this research study below:

* Our research group is experienced in the assessment and treatment of children and adolescents. Dr. Levine's work on postpartum relapse has included subjects in a similar age range to that expected in the proposed clinical trial, and Dr. Marcus is the Principal Investigator on a study of a family based behavioral weight control program for children aged 8-12 years. Thus, our group is equipped to handle the needs of children for the proposed investigation.

3.5.4 Describe the adequacy of the research facilities to accommodate children of the specific age range(s) to be included as participants in this research study below:

* Addressed below:
Describe adequacy of facilities to accommodate children of specified age ranges:
Our research group has used our facility for past research studies in the assessment and treatment of children and adolescents. Dr. Levine's work on postpartum relapse has included subjects in a similar age range to that expected in the proposed clinical trial, and Dr. Marcus is the Principal Investigator on a study of a family based behavioral weight control program for children aged 8-12 years. Data collection for all of these projects have been conducted in the facility we plan to use for this study. Thus, our facility is equipped to handle the needs of children for the proposed investigation. Additional assessments may occur in community locations convenient to study participants.

3.5.5 Permitted Categories of Research: The Federal Policy and FDA regulations governing human subject protections specify that research involving children must fall into one of the following permitted categories. Check which category of permitted research that you feel is applicable to this research study(below:) and provide a complete\(^1\) justification for this designation below:

* Select the appropriate category:
The research does not involve greater than minimal risk\(^2\): [45 CFR 46.404].

* Provide justification for your permitted category designation:
Risks involve those associated with participant completion of assessments as some of the questions administered may be upsetting. There is also a risk that the program will not help participants remain abstinent from cigarettes.

Subjects will be instructed that they are free not to answer any question they do not wish to answer and that they may withdraw from the study at any time. They will also be made aware in the informed consent document that the program will not guarantee their continued smoking cessation.

All assessors involved in the study will be master's level clinicians with appropriate training on the specific pre and post partum counseling that is part of study protocol. Overall, we believe that the risks to the subjects are reasonable given the potential knowledge to be gained from the study. We also believe that the potential risks are no more probable or of higher magnitude than those encountered in ordinary, daily life.

3.6 Prisoners: Does this research study involve prisoners, or is it anticipated that the research study may involve prisoners?

* no
3.7 Pregnant Women: Will pregnant women be knowingly and purposely be included in this research study?
*

The Federal Policy and FDA regulations governing human subject protections specify that for research involving pregnant women and/or fetuses, in situ, must conform to each of the following general requirements

3.7.1 Where scientifically appropriate, preclinical studies (including studies on pregnant animals) and clinical studies (including studies on non-pregnant women) have been conducted and provide data for assessing potential risks to pregnant women and fetuses [45 CFR 46.204 (a)]. Provide, for this requirement, a justification or statement of its applicability to this research study below:

* Discuss assessment of potential risks to pregnant women and fetuses: There is no specific risk to pregnant women or fetuses as this study implements a cognitive behavioral treatment approach to smoking relapse after birth. The only risks associated with this study are that the participant might find certain questions to be distressing and she is not guaranteed to remain abstinent from cigarettes as a result of participating in the study. She is instructed that she has the right to not answer any questions about which she feels uncomfortable and that she may withdraw from the study at any time. She is also made aware, as part of the consent form, that she is not guaranteed to remain smoke-free as a result of participating in this study. If anything, a treatment program that could potentially aid in participants’ continued abstinence from smoking will benefit their health as well as that of their babies or fetuses.

3.7.2 The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the women or the fetus1-2; or, if there is no such prospect of direct benefit, the risk to the fetus is not greater than minimal3 and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means [45 CFR 46.204 (b)]. Provide, for this requirement, a justification or statement of its applicability to this research study below:

* Discuss cause of risk to fetus: Not applicable.

3.7.3 Any risk is the least possible for achieving the objectives of the research [45 CFR 46.204 (c)]. Provide, for this requirement, a justification or statement of its applicability to this research study below:

* Discuss limiting risk to minimum needed to achieve objectives: Not applicable, as there are no risks associated directly with pregnant women or fetuses.

3.7.4 Confirm that no inducements, monetary or otherwise, will be offered to terminate the pregnancy below [45 CFR 46.204 (h)]:

* Confirm no inducements to terminate pregnancy will be offered: No inducements, monetary or otherwise, to terminate the pregnancy will be offered.

3.7.5 Confirm that individuals engaged in the research will have no part in any decisions related to the timing, method, or procedures used to terminate a pregnancy below [45 CFR 46.204 (i)]:

* Confirm that individuals engaged in research will have no involvement in terminating pregnancy:
Individuals engaged in research will have no involvement in terminating pregnancies.

3.7.6 Confirm that individuals engaged in the research will have no part in determining the viability of a neonate
[45 CFR 46.204 (j)].

* Confirm that individuals engaged in research will have no involvement in determining viability of a neonate:
Individuals engaged in research will have no involvement in determining viability of a neonate.

[reviewer notes—]

3.8 Does this research study involve neonates?
* no

[reviewer notes—]

3.9 Fetal Tissues: Does this research involve the use of fetal tissues or organs?
* no

[reviewer notes—]

3.10 What is the total number of subjects to be enrolled at this site, including subjects to be screened?
* 300

3.11 Identify below, each of the disease- or condition-specific subgroups (e.g., normal, healthy volunteers; disease or condition A; disease or condition B; etc.) that will be enrolled into this research study.

Specify for each subgroup: 1) how many subjects will undergo research related procedures at this site; and 2) how many subjects, based on your estimate, will be required to undergo screening procedures, if applicable, in order to meet the projected enrollment at this site.

* Provide subgroup information:

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Number to undergo research related procedures</th>
<th>Number to be screened</th>
</tr>
</thead>
<tbody>
<tr>
<td>pregnant women</td>
<td>300</td>
<td>450</td>
</tr>
</tbody>
</table>

[View]

3.12 Provide a statistical justification for the total number of subjects to be enrolled into this research study at the multicenter sites or this site.

* Addressed below:

Sample size was estimated based on the power to detect differences in the proportion of women relapsing to smoking in CBT (pink) and SBT (blue) at six months (Aim 1). Between 60% and 70% of women will return to smoking by six months postpartum (Fingerhut et al., 1990; McBride et al., 1990; Mullen et al., 1990; Ratner et al., 2000). Thus, we estimate that 65% of women will resume smoking at six months without intervention, and based our prediction of the improvement in relapse rates in CBT (pink) relative to SBT (blue) on this rate, our pilot data and recent postpartum relapse prevention interventions in which individuals (rather than clinics) were randomized to treatment and comparison groups.

Although differences between intervention and control depend, to some extent, on the method of abstinence assessment, previous studies have demonstrated between 11% and 27% improvements in
abstinence rates at six months postpartum (Higgins et al., 2004; Johnson et al., 2000; McBride et al., 1999, 2004). Together, previous interventions have decreased postpartum relapse by an average of 15% relative to usual care. Because our intervention will be intensive and will continue throughout the first six months of the postpartum period, we estimated a decrease of 18% in relapse rates for CBT (pink) relative to no treatment at six-months postpartum. However, because we believe that the supportive, nonspecific treatment (i.e., SBT (blue)) will also increase rates of sustained abstinence above those of no treatment, we project that 62% of women will relapse in SBT (blue) and estimate a 16% improvement in relapse rates in CBT (pink) relative to SBT (blue), which corresponds to abstinence rates of 53% vs. 37% at six months postpartum in CBT (pink) vs. SBT (blue), respectively. Using an alpha of .05 and a two-tailed test for differences in proportions, 150 women per group (300 total) yields 80% power to detect a 16% improvement in the proportion of women remaining abstinent at six months postpartum. Our power to observe differences using survival analysis techniques is slightly higher (88%), based on a two-tailed logrank test with a sustained abstinence rate of 53% in CBT (pink) and 37% in SBT (blue).

Because the intervention includes face-to-face visits at locations convenient to participants as well as sessions delivered via telephone, we project a low attrition rate. We estimate that 15% of women will drop out of treatment or be lost to follow-up at 12 months postpartum in both groups. Although it is possible that more women assigned to SBT (blue) will be lost to follow-up, the attrition rate in our current postpartum study in which women do not receive treatment has been 16%. Similarly, the rate of attrition in the STOP program is 14%. Moreover, the primary analysis concerning the relative efficacy of CBT (pink) and SBT (blue) will be conducted using an intent-to-treat approach, in which women who drop out will be considered to have relapsed.

We estimate that 90 women per year will be potential candidates and will be screened for this study. We further expect approximately 6-7 women per month, or 18-21 women per quarter, to meet all remaining eligibility criteria and agree to participate. Thus, we propose to recruit approximately 80 women per year beginning in the second quarter of the Year 1 and assign 300 women to CBT (pink) or SBT (blue) by the first quarter of year 5.

3.13 Inclusion Criteria: List the specific criteria for inclusion of potential subjects in this research study below:

* Women will be eligible to participate if they: (1) report having smoked daily for at least one month during the 3 months prior to becoming pregnant; (2) smoked at least 5 cigarettes per day before quitting; (3) report no smoking in the four weeks prior to enrollment; (4) are not currently smoking as verified by a CO less than 8ppm; (5) are at least ‘somewhat’ motivated to remain abstinent postpartum and (6) are at least 14 years of age. Women who do not meet eligibility requirements and are interested in additional smoking cessation treatment will be referred to local smoking cessation programs (e.g., American Lung Association, American Cancer Society).

3.14 Exclusion Criteria: List the specific criteria for exclusion of potential subjects from participation in this research study below:

* Women with current, acute psychiatric disorders, including other substance use problems and symptoms that warrant immediate treatment will be referred for care and excluded from this trial. Women with psychiatric disorders (e.g., depressive or anxiety disorders), who are not acutely suicidal and in whom the symptoms are not severe enough to preclude participation in a randomized trial, will be eligible to participate. However, women taking psychiatric medications that may affect the mediators of treatment, such as antidepressant, anxiolytic or weight control medications, will be excluded from participation. Women who endorse current suicidality will be discussed immediately with the consulting physician and referred to the psychiatric emergency room for further evaluation as indicated.

3.15 Will HIV serostatus be evaluated specifically for the purpose of participation in this research study?

* no

If your answer is Yes, provide a justification for the HIV
4.1 Will potential research subjects be identified through the use of advertisements?

* yes

If you answer Yes, append, to this application, a copy of the advertisement(s) that will be used for the recruitment of potential research subjects.

Append advertisement(s):

<table>
<thead>
<tr>
<th>Name</th>
<th>Modified Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01 flyer 4-25-08 MOD.doc</td>
<td>4/25/2008 4:03 PM</td>
</tr>
<tr>
<td>STARTS Pgh Parent ad 4-25-08.doc</td>
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<tr>
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</tr>
<tr>
<td>STARTS brochure.pub</td>
<td>5/2/2008 1:24 PM</td>
</tr>
</tbody>
</table>

4.2 Will potential research subjects be identified and recruited through the use of a "honest broker" system/process?

* no

4.3 Will potential research subjects be identified for subsequent contact through the review and recording of identifiable medical record information?

* no

4.4 Will methods other than advertisements, an honest broker system/process, or the review of identifiable medical record information be used for the identification of potential research subjects?

* yes

If Yes, describe the method(s).

The Pittsburgh Stop Tobacco in Pregnancy (STOP) Program, directed by Dr. Cluss (Co-Investigator) is closely affiliated with Magee Women's Hospital, and will provide the bulk of referrals. In addition to reviewing identifiable medical information to determine eligibility and sending us patient contact information, for which we are requesting a waiver of informed consent, the STOP Program will also provide eligible women with our phone number, encouraging them to call us.

The STOP program has treated approximately 500 women since its inception in 2000 and yearly enrollment has increased over time. Currently, the STOP program enrolls 200 pregnant women yearly, 65% of whom are currently smoking and the remaining (35%) have recently quit (i.e., quit during the very early part of pregnancy, but prior to enrollment in STOP). In the STOP program, 27% of those enrolling as pregnant smokers (65% of participants) will stop smoking prior to delivery, and 78% of recent quitters (35% of participants) will sustain abstinence throughout pregnancy. This 45% (i.e., 27% of pregnant smokers + 35% of recent quitters) cessation rate is consistent with previous studies of smoking cessation during pregnancy (Fingerhut et al., 1990; McBride et al., 1990; Mullen et al., 1990; Owen et al., 1998; Severson et al., 1995). Both those who quit during pregnancy and those entering STOP as recent quitters will be candidates for the postpartum relapse prevention trial. Thus, 45% of the 200 women enrolling in STOP yearly will quit smoking prior to week 34 and 96% of these women, or 86 women per year, are expected to be motivated to remain quit postpartum and will be potential...
candidates for the proposed trial.

We will also be utilizing the Magee-Womens Hospital research registry to contact pregnant women who have agreed to be approached with research opportunities. Women who agree to hear about research through the Magee research registry will be called by study staff and screened by phone using the approved screening script to determine eligibility.

4.5 How will potential research subjects be initially contacted to ascertain their interest in study participation?*

* Potential subjects will be contacted by telephone. Append, to this application, a copy of the telephone script that will be used to ascertain the potential subjects' interest in study participation.

<table>
<thead>
<tr>
<th>Subject Recruitment Letter/Phone Script: Name</th>
<th>Modified Date</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01 screening script 3-08MOD.doc</td>
<td>3/28/2008 1:23 PM</td>
<td>0.05</td>
</tr>
</tbody>
</table>

If Other, describe initial contact method.

4.6 Are you requesting a waiver of the requirement to obtain a signed, written informed consent form from some or all potential subjects for participation in this research study, or any procedures (e.g., screening interview) associated with the conduct of this research study? (I.e., verbal consent will be sought from potential subjects, but the subjects will not be required to sign a written informed consent form.)

* yes

4.6.1 Identify the specific research procedures (e.g., screening interview) and/or the specific subject populations (e.g., parents of child-subjects) for which you are requesting a waiver of the requirement to obtain a signed, written informed consent form.

* Specify the procedures and/or subject populations:
  Addressed below:

If not all, identify the specific procedures and/or subject populations for which you are requesting a waiver:

We are requesting a waiver of the requirement to obtain written informed consent for screening interviews for all callers and potential participants. All callers and potential participants will be required to provide verbal consent in order to undergo the screening interview process.

4.6.2 Indicate which of the following regulatory criteria is applicable to your request for a waiver of the requirement to obtain a signed consent form.

* Indicate applicable regulatory criteria:
  The research (or research procedure(s)) presents no greater than minimal risk of harm to the subject and involves no procedures for which written informed consent is required outside of the research context [45 CFR 46.117 (c)(2)].

4.6.3 Address the procedures that will be used and the information that will be provided (i.e., script) in obtaining and documenting the subjects' verbal informed consent for study participation.

* Procedures and information for verbal informed consent:
  Study staff will respond to incoming calls, return calls from interested women who have called into the
study line to inquire about the study, or call women who have been identified through physicians, the
STOP Program, or the Magee-Womens Hospital research registry and have agreed to have their contact
information passed to study staff. They will read a script (attached in section 4.5) that will briefly
explain study procedures and will inform participants of potential risks and that they have the right to
not answer any questions they do not wish to answer. If callers are under the age of 18, study staff will
obtain and document consent from a parent or guardian to conduct the phone screen with the child
before further explaining the study or asking the child any further questions concerning her eligibility.
Study staff will then document callers’ verbal consent to completing the screening interview. If a caller is
eligible, study staff will gather contact information from her and set up a time to meet for the screening
and potential prenatal appointment or make plans to contact the caller when she is within the
scheduling window, 34-38 weeks into her pregnancy.

4.7 Are you requesting a waiver of the requirement to obtain informed consent (from some or
all potential subjects) for participation in this minimal risk\(^1\) research study, or any minimal
risk procedures associated with the conduct of this research study?
* no

4.8 Are you requesting an exception to the requirement to obtain informed consent for
research involving the evaluation of an "emergency" procedure?
* no

4.9 Append, to this application, the written informed consent form(s) corresponding to this
proposed research study.

Draft Consent Form(s):

<table>
<thead>
<tr>
<th>name</th>
<th>Last Modified</th>
<th>Version</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td>STARTS Adult consent 3-08.doc</td>
<td>9/23/2008 11:30 AM</td>
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</tr>
</tbody>
</table>

** Do not use the "Add" button to upload a revised consent form**

Approved Consent Form(s):

<table>
<thead>
<tr>
<th>Name</th>
<th>Modified Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>STARTS Child Consent 4-08.doc</td>
<td>9/23/2008 11:31 AM</td>
</tr>
<tr>
<td>STARTS Adult consent 3-08.doc</td>
<td>9/23/2008 11:30 AM</td>
</tr>
</tbody>
</table>

4.10 Will all potential adult subjects be capable of providing direct consent for study
participation?\(^1\)
* Yes

4.11 At what point will you obtain the informed consent of potential research subjects or
their authorized representative?
After performing certain of the screening procedures, but prior to performing any of the experimental interventions

If Other, address below:

4.11 (b) Taking into account the nature of the study and subject population, indicate how the research team will ensure that subjects have sufficient time to decide whether to participate in this study. In addition, describe the steps that will be taken to minimize the possibility of coercion or undue influence.

4.11.1 Address why you feel that it is acceptable to defer obtaining written informed consent until after the screening procedures have been performed.

Address why it is acceptable to defer:
We believe we meet the criteria that the respective research procedures present no more than minimal risk of harm to the involved participants. We believe the information being obtained from the screening script form is the same type of information that would be collected from patients during a doctor's appointment. Please see screening form (attached in section 4.5). If the subject does not meet inclusion criteria, all the information collected during the screening process will be retained without any identifiers, and the patient will be notified of this procedure. In addition, written informed consent will be obtained at the screening appointment visit prior to any research activities.

All information collected from physicians, The STOP Program, and the Magee-Womens Hospital research registry will also be handled in the same confidential manner. Information we obtain from The STOP Program, physicians, and the Magee-Womens Hospital research registry for the purpose of recruitment will contain no more than that which will be obtained during a screening interview. Any information that we receive for patients or STOP clients who are ineligible will be retained without identifiers.

4.12 Describe the process that you will employ to ensure, prior to obtaining their written consent for study participation, that potential subjects are fully informed about this research study.

Addressed below:

This description must include the following elements: 1) who from the research team will be involved in the consent process (both the discussion and documentation); 2) person who will provide consent or permission; 3) information communicated; and 4) any waiting period between informing the prospective participant about the study and obtaining consent.

Potential participants will be approached at an appointment with their physician or the STOP program by part of our research team. If approached by a physician or the STOP Program, they will complete a short form (attached) that will document their release of contact information to the STARTS study for the purpose of recruitment. Some women will join a research registry at Magee-Womens Hospital that indicates that they would like to be approached by UPMC with research opportunities. They may also respond to a study flyer, which will be posted in local public places, such as clinics and WIC offices. They will be briefly introduced to the study and presented with the study phone line. If they express an interest in the study, they may call into the study line for screening, have the study explained to them in further detail, and possibly set up an appointment to meet for further screening and potentially the first data collection time point. If their contact information is forwarded to us from physicians, the STOP Program, or the Magee-Womens Hospital research registry, we will contact them first, and complete the phone screen described above.

4.13 Are you requesting an exception to the IRB’s standard policies mandating the involvement of a listed physician investigator (i.e., for research studies involving a drug, device or surgical procedure) or a listed investigator (i.e., for other types of research studies)
in the informed consent process?

* yes

If Yes, provide a justification for the exception:
The majority of baseline assessments, during which informed consent will be obtained, occur in community locations, such as clinics, restaurants, or doctor's offices, or in participants' homes. Therefore, it is impractical to involve the investigators in the informed consent process. The project coordinator or research specialist, who are both trained in obtaining informed consent, will be directly involved in the consenting process under Dr. Levine's supervision.

4.14 Will you inform research subjects about the outcome of this research study following its completion?

* no

If Yes, describe the process to inform subjects of the results:
5.1 Risks of Screening Procedures: Are there any potential risks (e.g., physical, psychological, social, etc.) associated with the screening procedures (i.e., procedures to determine research subject eligibility) that will be performed for the purpose of this research study?

* Yes - Describe, using the following format, the risks of the screening procedures.

5.1.1 Expected Incidence of Screening Procedure Risk:

* Intervention(s)

5.1.2 Describe the steps that will be taken to prevent or to minimize the severity of the potential risks associated with the screening procedures:

* All screening records and information will be kept locked in the research facility and will only be accessible to research staff. Callers will be given a unique identification number, a "call number", separate from a study ID number that will be used instead of a name to decrease the chance of a breach in confidentiality. Callers will be informed that there is always a chance that confidentiality will be broken, but that every effort is being made to maintain it.

5.2 Risks of Experimental Interventions: Are there any potential risks (e.g., physical, psychological, social, etc.) associated with the experimental interventions that will be performed for the purpose of this research study?

* yes

If your answer is Yes, describe, using the following format, the risks of the experimental interventions.

5.2.1 List Expected Incidence of Experimental Intervention Risk:

* Intervention(s)

5.2.2 Describe the steps that will be taken to prevent or to minimize the severity of the potential risks associated with the experimental interventions:

* The participant is made aware that she does not have to answer upsetting questions and may choose to discontinue participation at any time. She is also made aware, as part of the consent form, that one of the risks is that she is not guaranteed to remain smoke-free as a result of her participation in this study. All clinicians will be master's level and will have appropriate training.

All records and information will be kept locked in the research facility and will only be accessible to research staff. Participants will be given a unique identification number that will be used to decrease the chance of a breach in confidentiality. Participants will be informed that there is always a chance that confidentiality will be broken, but that every effort is being made to maintain it.

Overall, we believe that the risks to the subjects are reasonable given the potential knowledge to be gained from the study. All patients will be carefully informed about potential risks.
5.3 Risks of Follow Up Procedures: Are there any potential risks (e.g., physical, psychological, social, etc.) associated with the follow up procedures (e.g., tests to measure the efficacy and/or safety of the experimental intervention(s); to include monitoring procedures and/or outcome measures) that will be performed for the purpose of this research study?

* Any risks associated with follow up procedures performed:
Yes - Describe, using the following format, the risks of the follow up procedures.

5.3.1 List Expected Incidence of Follow Up Procedure Risk:

Intervention(s)

| View | All research procedures |
| View | Assessment questionnaires and interviews |
| View | Treatment intervention - CBT (pink) and SBT (blue) conditions |

5.3.2 Describe the steps that will be taken to prevent or to minimize the severity of the potential risks associated with the follow up procedures:

* The participant is made aware that she does not have to answer upsetting questions and may choose to discontinue participation at any time. She is also made aware, as part of the consent form, that she is not guaranteed to remain smoke-free as a result of participating in this study. All clinicians will be master’s level and will have appropriate training.

All records and information will be kept locked in the research facility and will only be accessible to research staff. Participants will be given a unique identification number that will be used to decrease the chance of a breach in confidentiality. Participants will be informed that there is always a chance that confidentiality will be broken, but that every effort is being made to maintain it.

Overall, we believe that the risks to the subjects are reasonable given the potential knowledge to be gained from the study. All patients will be carefully informed about potential risks.

5.4 Do any of the research procedures pose a physical or clinically significant psychological risk to women who are or may be pregnant or to a fetus?

* no

5.5 Do any of the research procedures pose a risk of causing genetic mutations that could lead to birth defects?

* No

5.6 Describe, in detail, any alternative, accepted (i.e., clinically utilized) diagnostic/treatment approaches to which the potential research subjects would normally be exposed and/or which may be of benefit to the potential research subjects.

* Other - Describe below:

The written materials and counseling for cessation that participants will receive as part of this study are similar to those used in other treatments for smoking cessation, but have been adapted for women after childbirth. There are other treatments for smoking cessation available in the Pittsburgh area, such as
classes given by the American Cancer Society and nicotine gum or patch, available without a prescription. If callers decide not to participate in the study, they will have the routine follow-up provided by their doctor or clinic.

5.7 Address the specific endpoints (e.g., adverse reactions/events, subject’s worsening disease or condition, failure to demonstrate effectiveness) that will result in discontinuing a subject’s participation in this research study.

* Addressed below:

Participants who experience a serious adverse event directly related to study participation may be withdrawn. In addition, participants may be removed if they become unable or unwilling to participate in the research procedures.

5.8 Will any individuals other than the investigators/research staff involved directly in the conduct of this research study and authorized representatives of the University Research Conduct and Compliance Office (RCCO) be permitted access to research data/documents (including medical record information) associated with the conduct of this research study?

* yes

If your answer is No, describe the processes/procedures that will be utilized to ensure that access to research data/documents (including informed consent documents) is restricted to the research investigators/staff involved directly in the conduct of this research study and authorized representatives of the RCCO below:

5.8.1 Identify the “external” persons or entity representatives (i.e., persons other than the investigators/research staff involved directly in the conduct of this research study and authorized representatives of the RCCO) who may have access to research data/documents and the purpose of this access.

* If the investigators learn that a participant or someone with whom a participant is involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies. Authorized representatives of the sponsor of this research study, National Institute on Drug Abuse (NIDA), provide funding and may request identifiable research information related to participants involved in the study.

5.8.2 Will these “external” persons or entity representatives have access to the research data/documents to include subject identifiers (i.e., subject names, medical record numbers, social security numbers, etc.)?

* External access to subject data identifiers:

Yes - Describe below, the assurances that will be invoked to ensure that these “external” persons are provided access only to data/documents associated with the conduct of this research study and that the confidentiality of these research data/documents w

Describe assurances that external persons access to data maintains subject confidentiality:

Any information about participants, including their identifiable information or research data, will be handled in a confidential manner consistent with other research records. Participants will not be specifically identified in any publication of research results.
5.8.3 Describe the procedures that will be utilized to ensure that access to research data/documents (including informed consent documents) is restricted to the investigators/research staff involved directly in the conduct of this research study and the "external" persons identified above.
* The Principle Investigator will assume overall responsibility for storage of all research data. Data will not include participant names or any other identifying information, and will be labeled using only an identification number. Any identifying information, such as names, will be kept in a securely locked storage cabinet to which only the Principal Investigator and her study staff have access.

[reviewer notes]

5.9 Has or will a Federal Certificate of Confidentiality be obtained for this research study?
* no

5.10 Describe the procedures (e.g., destruction of research records; removal of identifiers; destruction of linkage code information; secured long-term retention) that will be employed following the required data retention period so as to ensure research subject confidentiality.
* All information linked with patient research or medical records will be kept for at least seven years following study completion. Hard copy records will then be shredded and computer files will be deleted from our database.

5.11 Address what will happen (e.g., destroyed, rendered anonymous) with regard to the subject’s research data and, if applicable, biological specimens or genetic material should the subject decide to withdraw from study participation.
* Should the participant decide to withdraw from the study, any information collected will continue to be stored in the same manner. However, samples may be destroyed upon request of a participant who is withdrawing or the participant’s legal guardian.

[reviewer notes]

5.12 Does participation in this research study offer the potential for direct benefit to the research subjects?
* No - Describe the general benefits to society (e.g., increased knowledge; improved safety; better health; technological advancement) that may result from the conduct of this research study.

* Describe benefits:
Participants may find that the counseling and questions about mood and smoking are helpful in preventing them from returning to smoking. However, it is also possible that this approach will not be helpful and they will resume smoking. They will also receive written materials designed to help them stay smoke-free after they quit. Participants are not expected to receive any other benefits. Ultimately, this research may lead to further interventions for other women who quit smoking and are interested in remaining abstinent in the future.

5.13 Describe the data and safety monitoring plan(s) associated with the conduct of this research study. If the research study involves multiple sites, the plan must address both a local and central review process.
* Data and Safety Monitoring Plan.
The proposed research will be reviewed and approved by the Institutional Review Board of the University of Pittsburgh. The Principal Investigator will be responsible to monitor the safety of participants and integrity of the data. Specifically, she will continually evaluate the progress of the study...
at weekly meetings with study staff. The study procedures addressed at these meetings will include: (1) subject safety and confidentiality issues; (2) participant recruitment, accrual, and retention and (3) data quality and integrity issues. As participant data accrues, Dr. Levine will analyze aggregate data to identify any changes in participant risk. If over the course of the study there is concern about changes in the risk-benefit ratio, interim analyses will be conducted to determine if the study should proceed as originally designed. A summary of the data and safety monitoring plan and activity will be submitted to the IRB at time of renewal.

Given the nature of the study, problems with subject recruitment, dropouts or data management would be most likely to trigger cessation of the protocol rather than adverse events. However, both types of information will be monitored. All adverse events reported during enrollment in the study will be recorded. Each event will be rated for severity (1=mild; 2=moderate; 3=severe; 4=life threatening) and degree of association with study participation (0=definitely unrelated; 1=unlikely, 2=possibly related; 3=probably related; 4=definitely related). The action taken and outcome will also be recorded. If a participant is found to have a condition that requires additional follow-up or referral, she will be referred to appropriate medical follow-up. Emergency medical treatment for injuries solely and directly relating to participation in this research will be provided to participants by the University of Pittsburgh Medical Center.

It also is possible that missing data and excessive attrition from the study would limit the data analysis, although we have accounted for subject attrition in determining the power for testing the study hypotheses.

Additionally, there is a potential risk of breach of confidentiality for subjects enrolled in this study. To safeguard against this risk, all subject data records will be encoded with identification numbers and kept in locked filing cabinets in an office of the Western Psychiatric Institute and Clinic. Access will be given only to the study investigator and study staff supervised by the investigator.

Section 5 - Potential Risks and Benefits of Study Participation

5.14 What precautions will be used to ensure subject privacy is protected? (e.g. the research intervention will be conducted in a private room; the collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected, drapes or other barriers will be used for subjects who are required to disrobe)

*  

5.15 What precautions will be used to maintain the confidentiality of identifiable information? (e.g. paper-based records will be kept in a secure location and only be accessible to personnel involved in the study, computer-based files will only be made available to personnel involved in the study through the use of access privileges and passwords, prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information, whenever feasible, identifiers will be removed from study-related information, precautions are in place to ensure the data is secure by using passwords and encryption, because the research involves web-based surveys, audio and/or video recordings of subjects will be transcribed and then destroyed to eliminate audible identification of subjects)

*  

List Expected Incidence of Intervention Risk:

* Intervention: Screening  

Common Risks:
Infrequent Risks:
There is a potential risk that confidentiality will be broken and someone other than research personnel will gain access to identifying participant information.

Other Risks:

List Expected Incidence of Intervention Risk:
* Intervention:
  All research procedures

Common Risks:

List Expected Incidence of Intervention Risk:
* Intervention:
  Assessment questionnaires and interviews

Common Risks:

List Expected Incidence of Intervention Risk:
* Intervention:
  Treatment intervention - CBT (pink) and SBT (blue) conditions

Common Risks:

List Expected Incidence of Intervention Risk:
* Intervention:
  All research procedures

Common Risks:
Infrequent Risks:
There is a potential risk that confidentiality will be broken and someone other than research personnel will gain access to identifying participant information.

Other Risks:

List Expected Incidence of Intervention Risk:
* Intervention:
Assessment questionnaires and interviews

Common Risks:

Infrequent Risks:
The participant may find that completing the assessment questionnaires and/or participating in the interview is distressing or anxiety provoking.

Other Risks:

List Expected Incidence of Intervention Risk:
* Intervention:
Treatment intervention - CBT (pink) and SBT (blue) conditions

Common Risks:

Infrequent Risks:
There is a risk that the treatment programs, CBT (pink) and SBT (blue), will not guarantee that women will remain abstinent from cigarettes after they deliver.

Other Risks:
6.1 Will research subjects or their insurance providers be charged for any of the procedures (e.g., screening procedures, experimental interventions, follow-up procedures) performed for the purpose of this research study?
* No

6.2 Will research subjects be remunerated for the time and inconvenience associated with their participation in this research study?
* yes

6.2.1 Describe the amount of payment or other remuneration offered for full (i.e., complete) participation in this research study.
*
Participants can be paid up to $125 for completing all study assessments. Payment will only be provided after all parts of the assessment, including breath or saliva collection, are completed at each timepoint. They also can receive up to $100 worth of grocery or baby store gift vouchers for attending all 6 face-to-face intervention appointments.

6.2.2 Address the amounts and terms of payment or other remuneration that will be provided for partial completion of this research study.¹
*
If participants are found to be ineligible after in person screening appointment, they will receive a $10 gift voucher for their time. They will not be enrolled into the study, and therefore, will not be eligible to receive any further remuneration. Participants who are eligible after undergoing in person screening procedures will not be offered this gift voucher, as they will be paid (detail in next paragraph) for the initial prenatal assessment that will immediately follow the screening procedures and will be part of the same visit.

Participants will receive $20 for completing the initial prenatal assessment, $25 for completing the 3 month postpartum assessment, $35 for completing the 6 month postpartum assessment, and $45 for completing the 12 month postpartum assessment for a total of up to $125. Payment will only be provided after all parts of the assessment, including breath or saliva collection, are completed at each timepoint.

They will also receive a gift voucher, redeemable at a local grocery or baby store upon completion of a face-to-face session with their counselor. Vouchers each will be for $10 or $20 depending on the session, and if they attend all six postpartum face-to-face sessions, they will be eligible to receive a total of $100 worth of vouchers.
7.1 Summarize the qualifications and experience of the principal investigator and listed co-investigators of this research study as they relate to the appropriate conduct of the indicated research procedures and oversight of the rights and welfare of involved research subjects.

Dr. Levine is well qualified to conduct the proposed study. Dr. Levine has conducted research on the women’s health behaviors and behavior change since beginning her graduate training in 1992. As specific background for the proposed investigation, Dr. Levine has been a co-investigator on NIH-funded clinical trials in the areas of women’s health behavior change. For example, she has collaborated on a study comparing three approaches to treating women’s concerns about weight gain following smoking cessation (Perkins et al., 2001) and a randomized controlled trial designed to evaluate the relative efficacy of two programs to prevent weight gain among normal weight or overweight women aged 25-44 years (Levine et al., 2007). In addition, as a recipient of a K01 award from NIH, Dr. Levine has been studying health behavior in pregnant and postpartum women, including an ongoing study designed to examine the roles of mood and weight concerns in postpartum smoking, pregnant women who have quit smoking are being recruited to participate in a study funded by NIDA (DA15396). Thus, Dr. Levine has considerable experience in the conduct of studies concerning women’s health and weight management and is well qualified to conduct this project.

Dr. Patricia Cluss is a licensed clinical and health psychologist and Associate Professor of Psychiatry at the University of Pittsburgh. She conducts research in the area of and in translating evidence-based health interventions into community practice settings particularly for health behavior change. She is the developer and director of the Pittsburgh Stop Tobacco in Pregnancy (STOP) project and has been a PI or Co-investigator on two Robert Wood Johnson Foundation grants.

Marsha Marcus, Ph.D., Co-Investigator, is internationally recognized for her work in adapting obesity and eating disorder treatments to the needs of special populations including obese women with Binge Eating Disorder (Cognitive Behavioral Treatment of Obese Binge Eaters; MH44828), adults with diabetes (Behavioral Weight Loss for Adults with Diabetes Mellitus; DK29757), weight-concerned women smokers (Bupropion and Weight Concerns for Smoking Cessation; DA04174), women with functional hypothalamic amenorrhea (Pathogenesis of Functional Hypothalamic Amenorrhea; MH50748), severely overweight children (Family-based Treatment of Severe Pediatric Obesity; HD38425), as well as prevention of weight gain in normal to overweight women (Prevention of Weight Gain in Women Aged 25 to 34; DK053942). Also, Dr. Marcus is Associate Director of the Pittsburgh Obesity and Nutrition Research Center, and Director of its Behavior Core.

Dr. Kenneth Perkins is internationally known for his work on sex differences in nicotine and tobacco use and the relationship between smoking and eating behavior in women. He has been the primary investigator on several NIDA-funded laboratory studies including a study on which he collaborated with Drs. Marcus and Levine to test the efficacy of a cognitive-behavioral treatment for women smokers concerned about postcessation weight gain (DA 04174).

Yu Cheng, Ph.D., Co-Investigator, is Assistant Professor of Statistics and Psychiatry, University of Pittsburgh, has particular expertise in the analysis of longitudinal datasets, including handling missing data, in obesity trials.

7.2 Indicate all sources of support for this research study and specify the identity of the corresponding sponsor(s).

Selections

Federal - Identify the federal sponsor and the institution that was awarded the corresponding Federal grant (i.e., the awardee institution). Append, to this application, a complete copy of the corresponding Federal grant application.

If your selection includes Federal, click the Add button below, to append a copy of the Federal grant application:
Append copy of federal grant application:

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If your selection includes **Commercial**, discuss below:

If your selection includes **Foundation**, discuss below:

If your selection includes **Other**, discuss below:

*reviewer notes*

**7.3 Does the principal investigator or any co-investigator or research coordinator involved in this study (or in aggregate with his/her spouse, dependents or other members of his/her household):

1. **Possess an equity interest in the entity that either sponsors this research or owns the technology being evaluated that exceeds 5% ownership interest or a current value of $10,000?**

2. **Receive salary, royalty, or other payments from the entity that either sponsors this research or owns the technology being evaluated that is expected to exceed $10,000 per year?**

3. **Have a financial relationship with a start-up company (which is being monitored by the Entrepreneurial Oversight Committee) that has an option or license to utilize the technology being evaluated?**

4. **Have an agreement with the University or an external entity that would entitle sharing current or future commercial proceeds related to the technology being evaluated (e.g., royalties through a license agreement)?**

**If any of the above are true, select Yes below.**

* no
### Other Attachments (e.g., Reference List)

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