

# **TURNAWAY STUDY OPERATING PROCEDURES MANUAL**

**A Project of the Advancing New Standards  
in Reproductive Health (ANSIRH) Program**

**Bixby Center for Global Reproductive Health  
UCSF Department of Obstetrics, Gynecology & Reproductive Sciences**

**Prepared By: Heather Gould, Rana Barar and Diana Foster**

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(Redacted staff names, study pseudonym, phone number & code name)**

**Principal Investigator**  
Diana Greene Foster, PhD

**Project Directors**  
Rana Barar, MPH  
Heather Gould, MPH

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# SECTION ONE: INTRODUCTION

## ***Study Overview***

### **What is the Turnaway Study?**

Researchers at the University of California, San Francisco Bixby Center for Global Reproductive Health are conducting a study to understand and document the sequelae of abortion and the consequences of carrying an unwanted pregnancy to term. This study explores the experiences and outcomes of women (including minor women) who obtain abortions, as well as women who are denied abortions because they present for care beyond the clinic's gestational limit. In order to determine how our study population compares to the universe of all women seeking abortion (the vast majority of whom have a first trimester abortion), we also include a third group of women who seek services in the first trimester of pregnancy. Although our primary focus is on women's experiences, we will also gather information about the health and wellbeing of children born to women who continued their pregnancies because they were unable to obtain an abortion as well as previous and subsequent children born to all women.

The Turnaway Study has three major aims:

1. To describe the mental health, physical health and socioeconomic outcomes of receiving an abortion compared to carrying an unwanted pregnancy to term,
2. To understand the effect of access to abortion services on women's lives, and
3. To address the recent spate of low quality research and paucity of high quality research on the sequelae of abortion.

This study has two names. Participants know the study as "XXXX," however we also refer to it as "the Turnaway Study." The acronym XXXX is easy to remember and using it helps to protect participants' privacy. While we usually refer to the study as the Turnaway Study in research settings, this manual uses both names interchangeably.

### **How the study is carried out:**

We work collaboratively with first and second trimester abortion clinics around the United States to recruit and enroll women into the study. Enrollment began at some sites in January 2008 and will continue at some sites through December 2010. Eligible individuals include English and Spanish speaking abortion patients fifteen years old and older who have no known fetal anomalies or fetal demise, and who present for care within three weeks above or two weeks below the clinic's upper gestational limit. A subgroup of abortion patients who are in the first trimester of pregnancy and who meet the other eligibility criteria are also enrolled. We recruit three types of participants:

- women whose gestational age is one day to three weeks *over* the gestational limit and are turned away from the clinic without receiving an abortion;
- women whose gestational age is one day to two weeks *under* the clinic's gestational limit and receive an abortion;
- and women who are in their first trimester of pregnancy (under 14 weeks) and receive an abortion.

In the clinic, prospective participants speak by phone with UCSF researchers who inform them of the study purpose, risks and benefits, obtain informed consent and schedule a confidential telephone interview to take place approximately eight days later. Prospective participants who take the time to talk with our staff to learn more about the study receive a \$15 gift certificate to a large retail store (either Target or Wal-Mart), *whether or not they choose to participate*. Women who choose to participate are interviewed over the phone (at their home or cell number) every six months for a period of five years. Interviews elicit information about changes in their mental and physical health, education, employment, economic situation, social support, family relationships and the use of social services. For women who carry their pregnancies to term, interviews also contain questions about their infant's health, his or her place of residence, and parenting issues. After each interview, participants receive a gift certificate card for Target or Wal-Mart valuing \$50 via mail. See the study flowchart in Appendix A for a visual overview of the study protocol.

Data analysis will be ongoing over the course of the study. Preliminary and final results will be shared with participating clinical sites directly and with the public health community through presentations at conferences and meetings and through articles published in peer reviewed journals.

### **What does the recruiting clinic have to do?**

Collaborating clinical sites designate a study point person to serve as a liaison between prospective participants and UCSF research staff. This point person ensures that all eligible participants are approached about the study, gives them an informational handout and recruitment packet about the study, and facilitates a phone call between interested patients and UCSF research staff. Research staff in Oakland, CA explain the study to patients, conducts an eligibility screening, invites eligible patients to participate, and gains informed consent. The point person keeps track of the number of eligible women, the number of women approached for participation and the number who declined to talk to UCSF research staff. The point person also dispenses the \$15 gift cards to each prospective participant who chooses to talk with UCSF staff to learn more about the study. Each clinic receives a quarterly stipend to compensate them for the time and effort spent on the study.

### **Who are we?**

The Turnaway Study is one of several studies being conducted by ANSIRH (Advancing New Standards in Reproductive Health) at the Bixby Center for Global Reproductive Health. The Center is housed within the Department of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco. The mission of The Bixby Center is to promote reproductive health, family planning and the prevention of sexually transmitted infections, including HIV, worldwide through research, training and policy analysis.

Diana Greene Foster, PhD, is the Principal Investigator for the project. Dr. Foster received her doctorate from Princeton University in a joint program in Demography and Public and International Affairs. She has worked in the University of California, San Francisco Department of Obstetrics, Gynecology and Reproductive Sciences since 1997 and has been active in the evaluation of public family planning programs, cost effectiveness studies and population-based surveys.

This study has been approved by the Committee for Human Research at UCSF and is being funded by the David and Lucille Packard Foundation, Wallace Alexander Gerbode Foundation and other private donors.

## **Study Sites**

Our recruitment sites span the United States from Maine to Washington State, from the southernmost point of Texas to northern Minnesota. Some are in major metropolitan areas, while others are located in small cities with a large rural patient referral area. Initially, potential study sites were identified through a three step process. First, we used the National Abortion Federation (NAF) registry to identify abortion providers in both remote geographic regions and urban centers in the United States. The compiled list was then checked with colleagues from the Guttmacher Institute who identified potential non-NAF sites and suggested additional geographic areas for the study. Finally, Dr. Diana Foster and the first Project Director, Sandy Stonesifer, called all the potential sites, introduced the study and the role of abortion providers as recruiters. Some potential sites reported that they rarely see women beyond the clinic's gestational limit or that they were not interested for other reasons.

All study recruitment sites serve as the clinic of last resort in their area, meaning that they have the highest gestational limit of all abortion providers within a 150 mile radius. Sites were selected based on the criteria that they must have the latest abortion gestational limit within 150 miles. Two different types of clinics meet this criterion. The first include abortion clinics with gestational limits in the first trimester or early to mid second trimester who are in small cities and whose clientele comes from the surrounding rural area. We approached all known clinics in this first group using the National Abortion Federation registry and contacts within the abortion research and provision community. In our screening call, we asked about gestational limits, referral patterns, and the frequency with which patients are turned away. All but one of these clinics agreed to participate.

The second, more numerous group of clinics, includes abortion clinics in major metropolitan areas whose gestational limit is at the legal maximum near the end of the second trimester. We contacted only a limited number of the second type of clinic, searching for geographic diversity and high patient volume. All but one of the second type of clinics that we contacted agreed to participate, and was replaced with a clinic with an identical catchment area and similar patient volume.

Early in the project, Sandy Stonesifer, the Program Manager at the time, or PI Diana Foster conducted on-site orientation visits to twenty-three of the clinics.

They met and trained the point people for the remaining clinics at the annual NAF meeting during the spring of 2008. Over time, additional clinical recruitment sites were added. In April 2010, we had 29 clinics participating in the study. In early 2010, Project Directors Rana Barar, Heather Gould, and other staff members visited all participating clinics, either to train them in participant recruitment (if they were new sites) or to motivate them to continue recruitment, and to share lessons learned from other successful recruitment sites.

The Project Directors, Project Assistants and Interviewers communicate regularly with the point people at each of the participating clinical sites. In addition to phone correspondence, the study team publishes and disseminates a quarterly newsletter to keep participating clinic staff apprised of our progress and up-to-date with administrative issues.

## ***Interviewer Training Plan***

### **Training activities**

Training activities for Turnaway study staff begin with an intensive orientation and include learning about the study purpose and design, becoming familiar with study protocol, procedures, documents and systems, reviewing strategies for conducting effective and sensitive telephone interviews, and practicing study interviews through role plays. Special emphasis is placed on the importance of protecting participant's privacy, obtaining fully informed consent and providing referrals or making reports when indicated. We anticipate that interviewers will be ready to start data collection after two to three weeks of orientation and training. However, they will not be asked to begin data collection until they feel that they are ready.

### **Training goals**

The goals of the training are to prepare new staff by helping them to:

1. Review relevant public health information regarding unintended pregnancy, abortion care, and adoption (ongoing).
2. Understand the study background, purpose, and procedures.
3. Learn about human subjects' protections and how to obtain informed consent.
4. Examine personal values about unintended pregnancy, abortion and adoption by participating in a values clarification session and strengthen their ability to be sensitive and objective interviewers.
5. Master the interview scripts and study forms, including the underlying research questions, skip patterns and proper documentation on data collection forms.
6. Learn the data collection process, including CASES (the computer based interviewing and data program we use) and systems for data management and quality assurance.
7. Practice and fine tune telephone interviewing skills, including establishing rapport with study participants, responding appropriately to participant needs and questions, and maximizing inter-rater reliability.
8. Learn when it is necessary to make mandated reports or referrals and how to do so.
9. Assist with the development or refinement of study systems (ongoing).



## Training overview

The following activities will be carried out during the two to three week interviewer training period.

1. Initial meeting with Principal Investigator and Project Directors to learn about the study background, aims, design and procedures.
2. Individual review of study materials and forms, including an in-depth review of the operations procedures manual, informed consent form, study interviews and sample summaries, and recruitment script.
3. Meeting with study team to review the initial interview script in detail. This review will cover the intent of each question, proper documentation of the data point, and how it will be analyzed.
4. Meeting(s)/in-service with Project Directors to build telephone interviewing and data collection skills and learn about pitfalls to avoid. We will also discuss guidelines for filling out debrief forms, the importance of informed consent (including how to obtain consent), as well as how to make mandated reports and referrals when necessary (i.e., review suicidal ideation/prevention module and child abuse module).
5. Complete training in how to use CASES.
6. Complete basic online course on protection of human subjects for social and behavioral science researchers through the Collaborative Institutional Training Initiative (<https://www.citiprogram.org>) and the online HIPPA training (Health Insurance Portability and Accountability Act) through UCSF (details provided in HR packet).
7. Observe at least one study interview and practice face to face and telephone interview role plays with research coordinator, other study staff and others outside our professional circle, if possible.
8. Individual review of research and policy articles and information with relevance to the experiences of study participants, including unintended pregnancy, abortion care and adoption (see Reading List in Appendix B). Training in this area will be ongoing and will also include participation in meetings and conferences, grand rounds, and regular formal and informal discussion with members of the study team.
9. Participation in a values clarification seminar regarding abortion, adoption and parenting. If possible and of interest to the interviewer, observation of a counseling session and/or procedure in an abortion clinic.

Before conducting study interviews, new staff observe at least one actual telephone interview and conduct at least three role plays. A Project Director

observes at least one role play and offers feedback and advice as appropriate. New staff use the Training Checklist (Appendix C) to document their progress. Once interviewers begin conducting interviews with study participants, they participate in regular debriefing meetings with the Principal Investigator and/or the Project Directors to review progress and address questions or concerns. Other monitoring and evaluation activities include routine review of the documentation on the study forms/databases and debrief forms and periodic observation of interviews by a Project Director.

Interviewers receive ongoing support from the Project Directors and Principal Investigator. We encourage all staff members to take an active role in identifying areas where they can use additional support or resources to assist them in excelling in their jobs. We will make every effort to respond to staff needs in a timely manner.

## SECTION TWO: STUDY PROTOCOL

### ***Recruitment Protocol for Interviewers***

#### **Overview**

The recruitment process is the first time that the participants interact with Turnaway Study research staff and it is important that the interviewers are professional, sensitive, and non-judgmental in their dealings with potential participants. In addition, it is imperative that all interviewers follow the study description, screening guidelines, and informed consent process consistently so as to not bias the sample and to uphold human subject protections. This section of the manual describes the procedures that interviewers follow to conduct recruitment. These procedures are also outlined in the *Recruitment Checklist* (See Appendix D) which is used for interviewer training purposes.

For the purpose of this study, “turnaway participants” (women who are turned away from the abortion clinic because they present for care one day to three weeks beyond the gestational cut off of the clinic) are identified and enrolled into the study before “abortion controls” (women who are within the two weeks under the clinic’s cutoff and who receive an abortion at the clinic). For every one turnaway participant, two abortion control participants and one first trimester participant (women who are 14 weeks pregnant or less and who receive an abortion at the clinic) are enrolled. It is up to the clinic staff at each recruitment site to keep track of when to recruit abortion clients to match to the turnaways recruited. However, the Turnaway Study Project Director monitors recruitment and alerts the interviewers and/or point people in the event of a discrepancy.

Recruitment clinic staff identify eligible participants as English or Spanish speaking women ages fifteen and older, within three weeks above or two weeks below the clinic’s gestational limit and without any known fetal abnormalities. Minors (ages 15-17) who are recruited in states that do not require parental notification or consent for minors to receive abortion services may consent to participate in the study themselves. Minors who are recruited in states that do require parental involvement for minors to receive abortion services need the permission of a parent or guardian who is present in the clinic at the time they are recruited to participate in the study. Women ages 18 and above can be recruited from all clinical sites.

After an eligible woman is identified, a clinic staff member or “point person” who has been designated to be the main study liaison asks her if she is interested in hearing about a voluntary study in which she may be eligible to participate. If she is interested, the point person hands her the clinic recruitment packet with a *Clinic Flyer* (see Appendix E) and briefly describes the study purpose, procedures and reimbursement. The point person informs her that if she is willing to learn more about the study by talking with a UCSF research staff member, she will receive a \$15 gift card to Target or Wal-Mart, whether or not she chooses to participate. The point person also tells her that the \$15 gift card is given specifically for participating in the phone call with the research staff, and not simply for accepting the study flyer and packet. If the woman is interested after reading the flyer, the clinic staff member directs her to a private place where she can conduct the call. The point person also gives each prospective participant a packet of study materials, including a study handout, the informed consent form with an additional signature page, and the UCSF Study Participant Bill of Rights. Using a special pre-paid and pre-programmed study cell phone (a “Firefly phone”), or the clinic’s phone lines, the point person calls the UCSF research office, where a research staff member answers the phone. The point person introduces herself by name, tells the research staff member which clinic she is calling from and informs her that he/she has identified a participant who is interested in learning more about the study. She also introduces the participant, *by first name only*, and turns the phone over to the potential participant. At this point, the research staff member informs the prospective participant about the study, conducts an eligibility screening and obtains informed consent, as appropriate. (These procedures are described in more detail below).

Once a turnaway patient has been recruited, the point person attempts to recruit the next abortion patient in the first trimester and the next two abortion patients whose gestation is one day to two weeks under the clinic’s gestational limit and who will receive an abortion at the clinic (controls). The point person keeps track of how many turnaway and non-turnaway patients are recruited using a tally sheet (devoid of personal identifying information) and approaches patients accordingly. If one of those patients declines to participate, the next patients of each type are approached until a full set of “cases” and “controls” is recruited. As in the case of turnaway patients, non-turnaway patients are identified and approached by the point person at some point during their clinic visit, but before receiving medication. The point person uses the same method to present the study to controls as she does for Turnaway patients.

## **Recruitment of Minors**

This study recruits eligible women ages 15-17 to participate in the study. Minor prospective participants who may be eligible to be recruited to this study seek care at clinics that are located in different legal and regulatory environments. While some minors seek abortion services at clinics in states which allow them to consent to the abortion themselves, others seek services in states which require parental involvement (i.e., notification or consent) or judicial bypass for abortion care.

### *Recruitment of Minors in States Where Parental Involvement is NOT Required for Abortion Care*

For potentially eligible women ages 15-17 in states in which the minor can legally consent to abortion services without parental involvement, the point person identifies the minor potential participant as described above. After giving the minor a brief description of the study and the study flyer, but before putting her on the phone with a UCSF research staff member, the point person asks five “pre-screening” questions to help determine whether the young woman would be able to adequately weigh the risks and benefits of participating in the study and provide informed consent. The pre-screening questions are designed to assess the minor’s capacity to understand and answer questions, her ability to cope with sensitive questions, and to help her consider the consequences of someone close to her (such as her parents) detecting her participation in the study. If the point person is convinced that the minor is an appropriate prospective participant, she gives her the telephone connecting her to UCSF and the recruitment process will continue. If not, the point person tells the participant that she is not eligible for the study and thanks her for her time. The point person completes the *UCSF Turnaway Study Minor Prospective Participant Pre-Screening Questions Form* and faxes it to a dedicated fax line in the UCSF research project directors’ office along with the minor’s signed consent form. This form includes checkboxes for the point person to document whether or not she has determined that the minor is a good candidate for the study. As the *Minor Prospective Participant Pre-Screening Questions Form* does not include any personal identifying information, the point person writes the study site number, initials and the date and time that they completed the minor pre-screening process on the *Minor Prospective Participant Pre-Screening Questions Form*. This allows UCSF research staff to link each pre-screening form with the appropriate consent form in the event that more than one woman’s paperwork arrives by fax at the same time.

## *Recruitment of Minors in States Where Parental Involvement IS Required for Abortion Care*

For potentially eligible women ages 15-17 in states where parental involvement is required for minors seeking abortion services, the point person again identifies and approaches the prospective participant. Although no pre-screening is conducted, the point person informs these minors that they will not be able to participate unless the parent or guardian agrees and signs an *Adolescent/Adult Consent Form*. In some cases, the parent may be present in the same room at the time the study is presented to the minor. In other cases, the parent may be waiting in another part of the clinic. In all cases, the parent or guardian is given a duplicate copy of the study materials that are given to the potential participants (the study flyer, the informed consent material and the UCSF Bill of Rights). The minor is offered the opportunity to discuss the study with her parent before speaking with a UCSF research staff member or to speak first with the research staff member and then discuss the study with her parent. We leave this to the discretion of the minor so that she can base her decision on her level of interest in the study, her personal willingness to participate, and her relationship with her parent. If the minor or the parent/guardian requests it, study staff can speak directly with the parent/guardian of a potential participant to answer any questions s/he may have. In order for the minor participant to be enrolled in the study, the parent/guardian must also sign the *Adolescent/Adult Consent Form*.

### **Recruitment Discussion with UCSF Research Staff**

Whether or not the prospective participant is an adult or a minor, the next step in the recruitment process is the conversation between the prospective participant and the UCSF research staff. Once it has been determined that the adult or minor prospective participant is interested and eligible, the clinic staff member calls the UCSF office from a dedicated study cell phone or a clinic phone, introduces herself using her first name and clinic site, and tells the interviewer the potential participant's first name *only*. Afterwards, the clinic point person hands the phone to the woman and directs her to return it to clinic staff after she is done with the recruitment process. The study cell phone is programmed to call the 1-888-855-XXXX number, which reaches the interviewers' office at UCSF. The research staff members have complete research recruitment packets<sup>1</sup> ready to enroll participants at any time. The on-call research staff member answers the

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<sup>1</sup> Each research recruitment packet will contain the Recruitment Checklist, Participant Screening Form, Participant Contact Form, and Participant Tracking Form.

phone and learns the potential participant's first name and clinic location from the clinic staff member. Knowing the clinic location enables the interviewer to consult the Recruitment Site List for the following pieces of information key to the eligibility screening process:

1. Whether a minor participant needs parental consent to participate in the study, and;
2. The clinic's gestational limit (used to determine what category of participant is being recruited).

Once the phone has been passed from the clinic staff to the potential participant, the research staff member greets the woman by first name and writes her name on the *Participant Contact Form* (see Appendix F). The research staff member then briefly describes the study, following the *Sample Recruitment Script* (see below). If the research staff member determines that the woman is interested in participating, she asks her to answer several questions to determine whether or not she is eligible to participate in the study. The research staff member then conducts an eligibility screening interview using the *Study Eligibility Screening Form* (see Appendix G).

### **Sample Recruitment Script**

*Hi [Participant's Name], thank you so much for taking the time to talk to me about the study we are conducting. My name is [Interviewer's Name], and I am part of a research team at the University of California, San Francisco. We should only be on the phone for 10-15 minutes. I want to tell you a little more about the study. Is that okay?*

*We are doing this study to learn more about how women's decisions and experiences with unintended pregnancy and abortion affect their lives—for example in the areas of health, employment, relationships and sense of wellbeing. There is little high quality, unbiased research about real women's actual experiences. Our goal is to talk with 2,000 women across the country to learn more about women's true experiences. We are recruiting both women who got an abortion and women who planned to get one but were turned away from the clinic because they were too far beyond the clinic's gestational limit—We think that gathering this information can make a big difference in terms of how well providers and policies meet women's needs.*

*Participating in the study would mean that you would do a 30-45 minute phone interview every six months for the next five years. After each interview, we will send you a \$50 gift card to either Target or Wal-Mart to thank you for your time. That ends*

*up being \$550 over the course of the study. Does this still sound like something you'd like to participate in? [Wait for confirmation. If not, thank the woman and ask her to return the recruitment materials to the clinic staff before she leaves.]*

*So, before we officially enroll you into the study, I need to ask you a couple questions to make sure that you are eligible. Is that OK? [Wait for confirmation and then follow the Eligibility Screening Form.]*

*[If not eligible, thank the woman and ask her to return the recruitment materials to the clinic staff before she leaves. Interviewers should then take the participant's screening form and place it in the Ineligible/Refused binder. If eligible, continue with recruitment.]  
Ok, you are eligible to participate so now we will go through the informed consent.*

### ***Sample Informed Consent Script***

*Did you get a packet about the study from the clinic? [Wait for response. If participant has not received packet ask to speak with point person]. In the packet, you should have a form titled 'University of California, San Francisco – Consent to Participate in a Research Study', do you see that? I'd like you to follow along with me as I go through this form. At the end, I will ask you if you feel comfortable signing the form and consenting to participate. If you have any questions while we are going through feel free to stop me and ask.*

*First, as I said before – this is a study being conducted by researchers at the University of California, San Francisco in order to learn more about how abortion and childbirth affect women's lives. The principal investigator is Dr. Diana Foster and our team of research staff is located in Oakland, CA. If you decide to participate, we will ask you to do a total of eleven phone interviews. In order to do this, we will need to keep track of any phone or address changes you may have during that time.*

*This study is completely voluntary and whether or not you choose to participate will have no effect on the care you receive in the clinic. Also, you can decide you no longer want to participate at any point during the study. All we ask is that you let us know so we stop contacting you for your interviews and check-in calls.*

*The interviews take about 30-45 minutes. Some of the interview questions are quite sensitive, such as why you decided to have an abortion, questions about drug and alcohol use and other personal topics. If at any point you do not want to answer a question, just let us know and we can skip it.*



*At the top of page three you will see a section called 'Will information about me be kept private?' This is a very important section to read because it details the steps we take to protect your privacy. No study can guarantee complete confidentiality; however, we do take special precautions. For example, we assign participants identification numbers, which we use instead of names in our data files. We also lock our files and offices, protect all of our computer records, and are especially careful when we call participants or send mail. However, it is possible that someone else could detect that you are participating in a study if they receive telephone messages or mail for you. Also, in the unlikely event that a participant's file is subpoenaed by a court, we may have to comply.*

*I also think it is important to look at the section about Mandatory Reporting. As researchers, we are legally required to report some instances of abuse, such as current child abuse or sexual abuse of a minor that we hear about in the course of our interviews. Also, we are ethically required to make a report if a participant expresses an intention to hurt herself or someone else. If you share something like this in an interview, we may be required to share information about the event with the authorities and we will give you referrals for support services.*

***For minors: It is important for teens involved in this study to understand that, while we will do everything possible to protect your privacy, there is still a small chance that your parents, roommates or others who you may not have told about your pregnancy could find out you that are participating in this study. If they contact us, we would not share any information about you or about the nature of the study. However, you should consider what this would mean for you before you enroll in the study. If you have any questions or concerns about this, let me know.***

*Even though there may be no direct benefits to you for participating in this study, you will be helping researchers better understand women who are in similar situations to you – and hopefully help us to better serve these women in the future. To thank you for your time, we will send you a \$50 gift card for Target or Wal-Mart after each interview you complete.*

*If you have any questions or concerns during the course of the study, you can call either the study 1-888- number that is on the last page of your consent form or the principal investigator, Dr. Diana Foster, at any time. If you have a concern about the study that you prefer not to discuss with us or Dr. Foster directly, you can call the number for the Committee on Human Research that is on your consent form.*

*Do you have any questions for me now or do you need more time to look over the form before signing? [Wait for response.]*

[If participant agrees to participate:] *Ok, thank you, do you see a pink or yellow copy of the form in your packet? [Wait for response]. If you could sign it and put today's date [Read date] and your birth date on the form and let me know when you've finished. [Wait for the participant to do so.] [If participant is in parental involvement state] Now, can you ask your parent or guardian to sign and date the form too and let me know when they're done? [Wait for participant to let you know parent/guardian has signed]. When the form is signed please give the signature page to the clinic staff along with the cell phone. The white pages are for you to take home. Ok?*

[Confirm understanding of procedure and move on to gathering contact information. If the woman specifically asks for more time, the interviewer will tell the woman to take some time in the clinic to look over the form; however she cannot take the information home with her. Ask her to call us back once she has looked over it again to let us know whether she would like to participate. Also offer to answer any questions or talk about any concerns she may have about the study before getting off the phone.]

If participant declines to participate: *OK, that's fine I understand. Thank you very much for taking the time to hear about the study. Could you please return all the papers and phone back to clinic staff?*

### ***Sample Contact Information Script***

*We're almost done for today, but first I need to get your contact information and set up your first interview date. [Reference Contact Information Form (see Appendix F).]*

*Your first name is [Participant's First Name], is that correct? Ok, [Participant's First Name], what is your middle name? Your last name?*

*Do you have a cell phone number we can reach you at? When we call the numbers you give us, we usually say that we are calling from the 'Health Study'. Or, we can use our code name 'XXX'. Which would you prefer? [record preference on form.] Do you have a home phone number where we can reach you? When we call that number, can we say we are calling from 'Health Study', or would you prefer we use the codename 'XXX'? [record preference on form.]*

*We sometimes use text messages to get in touch when it is time for a check-in call or an interview. Would it be OK to contact you via text? Which number is best to do so?*  
[record preference and repeat number].

*Do you have an address we can send the gift card to? Do you have a second address in case you move?* [Repeat with email address and birth date.]

*Also, we ask for the phone numbers of two people who always know how to get in touch with you in case something happens to your phone or we can't reach you for some other reason. We will always try to contact you at your preferred number first, and we will not tell them who we are calling from unless you say it is OK. Who would your secondary contacts be?* [Record name and number.] *What is your relationship to [Contact's Name]?* *When we call, we will say that we are from the 'Health Study', is that OK?* [If not, offer to use code name and record preference on form. Repeat process with Contact #2.]

*We'll call you every couple of months to keep in touch so we know if you are planning to move or change your phone number. It is very important to us to keep you in the study for as long as you are willing to participate.*

*Ok, all that's left is to schedule your first interview. We'd like to set up your first interview for eight days from today* [or the procedure day if it's on a subsequent day] *which is.....* [Specify date. If it is a holiday or Sunday, schedule for the next business day.], *will you be available that day? What time would be best for you to do the interview that day?* [Record date and time on both *Participant Contact Information Form* and *Participant Tracking Form* and on the Calendar. Interview date should be set within two weeks of recruitment date.]

*I'll also put an appointment reminder card in the mail to you so you know when we will be calling for your interview. Would you like a reminder call the day before your interview?* [Record response on tracking form].

*Before we get off the phone, I want to thank you again for taking the time to talk to me. The first interview is very important to the success of the study, so if you have any questions or need to reschedule your appointment, give us a call at the 1-888 number. Please give the pink or yellow page and the cell phone back to the clinic staff. You can take the white papers home with you. We really appreciate your willingness to share your experiences and opinions with us. Your responses will help us better serve women in the future. We can't do it without you. Take care and we'll talk to you on [interview date].*

Spanish versions of the above scripts are available in the “current documents” folder on the shared drive.

If the woman is not eligible and/or not willing to participate, the research staff member thanks her for her time and directs her to return the recruitment materials and phone to the clinic staff. In this case, no identifying information is recorded and no study ID is assigned. The clinic point person then gives the participant a \$15 gift certificate to compensate her for her time. After the woman is off the phone, the research staff member places the participant’s screening form (completed or semi-completed) in the Ineligible/Refused binder. If the participant declined to participate before the screening form was started, the research staff member just places the blank form (with only the recruitment date and site location filled out) into the binder. If the potential participant is ineligible or declines the research staff sends an email to PI, Project Coordinator and Project Assistant with the site number, date of recruitment and reason for ineligibility or decline.

## ***INFORMED CONSENT PROCESSES***

If the woman is eligible and willing to participate, the research staff member begins the informed consent process while still on the phone.

**If the prospective participant is an adult**, the UCSF research staff member asks the woman to take the *Informed Consent Form* out of the packet given to her by the point person and reviews it with her, following the *Sample Informed Consent Script*. (The principles and procedures involved in obtaining informed consent are described further in the informed consent section of this manual. It is imperative that prospective participants have a chance to learn about what is being asked of them, including all of the risks and benefits of the study, and have a chance to ask any questions that they may have.) After interested and eligible prospective participants have reviewed and discussed the informed consent form with a research staff member, the research staff member asks for her verbal consent to participate in the study. After obtaining informed consent verbally, the research staff member then clearly explains that the prospective participant should sign the pink copy of the form and return it to the clinic staff with the study cell phone. She also instructs the woman to keep the second copy of the informed consent form for her own records, along with the other study materials in the packet. The point person faxes each signed informed consent to a

designated, secure fax in the Project Directors' office and mails the originals to the office on a monthly basis

**If the prospective participant is a minor between the ages of 15-17 years old and is seeking an abortion in a state that *does not* require parental permission for abortion care,** the point person administers the *Minor Prospective Participant Pre-Screening Questions* (described above) before putting her on the phone with UCSF staff. If the point person is convinced that the minor is an appropriate prospective participant (she can provide informed consent and has considered the impact of a possible breach of confidentiality), she follows the same process she would with an adult woman and the consent process continues as described above. If not, the point person tells the participant that she is not eligible for the study and thanks her for her time. In either case, the point person completes the *Minor Prospective Participant Pre-Screening Questions Form* and faxes it to the dedicated line in the Project Directors' office.

**If the prospective participant is a minor between the ages of 15-17 years old and is seeking an abortion in a state that *does* require parental permission for abortion care,** the point person does not administer the pre-screening questions. In this case, it is the minor and her parent who decide whether she is an appropriate candidate for the study. With these minors, the research staff member conducts the informed consent process as described above. However, before completing the informed consent, the research staff member asks if the minor's parent/guardian is present and whether s/he is willing to sign the informed consent form. If so, the research staff member proceeds with enrollment. Both the minor and the parent/guardian must sign the *Adolescent/Adult Consent Form* and return it to the clinic point person. If the parent requests to speak with the research staff member, the research staff member can answer any questions the parent has immediately over the phone.

**For all women:** after the research staff member has conducted the informed consent procedure, the last thing to do is to gather her contact information and set an appointment date and time for her first interview. *It is extremely important that the research staff member obtain several contact numbers/addresses for the participant whenever possible. In addition, it is absolutely crucial to clearly ask and document the participant's preferences regarding telephone messages, text messages, emails, and postal mail, including her preferences for use of code names for each telephone number and blank envelopes for the addresses she provides.* The research staff members tell participants that they have the option receive messages by phone, text, and/or

email. The messages are brief and do not contain any information that would divulge the nature of the study. The research staff member refers to the *Participant Contact Form* to gather contact information and record the first interview date. The first interview date is set for a date and appointment time that is convenient for the participant, within the research staff members' work hours, and eight days after the recruitment date. If it is not possible to set the first interview date at exactly eight days, the research staff member will try to set up the interview for a different time within two weeks of the recruitment date.

After the research staff member fills out the contact form, she provides an opportunity for the participants to ask any additional questions. The research staff member will try to answer questions as best she can and consults with either the Research Coordinator or Project Director if she is unable to answer a question. After all questions are answered, the research staff member thanks the participant for her time, reiterates the date of the first interview, and asks the woman to hand the pink copy of the signed informed consent and the study cell phone back to the clinic staff. The point person at the clinic gives the participant a \$15 gift certificate to compensate her for her time. The point person documents dispersal of the gift certificates on a log using initials. The log is faxed to the Project Directors periodically.

After hanging up the phone, the research staff member immediately consults the *Participant Enrollment Log* (see Appendix I) to assign the participant a Study ID Number. This ID number is written on the *Eligibility Screening Form* and on the top of the *Participant Tracking Form* (on which the recruitment date and first interview date is recorded). The research staff member then opens a study folder for the participant and puts the *Participant Contact Form* and the *Participant Tracking Form* in the file. The first interview date is also recorded, using the participant's Study ID Number, in the electronic *Interview Calendar*. The research staff member places the Eligibility Screening Form in a binder in the Project Director's office separate from the participant's contact information.

For each recruitment, the research staff member sends an email with the participant's study ID, date and time of recruitment and whether the participant is a minor and/or Spanish-speaking to the PI, Project Director and Project Coordinator for tracking purposes. The research staff member also documents the participant's study ID, recruitment date, birth date and gestational age in the CASES set up log for the week.

## ***Receipt of Informed Consent Protocol***

Upon receipt of the *Informed Consent Form* via fax, the research staff member records the receipt on the *Participant Enrollment Log* (under Informed Consent Received, writing the date received in month, date, year form and initialing). The research staff member then files the *Informed Consent Form* in the CHR Binder, separate from the participant's study file. **Only after the informed consent is received and filed is the participant fully enrolled in the study.** After the informed consent is received, the research staff member mails an appointment reminder card, insert and refrigerator calendar magnet (see Appendix J) with the 1-888 number and the participant's first interview date circled to the participant at the mailing address indicated in their contact information form. When the original *Informed Consent Form* is received in the mail, the research staff member records receiving it in the *Participant Enrollment Log* (under Original Consent Received, writing the date received in month, date, year form and initialing) and files it in front of the faxed copy in the CHR Binder. For data security reasons, the participants' Study IDs should NOT appear on the original or faxed copy of the *Informed Consent Form*.

If the *Informed Consent Form* is not received within two days after the recruitment date, the research staff members must alert the Project Director and contact the clinic point person. If the informed consent is still at the clinic, the clinic staff is asked to fax it to the study fax immediately. **The first interview cannot be conducted unless either the fax copy or the original form is received in the study office.** If the clinic cannot find the informed consent and it has not been received at the study offices, the Project Director or delegated staff calls the participant and asks permission to send a new copy of the informed consent, with a pre-stamped pre-addressed envelope, to the participant's preferred address. If the participant does not agree, the Project Director or delegated staff asks whether or not the participant can return to the clinic to sign a new informed consent. If the participant does not agree to do that either, the participant is dropped from the study and is not contacted further.

## ***Interview Protocol for Interviewers***

A participant's first interview date and time are recorded in the electronic *Interview Calendar*. When an interviewer comes across a first interview date in the calendar, she must adhere to the following protocol. A checklist for conducting this interview is outlined in the *First Interview Checklist* (see L), which is used for interviewer training purposes.

First, the interviewer should retrieve the participant's file (labeled with the participant's Study ID Number) from the study filing cabinet. The research staff member must then check to make sure that the participant's signed *Informed Consent Form* has been received by verifying this in the *Participant Enrollment Log*. If the consent form has not been received, the interviewer needs to alert the Project Director and should not attempt to contact the participant for the interview until it has been received and filed.

If the signed informed consent form has been received, the interviewer can begin the interview process.

First, the interviewer should open the CASES interface in wave 1\_prod by clicking on the shortcut on her desktop and enter the participant's Study ID without the dash or letter (e.g., 15-001T should be entered as 15001). If the case is not set-up in CASES, the research staff member will get an error message and should inform the Project Director immediately. Research staff members should always be prepared to conduct an interview on paper in case she encounters problems with CASES. The most recent CHR-approved versions of all the interviews can be found in the "current documents" folder.

When the interviewer is ready to call the participant at the scheduled appointment time, she should make sure to know whether or not to use a code name when calling each contact number. **If the participant has opted for the use of a code name, the interviewer should block the telephone number from appearing on caller ID by pressing \*81+1 on the office phones.**

The interviewer should address whoever picks up with one of the following as appropriate:

Hi, my name is [Interviewer's First Name] from the Health Study. Is [Participant's First Name] there?



If the woman has chosen to only use a code name, the interviewer should say, “Hi. May I speak to [Participant first name]?” and, if asked, say “This is XXX.”

If the participant is not available, the interviewer can either leave a message with the toll-free number (1-888-855-XXXX) or not, depending on the participant’s preferences. If the person who picks up the phone (other than the participant) asks what the call is pertaining to or what the study is about – the interviewers should give as little information as possible and in no case say more than that it is a health study. If the participant has chosen to only use a code name, the interviewer should simply say that they are a friend of the participant.

If the participant is available, the interviewer can start the conversation:

Hi, [Participant’s First Name], this is [Interviewer’s First Name] from the Health Study. I’m calling for your first interview. Is this a good time to do your interview?

If the participant hesitates or says that she is not available, it is important to emphasize that the interview will take about 30-45 minutes and that the woman will receive a gift-card to compensate her for her time after the interview is completed. If the woman still says she is not available, the interviewer should try to reschedule her appointment time within the next two days and record that time on the *Interview Calendar*. If the woman is not available within the next two days, the interviewer should accept and record the next available time.

If the participant is available, the interviewer should use the script in the CASES program to reintroduce the study.

The interviewer will then conduct the interview following the *First Interview* protocol.

At the end of the interview, the interviewer should use the instructions in the CASES program to thank the participant for her time, confirm her contact information and let her know when we will be contacting her again.

The interviewer may use the following sample script to end the phone call:

Thank you so much for your time today. We really appreciate your participation in the study. Your next interview will be in six months and we’ll be contacting

you the week before to set up an appointment time that's good for you. I'm going to send you a refrigerator magnet with your gift card for your interview today that has the date of your next interview marked on it. We will also contact you every two months to make sure we have all of your contact information up to date. You can also call us at our 1-888 number (which is on the fridge magnet we'll be sending you) at any time if any of your contact information changes so we can keep in touch for future interviews. As I mentioned, I'll be sending you a \$50 gift card today to thank you for your time – you have a choice of either Target or Wal-Mart, which would you like? [Interviewer must record preference on the *Participant Tracking Form*.] In order to make sure that the gift card reaches you, can I check to make sure that the address I have for you is correct? [Interviewer must record any change on the *Participant Contact Form*.] We would also like to make sure that we have all your contact numbers. I have [read different types of numbers recorded on the *Participant Contact Form*], do you have any other numbers that we can use in case we cannot get a hold of you for your next interview? [Interviewer asks this only if contact has not already given us two secondary contact numbers. Interviewer also confirms preferences for the use of a code name or the study name for each number.] We will only use these numbers in the case that we cannot reach you on your preferred numbers. [Interviewer must record any additional numbers on the *Participant Contact Form*.] Thanks again for participating in the Study. These interviews are so important to us and we really value your willingness to participate. One of our study's goals and challenges is to keep women like you in the study. We can send text messages, emails, or call you on the phone. We want to make sure we are contacting you in the way that is most convenient for you. What do you suggest is the best way for us to continue to get a hold of you for the next few years? Please call us at 1-888-855-XXXX if you have any other questions. Thank you again, goodbye.

After the interviewer hangs up the phone, she must follow several steps to ensure that all the relevant information was collected and is stored appropriately

### *Completing Debrief Forms*

After completion of an interview, the interviewer should immediately enter the Salesforce database and complete the electronic debrief form for that interview and mark the contact as completed.

Although the debrief forms are intended to be informal and used primarily as internal documents, they represent a shift in the role of the interviewers from

data collectors to data “interpreters.” The debrief forms are a place where interviewers can record the elements of the interview that stand out the most—whether it be because the participant expressed a feeling strongly, or because the interviewer found a particular response surprising or illuminating. Interviewers can also document the interview experience or the nature of the interviewer-participant relationship (e.g., “participant seemed thoughtful and interested,” “participant seemed to have trouble understanding questions,” “participant appeared distrustful”), which may be useful for future interviews.

In the search bar the interviewer types the participant’s Study ID in the following format “15-001\*”. The “contact type” field can be left blank. All of the participant’s contact records will appear. The interviewer clicks on the appropriate line double-checking that it is the correct interview. The interviewer enters the date and time the interview was completed in the format “9/13/10 9:10am”. She should also choose her name in the “assigned to” field and proceed to answer the debriefing questions as appropriate.

It is important to remember that the interviewer’s experiences are important and interesting data. **The debrief form must be completed immediately following the interview to preserve the integrity of the qualitative data.** The following provides guidance specifically for the last two questions on the form

1. *What are your immediate impressions of the respondent and/or what stuck out about this interview?*

In answering this question, think about what you might say to someone right after you hang up the phone. Responses to this question might include:

- R was very short with her answers. I barely could finish the question before she answered. It seemed like she wanted to get the interview over with.
- Her tone changed and was more hostile when I asked her the questions about finances
- This interview made me realize I haven’t interviewed many women from the Midwest who aren’t really religious. R is Southern Baptist and regularly attends church.
- There was nothing of note. R answered every question clearly and succinctly. Her tone was calm and polite. Her responses and tone were similar to many other interviews I’ve conducted.

## 2. *What was this interview like for you?*

In answering this question, please reflect on your own experience of the interview. Response to this question might include:

- I found R's story very emotional. When she talked about X, I felt sorry for her.
- I had trouble concentrating on this interview because it was the 5<sup>th</sup> interview I conducted today.

### Additional techniques for a speedy write-up

- Use bullet points or incomplete sentences. As long as someone else can figure out what you mean, you don't need to write with perfect grammar and spelling.
- Use "R" to stand for respondent, the woman you've just interviewed
- Don't be self-conscious: you are the expert here. There is no right or wrong way to do a write-up. We want to know *your* impressions, positive, neutral, or negative.
- Next, the interviewer should confirm that the next check-in call date is recorded on the *Participant Tracking Form* (see Appendix M).

### *Mailing the Gift Card*

The interviewer should write the date of the next interview on the *Gift Card Insert* (see Appendix N) and write a short personalized thank you note to the participant. E.g. 'Sandy, Thank You! - XXX'. (Note: Personalized greetings are nice, however, to avoid biasing the participant they should not include any other sentiments other than "hello" and "thanks.")

The interviewer will then address the envelope (including return address, as appropriate), stuff the envelope with the insert and refrigerator magnet marked with the next interview date, place stamp (recording usage in the Stamp Log) and bring the pre-addressed envelope to the Project Director to add the gift card and mail. The envelope should have a note on it for the Project Director with the participant ID#, which number interview was conducted, the date the interview was completed and the type of gift card the participant would like to receive. The interviewer will return the participant's contact information file complete with updated contact information, completed tracking form, and new tracking form to the file cabinet in the interviewer's office.

### *Logging Follow-up Dates*

The interviewer should then record the next two check-in dates and next interview date in the electronic *Interview Calendar*.

Lastly, the interviewer will then return the participant's contact information file complete with updated contact information, completed tracking form, and new tracking form to 'Needs Date Check' file in the filing cabinet for another interviewer to check to make sure the next check-in dates, scheduling date and interview date have been scheduled.

### ***Phone and Messages Protocol***

The first study interview should take place approximately eight days after a participant is enrolled into the study. When trying to reach participants for an interview, interviewers should look at the contact form to see which form of communication the participant prefers. For those that prefer the telephone, interviewers should call the participant at her main number(s) once a day at different times of the day for a total of five days, which should include at least one Saturday. Interviewers may leave only one voicemail message per day. If a participant has opted to receive email or text messages, interviewers should send one message the first day to the specified number or email address, using the sample text messages and scripts located in the "current documents" folder. If a return message is not received by the second day, the interviewer should continue to attempt to contact the participant via phone call following the process from above.

If the participant does not respond to these initial attempts to contact her within 5 days, interviewers should send a *Follow-Up Letter* (see Appendix L) and/or email (if appropriate) and begin calling the participant's secondary contacts once per week for four weeks. If this does not succeed, after 5 additional days interviewers should send an additional *Follow-Up Letter* and/or email. In the event that a participant's main contact number is disconnected before the end of the five days, ***and if the participant stated that mail was welcome***, the interviewer should immediately send a *Follow-Up Letter* and/or email (if appropriate) and begin contacting the participant's secondary contact numbers. All stamp usage should be recorded in the Stamp Log kept in the interviewer's file cabinet. After the initial five days of attempts, the interviewer should try to

reach the participant once per day for five more days and begin contacting their secondary contact numbers if they haven't already. If the participant is reached during the attempts to contact her but the interview is not completed (e.g. she needs to reschedule for another time), the attempts to contact her protocol starts over again.

Each attempt, as well as any calls from the participant, will be recorded on the *Participant Tracking Form*. If the participant cannot be reached after all the contact attempts, the interviewer will stop making attempts to complete that specific interview. If the participant cannot be reached for her first interview, her file should be moved to the 'lost to follow-up' section of the study file cabinet and no further attempts should be made to contact her. If she does call back and complete her first interview, her file can be moved back into the 'active participant' section and the Project Director should again be informed. In all cases, when a participant is called 'lost', the Project Director should be informed via email. The Project Director should also be informed if a participant is moved back to active status after being called 'lost'. Missed interviews or other contacts should be recorded in the Salesforce database.

## Check-In Call Protocol

The participant's next two check-in call dates will be recorded in the electronic *Interview Calendar* scheduled for every two months after the recruitment date. After the completion of each subsequent interview, the interviewer will schedule the next two check-in calls leading up to the next interview. For example, if a participant is recruited on January 1, 2009:

Recruitment Date	1 <sup>st</sup> Int date	Check -in call	Check -in call	2 <sup>nd</sup> Int date	Check -in call	Check -in call	3 <sup>rd</sup> Interview date	Etc.
01/01/09	01/09/09	03/01/09	05/01/09	07/01/09	09/01/09	11/01/09	01/01/10	And on ...
Schedule 1 <sup>st</sup> Interview for 8 days later and record date in the electronic <i>Interview Calendar</i>	After interview, schedule next two check-in calls and 2 <sup>nd</sup> interview and record all dates in the electronic <i>Interview Calendar</i>  If this initial interview is missed, the participant is considered LOST to follow up and no further check-in calls or interviews are scheduled.			After interview, schedule next two check-in calls and 3 <sup>rd</sup> interview and record all dates in the electronic <i>Interview Calendar</i> .  If this interview is missed, the following check-in calls and interview are STILL SCHEDULED.			After interview, schedule next two check-in calls and next interview and record all dates in the electronic <i>Interview Calendar</i> .  If this interview is missed, but previous interview was completed, the following check-in calls and interview are STILL SCHEDULED  If this is the second missed interview in a row, the participant is LOST to follow up.	

The dates must be scheduled on days when interviewers are in the office. The interviewer will schedule the check-in calls for as close as possible to the recruitment date (two months, four months, etc.), while considering interviewer availability.

The interviewer should retrieve the participant's file (filed by study ID number) from the study filing cabinet. The interviewer must adhere to the following protocol to complete the check-in calls. Within the file, a new *Check-in Tracking Form* (see Appendix O) should be at the top of the file with the recruitment date, check-in call date, and recruitment site filled out.

**When the interviewer is ready to call the participant, she should make sure to know whether or not to use a code name when calling each contact number. If the participant has opted for the use of a code name, the interviewer should block the telephone number from appearing on caller ID by pressing \*67 on the office phones.** The interviewer should address whoever picks up with:

Hi, my name is [Interviewer's First Name] from the Health Study. Is [Participant's First Name] there?

If the woman has chosen to only use a code name, the interviewer should say, "Hi. May I speak to [Participant first name]?" and if asked "This is XXX."

If the participant is reached, the interviewer should close by saying something like "Thanks again for participating in the Study. These interviews are so important to us and we really value your willingness to participate. One of our study's goals and challenges is to keep women like you in the study. We can send text messages, emails, or call you on the phone. We want to make sure we are contacting you in the way that is most convenient for you. What do you suggest is the best way for us to continue to get a hold of you for the next few years?"

If the participant is not available, the interviewer can either leave a message with the toll-free number (1-888-855-XXXX) or not, depending on the participant's preferences. If the person who picks up the phone (other than the participant) asks what the call is pertaining to or what the study is about – the interviewers should give as little information as possible and in no case say more than that it is a health study. If the participant has chosen to only use a code name, the interviewer should simply say that she is a friend of the participant.

As in the case of interview calls, the interviewer should try to reach the participant for a check-in using her preferred communication method (e.g., text, email or phone) once a day at different times of the day for a total of five days, which should include at least one Saturday, and leaving a voicemail only once



per day). After attempting to reach the participant for five days, the interviewer should send a *Check-in Follow-Up Letter* (see Appendix P) and/or email as appropriate to the participant's address. If the participant has chosen text or email as her preferred contact method and does not respond to email or text by the second day, the interviewer should call the participant on the telephone.

If the participant cannot be reached for her check-in call, the interviewer should record that the check-in call was 'MISSED' in the Salesforce database and make sure to update and/or correct any necessary contact information in REDCap. Additionally, she should mark the 'Unable to reach participant' box on the *Check-in Tracking Form*, as well as note the date and initial. The interviewer will then return the contact information file to the study file cabinet in the interviewer's office to be ready for the next check-in call or interview attempt.

If the participant is reached, the interviewer reviews the participant's contact information with her and makes any changes or updates on the *Participant Contact Form*. If there are any blanks on the contact form, the interviewer attempts to fill these in (e.g. if the participant had only given one alternate contact, no email). The point is to always try to gather as much up-to-date information as possible.

If the participant mentions that she will be moving soon, make a note of this on her contact form and make sure she has the 1-888 number so she can contact us as soon as she has her new information.

If the form becomes cluttered or difficult to read due to changes, the interviewer should transfer the information to a new contact sheet, mark the date on the new contact sheet and place it on top of the old contact sheet in the participant's contact information file. Old contact sheets should never be removed from the file nor discarded.

On the tracking form, the interviewer will record her success and check the 'Participant contact information updated' box, date and initial. The interviewer will mark the contact as completed in the Salesforce database with the date and time and her name in the 'assigned to' field, make sure to update and/or correct any necessary contact information in REDCap, and then return the contact file to the study file cabinet in the interviewer's office.

## ***Interview Scheduling Call Protocol***

One week before the participant's subsequent interview dates, it will be recorded in the electronic *Interview Calendar* to conduct an 'interview scheduling' call. The interviewer must adhere to the following protocol to complete the interview scheduling call.

The interviewer should retrieve the participant's file (filed by study ID number) from the study filing cabinet in the interviewers' office.

**Before calling, the interviewer should review the *Participant Contact Form* to determine whether or not to use a code name when calling and her preferred method of contact.**

Once the interviewer is familiar with the participant's information, she can begin attempting to contact the participant to schedule her interview. The interviewer should address whoever picks up with:

Hi my name is [Interviewer's First Name] from the Health Study. Is [Participant's First Name] there?

If the woman has chosen to only use a code name, the interviewer should say, "Hi. May I speak to [Participant first name]?" and if asked "This is XXX."

If the participant is not available, the interviewer may either leave a message with the toll-free number (1-888-855-XXXX) or not depending on the participant's preferences. The interviewer may try to reach the participant up to three times per day for a total of five days, as described above. After five days if the participant has not been reached, the interviewer will proceed to 'Interview Protocol'. All attempts to contact the participant and any calls received from the participant should be recorded on the *Participant Tracking Form*. If a participant has opted to receive email or text messages, interviewers should send one message the first day to the specified number or email address, using the sample text messages and scripts (see Sample Text Scripts and Sample Email Scripts from above). If a return message is not received by the second day, the interviewer continues to attempt to contact the participant via phone call following the process from above.

If the participant is available, the interviewer can begin:

Hi [Participant's First Name], this is [Interviewer's Name] from the Health Study. I am calling to set your appointment time for your next interview which is scheduled for [interview day & date]. Is there a good time that day to do your interview? [Date and time are set] Would you like a reminder text, phone call or email the day before your interview?

The interviewer should set the appointment time for that day or the next available day at a time that is convenient for the participant and when an interviewer is available to conduct the interview. The interviewer will then record the appointment time and reminder contact preference on the electronic *Interview Calendar* and return the contact information file to the study file in the interviewers' office.

### ***Missed Interview Protocol***

At times, participants may miss an interview. **If a participant misses her second interview**, interviewers should complete the 2<sup>nd</sup> interview, even if it is already time for her 3<sup>rd</sup> or subsequent interview. This is because the second interview tool contains critical questions that are not included in the subsequent interviews.

**If a participant misses an interview but is contacted up to one month before her next interview**, the previous interview should be completed immediately **and** she should be scheduled for her next interview at the originally scheduled date. This will bring her back to the original schedule. For example: Let's say that participant #10-100 is due for her 3<sup>rd</sup> interview in January, however, she does not respond to our attempts to reach her. If she calls back randomly in mid-May, the interviewers should immediately complete her 3<sup>rd</sup> interview and then and call her back in July to complete her 4<sup>th</sup> interview so she is back on the 6-month schedule from her original recruitment date.

**However, if the participant contacts us back within a month of her next interview date**, the interview should do the subsequent interview unless the missed interview was a 2<sup>nd</sup> interview. For example: Participant #10-100 is due for her 3<sup>rd</sup> interview in January and calls back in mid-June instead of mid-May (as in the example above). Interviewers should complete her 4<sup>th</sup> interview then and leave the 3<sup>rd</sup> interview as missed.

If a participant cannot be reached for one of her follow-up interviews (i.e, the 2-11<sup>th</sup> interview), her file will remain in the 'active participant' section of the file cabinet and attempts will be made for subsequent check-in calls and interviews in accordance with the protocol described above. If the participant misses two interviews in a row (and the check-in calls in between), her file is to be moved to the 'lost to follow up' file and this will be recorded on the electronic *Interview Calendar*. No further attempts to contact the participant will be made and she will be officially considered 'lost to follow up'. There are exceptions and extraordinary circumstances to consider before a participant becomes officially 'lost to follow up', so the interviewer should discuss this decision with the Project Director before finalizing it. In all cases, when a participant is called 'lost', the Project Director should be informed via email.

### ***Follow-Up Interview Protocol for Interviewers***

The interview protocol for interviews two through eleven is essentially the same as the first interview protocol and the interview guides for interviews three through eleven are nearly identical. The participant's interview dates will be recorded in the electronic *Interview Calendar*. The interviewer must adhere to the protocol above to complete the follow up interviews. As above, this protocol is summarized in the *Second Interview Checklist* (Appendix Q) and the *Interview Checklist 3-11* (Appendix R). These checklists are used for training new interviewers and for reference purposes.

*In the case of the final interview*, the interviewer should use a slightly different script to close the interview:

Thank you so much for your time. We really appreciate your participation in the study over these past five years. We believe that your participation in this study will make a difference in women's health care policy in the future. I'll be sending you a \$50 gift card to thank you for your time. Would you like a Target card or a Wal-Mart card? [Record preference on *Participant Tracking Form*]. In order to make sure the gift card reaches you, can I check to make sure that the address I have for you is correct? [Interviewer must record any change to address on new *Participant Contact Form*]. Thank you again; you should receive the gift card in the next week. Thank you again, take care and goodbye.

After completing the final interview, all of the above procedures should be followed as in each of the earlier interviews. After the file is complete, it will be "closed."

## SECTION THREE: INTERVIEWER SKILL BUILDING AND RESPONSIBILITIES

### ***Confidentiality and Informed Consent***<sup>2</sup>

All study participants have a right to privacy, informed consent, and protection from harm. This section contains information about how interviewers can uphold these rights.

#### **Confidentiality**

Participants should be informed of the confidential nature of the interviews when they are first told about the study, as well as during the informed consent process. By agreeing to participate in this study, participants are entrusting interviewers with highly personal information that they may not have discussed with other people. Interviewers and all other members of the study must, in turn, keep the promise to protect their confidentiality. Please keep in mind that a breach in confidentiality could have severe, negative, and unknown consequences for a participant. You must protect the privacy of the people you interview.

To protect confidentiality, the following measures must be taken:

- **Participants should be interviewed in a private place, to the extent possible.** The presence of others always affects the interview, even if only one side of the conversation is audible. If the interview is interrupted or the participant expresses reservation about answering questions due to lack of privacy, reschedule the interview.
- **The only study documents that should have participant names recorded on them are the consent form, the study register, and the participant contact form.** These documents are kept in a secured location and are not be shared with anyone outside the study staff. All other study documents are linked to participants through study identification codes, rather than

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<sup>2</sup> This section of the OP has been altered from a similar section of an OP from Cynthia Harper's Telephone Access Survey 2007, Harper C., Blum M., Stratton L.

names. All electronic files are password protected. The server is also protected.

- **Interviewers should never reveal a participant's identifying information to anyone outside of the study.** In addition, interviewers should only discuss confidential information with each other and with other research staff when it is necessary for work-related reasons. Each time interviewers go through the consent process with a participant they agree to respect their privacy. Discussing experiences and sharing interview summaries among project staff is an important way to communicate important information, identify and resolve different issues, and to support each other. However, unless it is necessary for the purposes of the research, it is preferable to discuss interviews using generalities, such as, "I spoke with a participant yesterday who said...."
- **In the unlikely event that an interviewer personally knows a participant, that interviewer should not conduct the interview, and should ask another interviewer to do it instead.** Given the sensitive nature of the questions in the interview, participants may already have difficulty honestly answering these questions due to embarrassment and anxiety that confidentiality could be breached. Already knowing the interviewer could heighten these fears and further reduce their willingness to provide candid answers.

### **Informed consent**

Informed consent is a process by which an individual voluntarily expresses his or her willingness to participate in research, after having been informed of all aspects of the research that are relevant to his or her decision. The informed consent process is guided by three basic ethical principles that were first laid out in the 1979 Belmont Report (aka Ethical Principles and Guidelines of Protection of Human Subjects, [www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm)), and which are still relevant today. These principles include 1) respect for all persons (autonomy, protection of those with diminished autonomy), 2) beneficence (do no harm, maximize potential benefits), and 3) justice (just distribution of benefits). These ethical principles have been codified by law and articulated through guidelines and regulations that are overseen by the US Health and Human Services Office for Human Research Protections (<http://www.hhs.gov/ohrp>). Institutions that conduct research must work with Institutional Review Boards (IRBs), which are charged with the task of making

sure that the research is conducted in a legal and ethical manner. The study protocol, procedures and documents have been approved by the UCSF IRB (aka Committee on Human Research, or CHR) and will be reviewed on an annual basis, or more often if/when changes are made.

Through the informed consent process, researchers and participants make a mutual commitment to each other. This commitment, which is documented using an informed consent form, begins before the participant undergoes any study procedures and continues throughout the course of her participation in the study. In the case of this study, **both oral and written informed consent must be obtained from participants before any interviews are conducted. It is not acceptable to conduct an interview or to collect any data beyond basic contact information until oral consent has been granted *and* the signed consent form is on file in the research office.**

This part of the manual will specify the elements of informed consent that must be conveyed to research participants through the informed consent process. It is the responsibility of the Principal Investigator, and her assigned staff, to deliver all required information to potential research participants. However, responsibility for informed consent does not end with preparation of an adequate informed consent form. It also is the responsibility of the Principal Investigator and designated study staff to: deliver all required information in a manner that is understandable to potential participants, assure that informed consent is obtained in a setting free of coercion and undue influence, ensure that the participant understands the information, and adequately document the process. These four components of obtaining informed consent are described below.

### **Delivering information**

All prospective participants will receive a copy of the Informed Consent Form (Appendix H) in their clinic recruitment packets. If a prospective participant is determined to be eligible and willing to participate at the point of recruitment, the interviewer will lead her through the informed consent process. The interviewer should ask the woman to take the appropriate consent form out of the packet given to her, and follow-along while she guides a conversation about the study procedures, risks and benefits. The recruitment script (included in Section Two of this document) provides a guide for the informed consent conversation. However, it is important that there be adequate time and space given to the participant to ask any questions she might have.



While it is important that interviewers review all sections of the informed consent forms, it is equally important to keep the informed consent conversation simple and straightforward, and to avoid using medical jargon or “legalese.” It is essential not to focus on the written form at the expense of patient comprehension. It is acceptable for interviewers to paraphrase what is stated in the consent form, however, *the following key points must be highlighted:*

- the purpose of the study
- that participation is voluntary
- how confidentiality will be maintained
- the number and timing of study interviews and how long they will take
- the risks and benefits of participation
- the reimbursement protocol
- limits to confidentiality (mandated reporting guidelines)
- who to call with questions or concerns ( contacts and UCSF CHR contacts)

It is important that the participant feels he or she can ask questions, and that the interviewer takes the informed consent process seriously. Establishing a collaborative relationship during the informed consent process can facilitate an ongoing relationship that is trusting and positive.

### **Avoiding coercion and undue influence**

During the informed consent process, study staff members should take care not to overstate the possible benefits of the study, or to understate the possible risks. The staff member should encourage the participant to take as much time as she needs in deciding whether or not to participate before making a decision. However, for the study, enrollment and informed consent has to take place on the day of the abortion appointment. If the participant is to receive an abortion that day, the informed consent must occur before she is medicated (since mind-altering medications can impair her ability to give informed consent).

### **Ensuring participant comprehension of information**

The participant must not be asked to agree to take part in the study, or sign the Informed Consent Form until he or she fully understands the study.

Interviewers should avoid using complicated explanations of the study and should instead state the purpose of the study clearly and simply. In addition to ensuring comprehension, this approach decreases participant’s anxiety and contributes to a positive interviewing relationship.

If the participant appears not to grasp the purpose and procedures of the study even after they have been explained and questions have been answered,

interviewers should not ask her to sign the informed consent form. Similarly, if the participant has concerns about possible adverse impacts on her if she were to take part in the study, or indicates that she may have difficulty adhering to the study requirements (for example, if she states that she is unable to commit to interviews for the duration of the study), she should not be asked to sign the informed consent form or enroll in the study. Also, if the interviewer suspects or the participant reveals that she is under the influence of mind-altering medications, drugs or alcohol at the time of the informed consent process, she should not be asked to sign the form that day (This includes pain medications for an abortion procedure).

### **Documenting the process**

Regulations require that informed consent be documented by the use of a written informed consent form approved by the UCSF IRB and signed and dated by the participant. (In this study, these procedures will not happen on the same day. The participant will sign and date the form on one day and the staff member who administered the form will initial and date the enrollment log when the form arrives in the research office.) To fulfill this requirement, study staff must ensure that all signature and date requirements on the Informed Consent Forms are completed per IRB requirements. It is essential that the date documented on the form precede the in-depth interview date. Regulations also require that participants be given a copy of the Informed Consent Form.

In the case of the study, study staff must clearly explain that the woman should sign the pink or yellow copy of the consent page and return it to the point person after reviewing the form on the phone. The point person will fax the form immediately and send the original at a later date. The rest of the contents of the packet should be taken by the participant. If a participant chooses not to sign, she cannot participate in the study.

The signed Informed Consent Forms will be considered a permanent part of the participant's record but must be filed in a separate location as soon as they arrive in the mail. The consent forms will be audited in the same manner as other records. Study staff cannot sign participant names on Informed Consent Forms.

### **Ongoing informed consent**

As stated earlier, informed consent should be thought of as an ongoing process that continues throughout the entire study. Given the ongoing nature of

informed consent, key elements of informed consent also should be reviewed at any study contact. In the preface of each follow-up interview, participants are reminded that the study is confidential, that certain answers may trigger the necessity of reporting and that they have the right not to answer any questions that make them uncomfortable.

## ***Study Methods and Key Research Concepts***

### **Study Methods**

This is a multi-faceted study that will use both quantitative and qualitative methods to examine the research questions that it poses. The first phase of the study utilizes telephone interviews which are largely quantitative in nature— participants are asked to answer questions using a limited set of response categories— though there are a handful of questions with open-ended response options. Future study activities are being planned which will involve qualitative interviews with a subset of participants and providers. These interviews, which will be conducted by social scientists, will ask open ended questions and will allow the participants to answer more freely, using their own language and determining for themselves what is important to share. Quantitative and qualitative methods each have unique advantages and disadvantages; quantitative methods allow researchers to calculate rates and perform multivariate statistical analyses, while qualitative methods are especially useful to explore complex areas of research and to help develop hypotheses for future research.

### **Relevant Research Concepts**

The following research concepts are important to successful data collection for :

**Bias** of various kinds can influence participants' responses (intentionally or unintentionally). *Recall bias* occurs when someone can't accurately recall an event or events from the past. *Social desirability bias* occurs when participants perceive or worry that interviewers have an opinion about a specific issue and alter their responses to make themselves appear more favorable to the interviewer.

**Validity** is whether the researcher is capturing (or measuring) what is happening in reality. So, in our study, the study data is valid if the

information we collect about participants is accurate or correct, and not a distortion of reality.

**Reliability** is whether you are being consistent in what you measure, i.e. the data from different interviews are reliable if they are collected and recorded in a consistent manner.

**Inter-rater reliability** refers to consistency between the interviewers. High inter-rater reliability means that the interviews by one interviewer can be compared to those of another interviewer because they are conducting and recording the data in an objective and consistent manner, and have approached the interview process in the same way.

Some of the main data collection challenges of this type of study are:

- a) Social desirability bias
- b) Poor validity
- c) Poor inter-rater reliability
- d) Keeping data collection process steady while sounding “normal” on the phone

This section of the manual will discuss interviewing strategies that can help to minimize these challenges.

### ***Interview Strategies***<sup>3</sup>

Interviews are different from normal conversations in that the interviewer guides the dialogue using fixed questions from an interview script and doesn't share his or her own opinions or ideas. In quantitative interviews such as the ones that this study employs, all participants are asked the same carefully-worded questions in the same order. Most questions have fixed response categories that the participant can use to answer based on her own experiences and opinions. In order to allow for inter-interviewer reliability, **interviewers should read each question exactly as it is worded**, each and every time. This is the only way to provide consistency across interviews. If an interviewer notices that a particular question is difficult to ask, or difficult for participants to understand, she should

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<sup>3</sup> This section of the OP has been altered from a similar section of an OP for the Provide Diaphragm Study, PI: Cynthia Harper, PhD, primary author, Heather Gould, MPH (2005).

inform the Research Coordinator, Project Director or Principal Investigator (PI). **Any changes to the interview script must be approved by the PI.**

### **Becoming familiar with the interview script**

Read the interview script several times with an eye to the **overall questions** being asked. How will these questions be used to answer the research question? What is the overall “gist” and flow of the interview? What is the general format of the interview?

Read the interview script with a focus on **your role as an interviewer**—Read the prefaces and questions out loud. Notice the interviewer instructions and skip patterns. Notice the parts of the interview that require more careful attention to flow (e.g., skip patterns) or documentation (e.g., qualitative questions).

Practice through **role plays**. Start out by practicing administering the interview without worrying about documentation. When that becomes comfortable, move on to documenting responses as you go. Practice the informed consent process and the Child Health Development questionnaire, in addition to the primary interview script. Practice in person and over the phone with as many people as possible. Make sure to vary your participant scenarios so that you can practice administering all sections of the interview. Notice whether there are questions or sections that appear especially difficult to ask, and practice those some more! Before long, you will know the interview inside and out and may even find yourself practically reciting the questions word for word (but read them anyway).

### **Key interviewing strategies**

This section of the OP Manual provides an overview of key interviewing strategies to successful interviewing:

- Be prepared when you begin an interview
- Establish a collaborative relationship with participants
- Communicate a neutral and non-judgmental attitude
- Maintain objectivity during the interviewing process
- Read interview questions exactly as they are worded in the topic guide
- Ask all questions, even if they have already been answered
- Read interview questions dynamically
- Use your voice to elicit honest, accurate and thorough answers
- Set the pace of the interview
- Give participants time to answer the questions asked

- Be sensitive to participants' feelings
- Address participant fatigue, discomfort, boredom, or antagonism
- Be a good listener and never finish participants' sentences for them
- Use time wisely (and interrupt the participant if necessary)
- Be careful about self-disclosure

### **Be prepared when you begin an interview**

It will be easier for interviewers to maintain a natural flow of conversation if they are familiar with the study procedures and questions. Interviewers should prepare for conducting interviews field by reading and practicing the forms, questionnaires, study protocol, training materials, and handouts multiple times. In addition, interviewers should make sure that they have all the necessary supplies and documents before getting on the phone with a participant.

### **Establish a collaborative relationship with the participant**

The quality of the data gathered in study interviews depends in large part on the skill of the interviewer and his or her ability to establish a positive interviewing relationship with the participant. The goal of the interviewer is to ask study questions clearly and to record the participant's answers as accurately as possible. An interviewer uses verbal and non-verbal techniques to encourage participants to provide the most honest, accurate, and thorough answers they can (specific examples of these techniques are described below). Interviewers should demonstrate through their words and their actions that they are non-judgmental, friendly, encouraging, serious, and interested in what the participant has to say. In addition, acknowledging something positive about the participant and giving ample time to the informed consent process can help to build a trusting relationship. Providing positive feedback to the participant throughout the interview by expressing appreciation and praise (while not expressing judgment about their responses) helps him or her feel that the interview is worthwhile and helps to nurture a positive interviewer-participant relationship (Patton, 1990). Examples of such comments include the following"

- "Thank you for taking the time to answer these questions."
- "It is really helpful that you are giving these questions such careful thought."
- "Thanks for sharing your thoughts about that. I know your responses will be very useful for our research."
- "I really appreciate you being so thoughtful and sharing your experiences with me."

Perhaps the best way to think of the interviewer-participant relationship is as a “collaborative partnership.” In such a partnership, the interviewer fully explains the study purpose and procedures, encourages and responds to the participant’s questions, and asks the interview questions clearly, monitoring the quality of the data and asking for clarification when needed. The participant shares his or her observations and experiences as openly and accurately as possible, asking for clarification when it is needed. In this way, the interviewer and the participant work together to produce quality data that is useful to the research (Weiss, 1994).

### **Communicate a neutral and non-judgmental attitude**

A good way for interviewers to communicate a neutral and non-judgmental attitude is to act as “interested listeners” who “reward participation without evaluating the participant’s responses” (Fontana & Frey, 2003). This means letting participants know that their responses are being heard and appreciated, while not openly agreeing or disagreeing with what they say. Using expressions such as “I see,” “That is interesting,” or “Okay, thanks” communicates that one is paying attention, without suggesting agreement or disagreement. Interviewers should never respond to a participant with astonishment, impatience or criticism or suggest answers to questions. If a participant appears sensitive to judgment, it can be helpful to reinforce the confidential nature of the interview, to suggest that there are no correct or incorrect answers, or to remind her that it is an option to skip a question.

### **Maintain objectivity during the interview process**

While it is important for interviewers to establish a positive relationship with participants and to gain their confidence, it is equally important to maintain a degree of objectivity. Interviewers should aim for what is known as “balanced rapport,” which is casual and friendly but also directive and somewhat impersonal (Fontana & Frey, 2003). In other words, the interviewer should stay neutral—not too distanced or too connected to the experience or feelings of the participant (Weiss, 1994). This can be especially difficult when participants express feelings of isolation and sadness or when they express strong opinions—such as prejudices or biases—that differ from those of the interviewer. However, maintaining objectivity is crucial to the success of the interview. If it is not possible for an interviewer to maintain objectivity with a particular participant (or vice-versa), it is better to end the interview early and have another interviewer conduct it. If, according to the Referral Protocol, a participant should be provided with information or resources (e.g., domestic violence or sexual

assault referrals), the interviewer should do so only after the interview is complete, unless it is a suicide prevention referral.

Part of maintaining objectivity is taking care not to “bias” participants inadvertently. Especially since abortion is surrounded by social stigma, social desirability bias is a major concern. Interviewers must take care not to transmit their own opinions about the study questions to participants. To do this, it is important for interviewers to be aware of their own values and challenges with the issues at hand, to avoid the temptation to educate or “be the expert” and to intervene unless when required or allowed (see below for details on making reports and referrals).

### **Read interview questions exactly as they are worded in the interview script**

Interviewers should always read each interview question exactly as it appears in the interview script. It is extremely important to avoid re-phrasing questions, as doing so can change the meaning of the question and make it inconsistent with other participants’ interviews. Deviating from the question wording or sequence leads to difficulty comparing data across participants. This is extremely important in this study, since multiple interviewers will be conducting interviews. Any changes to the interview script must be approved by the PI.

### **Ask all numbered questions, even if they have already been answered**

Every numbered question in the interview script should be asked, even if it has already been specifically answered by the time the interviewer gets to it. If the interviewer senses that the participant is annoyed by this, it is OK to say, ‘I know you have answered this already, so forgive me for asking, but I have to ask all the questions in order.’

### **Read interview questions and response categories dynamically**

When asking questions, interviewers should speak slowly and clearly but also dynamically, to avoid sounding like a machine or a telemarketer. Adjust your voice tone and volume, as appropriate, and emphasize the important words in a sentence so that its meaning comes through. Be aware of how loudly or softly you need to speak in order to be heard and understood. Interviewers are expected to come to know the questions almost by heart. However, even if this is the case, they should read each question as it is worded.



### **Use your voice to elicit honest and accurate answers**

Even over the phone, where body language is not visible, interviewers can bias participants inadvertently by using a tone of voice, volume or vocal utterances that suggest an opinion about something that has been said. Therefore, it is essential for interviewers to be mindful about the way they use their voice throughout the interview, even when not asking a question. Paying attention to the communication of the participant is also essential as it can help interviewers understand and respond to participants' thoughts or feelings.

### **Set the pace of the interview**

As important as it is to allow enough time for participants to respond fully to all questions, it is also important to make sure that the pace of the interview is not too slow. Especially with the open ended questions, participants will often give longer or shorter answers based on how much time the interviewer allows for him or her to answer the questions that came before. Thus, pacing the questions in such a way as to elicit the information desired while keeping the interview moving is a skill interviewers must develop. Every participant is different. Some will respond to questions very quickly, while others may have to think longer to come up with a response, or may even change their response after giving more thought to the subject. Interviewers should always account for this variation when conducting an interview. If participants seem overly concerned about time, it is helpful to let them know approximately how much time is left until the interview is complete.

### **Give the participant time to answer the questions asked**

Interviewers should not be afraid of silence and should give the participant ample time to think over a question before responding. If an answer is not forthcoming after a reasonable amount of time, it may be because the participant did not understand the question, or was unsure how to respond. In these cases, you may need to repeat the question (as it is written in the interview script) or the response categories. If the participant still has trouble with the question, you should share it with the Research Coordinator, Project Director or Principal Investigator (PI) so that the question wording can be improved.

### **Be sensitive to participant's feelings**

As many of the survey questions ask participants to think and talk about highly personal and controversial issues, interviews can bring up a range of emotions for participants. Additionally, the process of answering a long list of survey

questions in itself can be mentally tiring. For these reasons, interviewers should be sensitive to how participants feel. If a particular question appears to make the participant feel uncomfortable or upset, it is acceptable to briefly talk about the issues brought up by the question, but only in general terms. For example, when an interviewer notices that a participant is struggling with a question, it can help for him or her to provide positive reinforcement by saying “I know that was a difficult question and I really appreciate you working with it because what you are saying is very meaningful and relevant to the research” (Patton, 1990).

### **Address participant fatigue, discomfort, boredom, or antagonism**

Interviewers should also be alert to indications of fatigue, discomfort, boredom or antagonism. If these arise, it is best to determine the cause and address it right away. Adjusting the speed of the interview, letting the participant know how close she is to the end of the interview, or reminding her about confidentiality may help her feel more comfortable. In the case of an antagonistic participant, it is also acceptable for interviewers to redirect the “blame” for the discomfort of the interview by saying that they are simply doing their job and are required to ask everyone the same questions.

### **Be a good listener**

Interviewers should be careful not to assume that they know what people are trying to say before they say it. Instead, they should listen carefully, and ask for clarification when a participant’s response is unclear. Interviewers should never finish people’s sentences for them or compete for control of the interview. **It is not the role of the interviewer to attempt to educate participants, challenge their opinions or beliefs, correct misinformation, or try to change their behaviors.**

### **Use time wisely and interrupt the participant, if necessary**

The time dedicated to an interview is limited and precious. If participants ramble off topic, the interviewer should carefully guide the conversation back to the question at hand. This can prevent mental fatigue and burnout for both the participant and the interviewer. (Remember, participants don’t know how many questions you plan to ask but they *are* aware of how much time they have). Interviewers are often concerned that it is impolite to interrupt a participant. However, if it is done with sensitivity, the participant will appreciate it when the interview is completed within a reasonable time frame. Patton (1990) suggests the following approach to interrupting a participant: “Let me ask you to stop for

a moment because some of what you are talking about now I would like to ask you about later. First, please tell me....”

### **Be careful about self-disclosure**

Interviewers should be very careful about self disclosure. While interviewers are encouraged to be themselves, it is best to avoid providing any information that will shift attention away from the participant (or influence his or her responses). If pressured to share an opinion on the study topic, interviewers can redirect the conversation by saying “I am here today to listen to your experiences” or “Your opinion/experience is what matters to the research, not mine.” Use discretion when participants ask about your opinions and experiences and opt out of such conversations as gracefully as possible. Remember, the Turnaway study is a long-term study and a conversation that occurs at one interview could change the way the participant thinks or responds to the next interview.

### **A word about intervention...**

Interviewers must not challenge participants’ knowledge or beliefs, correct misinformation, or try to change their behavior. It is not the role of the interviewers to educate or advocate for patients. However, even asking interview questions can serve as a type of intervention by spurring participants to think about their beliefs, opinions or behaviors. The next section of this manual describes the Turnaway Study’s reports and referrals protocols which interviewers can follow to respond to issues that challenging situations our participants may be facing and that we are required to report.

## ***Reports and Referrals Protocols***

As researchers, we have a responsibility to protect the interests of our participants. In the course of conducting study interviews, participants may reveal personal information that makes the interviewer concerned for their safety or well being, or that of someone else. In some cases, the information a participant shares may trigger a reporting requirement. In other cases, the information may compel the interviewer to provide the participant with a referral to an organization that can offer her support services. This section of the OP outlines Turnaway Study policies and protocols for when and how to make reports and referrals. These policies are informed by the legal and ethical directives of UCSF’s CHR, as well as applicable federal laws. Study staff are expected to learn and adhere to these policies at all times. A compilation of state-

by-state hotline and support service numbers, reporting forms and other resources can be found in the **Reporting and Referral Resource Binder** in the Turnaway Study interviewer's office. Specific modules for child abuse reporting and suicide prevention are described below and copies of these are also included in the resource binder.

### **What issues trigger a responsibility to make a report?**

Most information obtained as part of a research study is confidential. However, there are some types of information that, when revealed, necessitate an official report to an appropriate agency. These include:

- 1) Child abuse
- 2) Elder abuse (abuse of a dependent adult)
- 3) Intent to harm (e.g., injure or kill) another person
- 4) Imminent suicidal ideation

Reporting requirements vary from state to state making it difficult to synthesize the patchwork of laws into a policy that provides guidance for every circumstance that participants may report. We have relied on federal definitions as well as California state law in the creation of our reporting guidelines. According to CHR guidelines and federal and state laws, we are required to report instances of suspected minor child abuse (abuse of a person under 18 years of age by an adult who is responsible for them), to Child Protective Services (CPS) for the state in which they reside. We *must* make a report to the state's CPS if we discover child abuse, defined by federal law as: **“any recent act or failure to act on the part of a parent or caretaker, which results in death, serious physical or emotional harm, sexual abuse, or exploitation, or an act or failure to act which presents an imminent risk of serious harm.”** California law further defines the following forms of abuse:

- **Non-sexual physical abuse or neglect of a minor.** This includes any situation in which a child is physically injured by other than accidental means, is subjected to willful cruelty or unjustifiable punishment, or is neglected by a parent or caretaker who fails to provide adequate food, clothing, shelter, medical care, or supervision.
- **Sexual abuse**, which is defined as coercive, non-consensual, involuntary sexual conduct between a minor and a perpetrator of any age.
- **“Lewd or lascivious acts”** with a discrepancy in age between the minor and a partner. This includes acts that are voluntary and consensual. Refer

to the “age table” from the National Center for Youth Law” in the **Reporting and Referral Resource Binder**.

**Keep in mind that we must report abuse of participants in our study who are minors, as well as the minor children of our study participants. Reports of abuse by adult participants does not need to be reported to CPS or the police; however, referrals can be made when an adult participant reports domestic violence or sexual abuse, including rape, occurring in the past six months.**

In general, child abuse definitions in state laws exempt hitting or spanking that occurs in the course of “reasonable punishment” or neglect as a result of a lack of financial resources. Complete information on state-specific laws for minor abuse is included in the **Reporting and Referral Resource Binder**. A specific *Child Abuse Reporting Module* and protocol is described below.

In addition to child abuse, we are required to report instances of elder abuse and stated intention to harm another person (such as if a participant says she plans to hurt or kill another person). Protocols to use if a participant divulges committing elder abuse or a plan to hurt or kill someone else are described below. These reports should be made to either the California police department, who will follow up accordingly with authorities in the state where the participant lives or the state or county specific reporting numbers listed in the **Reporting and Referral Resource Binder**. While it is unlikely that we will come across these latter two scenarios, we need to be prepared to handle them if we do.

In some cases, suicidal ideation (an intention to hurt or kill ones self) requires a report for both adult and minor participants, and in other cases it requires a referral. A report may be required when suicide is imminent, while a referral is required in non-imminent cases. A specific *Suicidal Ideation/Prevention Module* is described below.

### **What issues trigger a responsibility to make a referral?**

As described above, the research team is ethically compelled (and compelled by our CHR) to refer participants to support service organizations when participants express suicidal ideation. Each Turnaway Study interview asks participants to answer a question regarding how much they have been bothered during the past 7 days by “thoughts of ending your life.” If a minor or adult participant answers “a little bit,” “moderately,” “quite a bit,” or “extremely” to this question, or if she spontaneously raises the issue herself, interviewers MUST

adhere to the suicide prevention protocol described below. **It is the policy of the Turnaway Study to take statements about suicide extremely seriously and to address such statements directly, each and every time that they are raised.** If a participant refuses to answer the suicide question in an interview, the *Suicidal Ideation/Prevention Module* would not be employed; however, the interviewer should give the participant the hotline number at the end of the interview.

In addition to abuse of minors, **it is also Turnaway Study policy to offer adult women referrals for current or recent domestic violence or sexual abuse, including rape.** When adult women divulge information about being a victim of abuse we are not required to make a report to law enforcement.

In the course of responding to the survey questions, it is likely that some participants will share other types of personal information that is of concern to the interviewer. For example, participants may report sexual risk taking, emotional problems, drug and alcohol use/abuse, physical health problems, etc. In concert with expert advisors, we have decided NOT to make referrals for these issues, which are sometimes described as “lifestyle” issues.

**To summarize, the Turnaway Study interviewers should make reports or give referrals to the appropriate agency every time a participant divulges information about current or recent child abuse, elder abuse, intentions to hurt herself or someone else, domestic violence or sexual abuse, including rape.** Interviewers should NOT offer referrals for “lifestyle” issues, such as drug or alcohol use or for post-abortion or post-partum counseling until AFTER the final study interview (interview 11). At that point, interviewers can use their discretion and the list of available services and hotlines to discuss such issues with participants.

<b>Issue</b>	<b>Action Required</b>	<b>Agency to Report or Refer to</b>
Child abuse, including sexual abuse of minors (participants and non-participants)	Report	Child Protective Services (CA or state specific CPS)
Elder abuse	Report	Police or other state authority listed in <b>Resource Binder</b>
Intent to hurt someone else	Report	Police
Intent to hurt or kill self	Referral or Report, depending on risk assessment	<i>Non-Imminent Risk:</i> National Suicide Hotline <i>Imminent Risk:</i> 911 or other, as per protocol
Current or recent domestic violence (adults)	Referral	Domestic violence hotline
Current or recent sexual abuse/rape (adults)	Referral	Sexual abuse hotline

**Now that I know what issues trigger a responsibility to make a report or a referral, how do I do it?**

The Turnaway Study has developed the following protocols and modules for making reports and giving referrals, and for documenting these actions in the participant’s study record. These protocols are designed first and foremost to serve the participants. In addition, they make the report and referrals process streamlined and consistent across interviewers and participants, which is important to decrease bias in data collection. Further, these protocols are designed to assist the interviewers in carrying out what is sometimes a difficult task.

This task is also made easier by the fact that the limits of confidentiality are clearly and routinely discussed during the informed consent process, and again at the beginning of each interview. Our experience instructs us that being forthright about the limits of confidentiality from the outset, and reminding participants about those limits periodically, prepares them to be more receptive when reports or referrals are needed. In some cases, participants may willingly share information with us specifically because they want us to act on their behalf. For example, a minor who is being abused may tell us about it because she knows we will make a report to the authorities who can help her. In other cases, participants may prefer that a report not be made or a referral not be offered, even when we are required or compelled to do so. In either case, if we are

transparent about our responsibilities and respond to participants with sensitivity, we can promote a positive and trusting relationship, even when reports or referrals are needed but not wanted.

### **General guidelines for making reports and referrals**

- Be aware of the types of information that trigger a report or referral so that you can respond quickly when the need arises.
- Become familiar with the modules, reporting forms and lists of referrals in the **Reporting and Referral Resource Binder** so that you can call them up at a moment's notice.
- Use the PI, Project Director and Research Coordinator as resources when making a report and/or dealing with an imminent suicide situation.
- Use your own discretion to decide whether to discuss reports and give referrals during the interview or afterwards. Imminent suicide is dealt with immediately (interrupting the flow of the interview) and other referrals are given at the conclusion of the interview.
- Use Turnaway Study scripts/modules that appear in CASES at the end of the interview or the **Reporting and Referral Resource Binder** as references when making reports or offering referrals. Read the scripts word for word in a natural voice or paraphrase the text *very closely* to ensure consistency across interviewers.
- Don't probe for information that could lead to a report. Reports and referrals should arise when the normal course of the interview reveals information that leads to a reporting responsibility or referral. While we do have a duty to report abuse, as outlined above, it is not our role to probe for information that will be of interest to investigators. For example, it is not appropriate to ask minor participants the names or ages of their sexual partners or even perpetrators of sexual abuse since these are not questions that we normally ask in the Turnaway Study interviews.
- Reports must be made even if the participant tells us that the incident(s) have been reported in the past unless a report was previously made by another member of the Turnaway team.
- We only need to report incidents where the participant was a victim (or survivor) of abuse, not incidents where she was a perpetrator, except in cases of child or elder abuse.
- When making reports, it is best to let the participant know that you are making a report. Tell her that you are following the rules required of you and that you have her interests in mind. Answer her questions as fully and openly as possible. An exception to this is in the case of a participant



who has told you that she plans to hurt or kill someone else. In this case, it is recommended but not required to let her know that you will be making a report.

- Use the *Reporting and Referral Form* (Appendix U, and see below) to document the actions you took. Discuss the report or referral with the Project Director and have her sign and date the form. The form is then filed in the Reporting and Referral Binders in the Project Director's office and a pink 'chart flag' is placed in the participant's brown file on top of the tracking form that coincides with the interview when the incident was reported.
- After a report or referral is made, if the referral was accepted, follow up with participants at subsequent interviews by asking, "During your last interview, we gave you the number of an organization that offers support for people who [behavior that warranted report/referral]. It's okay if you didn't, but I was wondering if you ever contacted them and, if you did, whether they were they helpful in any way?" Document participant responses on the *Reporting and Referral Form*.

## **Reporting and Referral Form**

The *Reporting and Referral Form* is used to document every report made and referral given. The *Reporting and Referral Form* documents the following:

- Incident or information that prompted report/referral
- Summary of conversation with participant regarding reporting or referring
- Discussed with supervisor/supervisor signature
- Reports
  - Name and phone number of organization report was made to
  - Date and time report was filed
  - Summary of report made
  - Reporting organization's comments
- Referrals
  - Name and phone number of organization to which participant was offered a referral
  - Whether the participant accepted or declined the referral
- Comments
- At Follow-Up Interviews
  - Did participant call referral number?
  - Did participant find the referral helpful?

## □ Updates

This form must be filled out for every report made or referral given. This will allow us to follow up with participants appropriately, and to analyze the frequency and usefulness of our report and referral protocol at the end of the study. In addition, when reports are required, interviewers should alert the Project Director, who can assist with making reports if necessary.

## Report and Referral Modules and Scripts

### Child Abuse Reporting Module

Suspected cases of child abuse *must* be reported to CPS. While state requirements vary, many require that we make a verbal report (by phone) as soon as possible and submit a written report shortly thereafter. If you are uncertain of whether the information you have constitutes abuse, the CPS hotline is available for anonymous consultation. This number, sample reporting forms and other relevant information is located in the **Reporting and Referral Resource Binder**.

If a participant answers a question in a way that makes you suspect that she is either a perpetrator or victim of child abuse—or discloses knowledge of any child abuse, interviewers *must* adhere to this child abuse reporting protocol.

- 1) When a participant divulges information that leads you to suspect child abuse, **offer support** through reflections and empathetic statements.

Do NOT: Ask probing questions (i.e., “When did that happen, “Who did that to you?”, “Who was involved?”)

Do NOT: Make interpretations (“You must be very angry with...”, “Maybe you did that because you felt...”)

Do NOT: offer opinions or advice other than the use of referrals (“You should tell/confront him.”)

- 2) **Remind** the participant of the limits of confidentiality and tell her that you think a report is warranted.

- 3) Provide the participant with appropriate **referrals** and support their decision to talk to someone. Ask the participant to call you back if none of the referrals work.

*“I have a phone number for a talk line where you could speak with a trained counselor and get information about local resources. I’d like to give you that number so you can call them when we get off the phone or for you to hold on to in case you need it in the future. Would that be okay? Do you have a pen? The number is for the [Appropriate Referral]. You can call them any time and they will provide you support and let you know about other resources in your area. The number is: [Appropriate Referral Number].”*

For MINORS, if appropriate:

*“I am really very concerned about your welfare and I want to encourage you to talk with your parents or another adult. Even if it is hard to talk about how you are feeling, there are people who care about you who can help.”*

- 4) Immediately after you are off the phone with the participant, **consult** with the Project Manager or PI to review the case and to determine what steps are necessary. They will either ask you to make the report, or make the report themselves.
- 5) **Complete** the *Report/Referral Form* and file it appropriately. Place a pink chart flag on top of the tracking sheet that coincides with the interview where the incident was recorded in the participant’s brown file.
- 6) If appropriate, **follow-up** with a call that afternoon or the next day to check-in with how the participant is doing and to see if she needs additional referrals.

### **Suicidal Ideation/Prevention Module**

Each interview includes a question about suicidal ideation. If a participant answers “a little bit,” “moderately,” “quite a bit,” or “extremely” to this question, or if she spontaneously raises the issue herself, interviewers *must* adhere to this suicide prevention protocol. **Typically, interviewers find it most comfortable to initiate the protocol immediately, rather than at the end of the interview. We recommend this practice.**

*I appreciate your honesty and I want to take a quick break from our interview to ask you a few more questions about what you just told me. First, can I confirm you are at the address at [contact address]? Are you there by yourself? If not, who is there with you?*

**SECTION A. Screen for suicide risk<sup>4</sup>**

*Q1. Suicide last week*

**Over the past week, how seriously did you:**

	Not at all	A little	Moderately	Very	Extremely
<b>Think that you would be better off dead or wish you were dead?</b>					
<b>Want to harm yourself or to hurt or injure yourself?</b>					
<b>Think about suicide?</b>					
<b>Plan for a suicide?</b>					
<b>Take active steps to prepare for a suicide attempt in which you expected or intended to die?</b>					

*Q2. Suicide injure on purpose*

**Over the past week, did you injure yourself on purpose, in an effort to kill yourself?**

1. Yes
2. No

If the participant answers “moderately” or above to *all* of the items in question one and/or “yes” to question two, this means that she is imminently suicidal. Continue to **Section B** and follow the steps outlined in the *Imminent Suicide Risk Plan*. **If she does not answer “moderately” or above to all of the items in question one and/or “yes” to question two, but you feel strongly that she is imminently suicidal, you may still invoke the *Imminent Suicide Risk Plan*.**

If the participant answers “not at all” or “a little bit” to the above items in question one and “no” to question two this means that she is probably not

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<sup>4</sup> Screening adapted from the Sheehan Suicidality Tracking Scale (Psychiatry (Edgemont) 2009;6(1): 26-31

imminently suicidal. Continue to Section C and follow the steps outlined in the *Non Imminent Suicide Risk Plan*.

### **SECTION B. Imminent Suicide Risk Plan**

If the participant is imminently suicidal,

- 1) Ask the participant if she is under the care of a mental health professional. If she is already under the care of a mental health professional, state the following:

*It seems important that you talk to someone immediately. You mentioned that you are seeing a mental health professional. What is your agreement with them about what to do if you have thoughts like these?*

---

*I would like your permission to contact your provider. Would you please give me their number and/or their name and address?*

If the Participant says YES, call the mental health provider *immediately* on a second phone line; keep the participant on the phone. Tell the provider that the woman is imminently suicidal and ask him/her to work with you to ensure the immediate safety of the participant. **Do NOT divulge the nature of the study.**

- 2) If the participant is NOT under the care of a mental health professional, or you cannot make contact with the provider—either because they are not willing to seek help from them or the provider is not reachable by phone—state the following:

*It seems important that you talk to someone immediately. Are you willing to go to emergency psychiatric services at a local hospital?*

If the participant says YES, ask:

*Is there someone else with you who can go with you? May I speak to that person?*

**If the participant is a MINOR, the individual must be a parent or guardian.**  
If you speak with a parent/guardian, tell them that the participant is

imminently suicidal and ask him/her to work with you to ensure the immediate safety of the participant. You may tell the parent/guardian that the minor is participating in the study, **however**, do not divulge the nature of the study.

**If the minor is unwilling or unable to put a parent/guardian on the phone, you MUST call 9-1-1.**

- 3) If the woman is alone or will not let you speak to someone who can escort them to psychiatric help, let her know you will call 9-1-1. State the following: *If you are not willing to get psychiatric services, we will need to send the police out to make sure you are okay. Do I have your permission to call them? Will you open the door when they arrive?*

You must call 9-1-1 even if the woman does not give you permission. To reach emergency services outside of California, call 4-1-1 and ask to be connected to 9-1-1 in the participant's location.

In the event that you need to call 9-1-1 for immediate intervention, provide the responders with the participant's name and address. While you can divulge that the woman is participating in a health study, do NOT divulge the nature of the study.

*Immediately* after you have ensured the immediate safety of the woman and are off the phone:

- 1) **Consult** with the Project Manager or PI to review the case and to determine if further steps are necessary. They will consult with a Dr. Spielvogel, Clinical Professor of Psychiatry, to ensure that all necessary steps were taken.
- 2) **Complete** the *Report/Referral Form* and file it appropriately.
- 3) Place a pink chart flag on top of the tracking sheet that coincides with the interview where the incident was recorded in the participant's brown file.
- 4) **Follow-up** with a call that afternoon or the next day to check-in with how the participant is doing and to see if she needs additional referrals.

### **SECTION C. Non-Imminent Suicide Risk Follow-up**

If the participant is NOT imminently suicidal,

- 1) Provide her with appropriate referrals and support her decision to talk to someone. If the participant is a teenager, encourage them to talk with their parents, and offer to do it for her. If you do speak with her parents, do NOT divulge the nature of the study. (In the case of non imminent suicide risk, it is *not* appropriate to breach the participants' confidentiality without her expressed permission to do so).

*"I have a phone number for a 24-hour toll-free talk line where you could speak with a trained counselor and get information about local resources. I'd like to give you that number so you can call them when we get off the phone or for you to hold on to in case you need it in the future. Would that be okay? Do you have a pen? The number is for the National Suicide Prevention Lifeline. You can call them anytime and they will provide you support and let you know about other resources in your area. The number is: 1-800-273-TALK(8255)."*

For MINORS:

*"I am really very concerned about your welfare and I want to encourage you to talk with someone/your parents. Even if it is hard to talk about how you are feeling, there are people who care about you who can help."*

*"Would you like me to contact them/someone else for you and tell them how you are feeling? Who can I contact and how can I reach them?"*

**Remember**, if you do speak with her parents, do NOT divulge the nature of the study. Ask participants to call you back if the referrals don't work.

- 2) **Consult** with the Project Manager or PI to review the case
- 3) **Complete** the *Report/Referral Form* and file it appropriately. Place a pink chart flag on top of the tracking sheet that coincides with the interview where the incident was recorded in the participant's brown file.

The *Suicidal Ideation/Prevention Module* in Spanish can be found in the "current documents" folder on the shared drive (Z:\Turnaway\_)

### *Script for Domestic Violence Referrals*

If participant answers 'Yes' to either of the following interview questions,

dvthreat

**In the last six months, were you ever frightened for your safety, as a result of anger or threats made by another person? , and**

dvhurt

**In the last six months, were you ever pushed, hit, slapped, kicked, choked, or physically hurt in any way by another person?,**

And the answer to the following question falls **within the last six months**,

**When was the most recent event? (Date) \_\_\_\_\_**

And the answer to **Who made you frightened?**

--OR--

If the participant describes **violence or threats** by: **partner, boyfriend, husband, ex-husband, or family member** for the following question:

ptsdwhat

**What was the event that was so upsetting?, then**

Read or paraphrase the following at end of interview:

*What you told me earlier about feeling frightened for your safety makes me concerned for you.*

*Many people who have had similar experiences with being frightened for their safety have found it very helpful to speak to someone about it. Some people talk with family, friends, a counselor, or someone from their church; others call a confidential talkline. I have a phone number for a 24-hour toll-free talkline where you could speak with a trained counselor and get information about local resources. I'd like to give you that number so you can call them when we get off the phone or for you to hold on to in case you need it in the future. Would you like the number? Do you have a pen?*

*The number I have is for the National Domestic Violence Hotline. They offer crisis intervention, safety planning, information about domestic violence and referrals to local service providers. You can call their number 24/7.*

*The number is: 1-800-799-SAFE (7233)*



- 1) After getting off the phone with participant, complete the *Report/Referral form*, **discuss** it with the Project Director and file it appropriately.
- 2) Place a pink chart flag on top of the tracking sheet that coincides with the interview where the incident was recorded in the participant's brown file.

### *Script for Sexual Assault/Rape Referrals*

If participant reveals during an interview that she has been sexually assaulted or raped in the past six months, ---OR--- describes **sexual assault** or **rape** for the following questions:

*ptsdwhat*

**What was the event that was so upsetting?**

*rapethispreg*

**Could this [current/recent] pregnancy have been the result of a rape?**

Read or paraphrase the following at end of interview:

*Something you told me earlier in the interview makes me concerned for you.*

*Many women who have had a similar situation with sexual assault or rape have found it very helpful to speak to someone about it. Some people talk with family, friends, a counselor, or someone from their church; others call a confidential talkline. I have a phone number for a 24-hour toll-free talkline where you could speak with a trained counselor and get information about local resources. I'd like to give you that number so you can call them when we get off the phone or for you to hold on to in case you need it in the future. Would you like the number? Do you have a pen?*

*The number I have is for RAINN: The Rape, Abuse, and Incest National Network. You can call their number 24/7.*

*The number is: 1-800-656-HOPE*

- 1) After getting off the phone with participant, complete the Mandated Report/Referral form, discuss it with the Project Director and file it appropriately.

- 2) Place a pink chart flag on top of the tracking sheet that coincides with the interview where the incident was recorded in the participant's brown file.

### ***Reporting of Irregular Incidents and Protocol Violations***

In the course of conducting research, irregular incidents and protocol violations may happen. If they do, it is imperative to involve the Project Director and to document the incidents/violations and the steps taken to remedy them. In some cases, irregular incidents or protocol violations will need to be reported to the UCSF Committee on Human Research. Examples of irregular incidents and protocol violations include:

#### **Examples of Irregular Incidents**

- A parent of a minor participant called the study with questions
- A person who is not the participant calls and requests information about the study or a participant

#### **Examples of Protocol Violations**

1. A minor in a parental consent state was enrolled without a parent's consent
2. Information was erroneously divulged to a participant's partner

If an irregular incident or protocol violation occurs, Turnaway study research staff must adhere to the following protocol:

1. Discuss the incident or violation with the Project Director to determine next steps.
2. Complete a *Turnaway Study Reporting Form for Irregular Incidents and Protocol Violations* (Appendix V).  
Describe the incident or violation and the action(s) taken. If further action is needed, mark the appropriate box on form and indicate the timeline for further action. When incident is resolved, document this on the form, along with your initials and the date of resolution.
3. When form is complete, give it to the Project Director. She will add the information from the report to the participant database (for tracking

purposes). Once this is done, the report will be filed in the Irregular Incident Binder.

### ***Reporting a Participant Death***

If an interviewer learns of the death of a study participant or an infant born to a participant, she should follow the procedure outlined below to attempt to obtain some basic information about the death:

1. Express your condolences to the person you are speaking with. Be succinct and empathetic. You might consider saying “I am sorry to hear that. That is very sad news and I am so very sorry.” Whatever language you choose to use, remember not to divulge any information about the nature of the study or any personal information about the participant that would breach her privacy or confidentiality.
2. If the participant listed the person you are speaking with as a secondary contact, **do** complete a verbal autopsy report (below). However, please remember that it is important not to divulge any information about the nature of the study or any personal information about the participant.
3. If the participant **did not** give express permission to speak with the person you are speaking with (by suggesting them as a secondary contact), **do not** complete a verbal autopsy report. For example, if the participant gave the name and number of the person you are speaking with, but requested that a code name be used, do not complete a verbal autopsy report.

## Participant Death Reporting Form

ID# \_\_\_\_\_

Date of report: \_\_\_\_\_

### Script for Verbal Autopsy:

"I am very sorry to hear that [participant's name] has passed away. As you may know, she was a participant in a research study that we are conducting. Whenever we learn that one of our study participants [infants of one or our participants] has died, we like to be able to make note of their death in our research records. Would it be okay with you if I ask you a few questions about when and how [participant's/infant's name] died so that I can let our research team know, and document it in our records? The information you share with me will be kept confidential. I know it is probably difficult talk about such a great loss, so I promise not to take too much of your time. Would that be okay?"

**Respondent agrees to be interviewed**    YES            NO

[If Yes, continue with questions below. If No, thank the person you are speaking with. Express your condolences and end call.]

**Q1. When did [participant/infant name] die?**

Probe (ask only if appropriate): **What was the month day and year that she died?**

\_\_\_\_/\_\_\_\_/\_\_\_\_

\_\_\_\_ Don't know

**Q2. What city and state was she in?**

City: \_\_\_\_\_ State: \_\_\_\_\_

\_\_\_\_ Don't know

**Q3. Where was [participant/ infant name] when she died? Was she in the hospital, another health facility, at home, or someplace else?**

\_\_\_\_ Hospital

\_\_\_\_ Other Health Facility

\_\_\_\_ Home

\_\_\_\_ Other (Specify): \_\_\_\_\_

\_\_\_\_ Don't know

**Q4. Could you tell me about the illness or events that led to her [his] death?**

**Probes (ask only if appropriate):**

(If non-accidental death): To your knowledge, did she have a previously known medical condition, or a history of illness or injury that contributed to her death?

(If post-partum death): Do you think her death was related to her pregnancy or birth?

Do you think her death was at all related to her mental health status?

How do you know the cause of death (doctor's account, coroner's report, present at death?)

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\_\_\_\_\_ Don't know

**Q5. What is your relationship to [participant's name]?**

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**Q6. What is your name?**

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"Thank you for answering these questions. I am very sorry for your loss. We will not call you again.] Goodbye."

After completing the autopsy report, please turn it in to the Project Director. She will review it and file it in a designated folder in her office.

Project Director's initials: \_\_\_\_\_

Date reviewed: \_\_\_\_\_

## SECTION FOUR: DATA COLLECTION, MANAGEMENT AND STORAGE

### Data Collection Nuts and Bolts for Paper-Based Documentation

- Use blue or black ink when collecting data (it's easier to read if Xerox copies are made)
- Write legibly and mark forms clearly so there is no ambiguity during data entry
- If you make a documentation error, make one thin "strike out" line through it (so it is still legible), initial and date it, and make the appropriate corrections
- Special instructions for qualitative questions:
  - write the participant's response to each question as accurately and fully as possible, paraphrase when necessary
  - Use quotation marks to capture the exact wording of a phrase
  - If the participant is not forthcoming, allow time for her to think about her answer and encourage her by asking "Is there anything else that comes to mind?," "Would you like to say any more about that?" or a similar probing question
  - If you feel you didn't capture everything that was said, spend time immediately after the interview to write down additional notes while the interview is still fresh in his/her mind
- Most importantly, read every question EXACTLY as it is worded in the interview script, to maximize inter-rater reliability
- Review forms for completeness before considering them "done"

### Data Management and Storage

Whether data is collected using paper-based methods or electronic methods, it must be protected at all times. Paper-based documents are secured in locking file cabinets in locked offices. Electronic data are protected using computer passwords and a secure server. In addition, back-up files of all our electronic data are made weekly and kept in a safe in the Project Director's office. Monthly the most recent backup is move to a safe in a secure office (Petty Cash Manager Jane Wong) at the Laurel Heights campus. Paper based documents containing participant's personal information should not leave the office. These methods ensure that participant's private information will remain private and that the data needed for analysis remains safe.

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## SECTION FIVE: DATA ANALYSIS

### Study outcomes

Our main study outcomes include mental health, physical health, and socioeconomic (SES) variables. Our secondary outcomes include emotions, intimate partner violence, relationships, future aspirations, pregnancy intentions, children's well-being, contraceptive use, and subsequent pregnancies.

### Study groups

Our three main study groups include women who present for abortion just above a facility's gestational age limit and is denied an abortion (Turnaways), women who present for abortion just below the facility gestational age limit and receives an abortion (Near-limit abortion group) and women who receive a first trimester abortion (First-trimester abortion group).

### Analysis Plan

Our main statistical analyses will assess whether the levels and trajectories of our main and secondary outcomes differ by study group or change over time using longitudinal statistical methods. Our main predictor variables will be time since seeking abortion, study group, and group by time interactions. All analysis will adjust for clustering by site and individual and control for factors known to be associated with the outcome variables. We will also conduct a series of baseline analyses to assess the reasons women sought abortion, their emotions, and access to care. Findings from this study will be published separately by topic area and as the data become available. First we will publish a series of papers utilizing the baseline data, then we will publish a series of mid-study findings, and once all five-years of data are available, we will publish the five-year papers.

### Starting Work on the Turnaway Study

Permission to utilize Turnaway Study data and publish analyses can only be granted by the Study's PI, Dr. Diana Foster. Interested researchers must submit a proposal to Dr. Foster prior to starting any analysis projects. The proposal must include the following:

1. **Completed [Analysis/Publications Proposal Form](#)**
2. **Analysis plan:** The proposal should describe the applicant's expertise in the chosen topic, specific aims of the proposed project and the research approach to the Turnaway data.



### 3. Curriculum Vitae

4. **Writing sample**, preferably an article published in a peer –reviewed journal indicating the extent of involvement of the applicant in writing the publication.

### 5. Two academic letters of reference

Once a proposal is accepted, the researcher must review the [Turnaway Publication and Presentation Policy](#) and sign the [Turnaway Data Use Agreement](#).

Using Turnaway Study Data

**Folders located here Z:\Turnaway\_SOUP\Data Analysis\Data and programs contain two programs for each wave that are used to first label and code the data from CASES and then to create some basic variables. Researchers do not need them for analysis, but they are included to record how the raw data were modified.**

## APPENDICES

Appendix A: Turnaway Study Flowchart

Appendix B: Reading List

Appendix C: Training Checklist

Appendix D: Recruitment Checklist

Appendix E: Clinic Flyer

Appendix F: Participant Contact Information Form

Appendix G: Study Eligibility Screening Form

Appendix H: Informed Consent Form

Appendix I: Enrollment Log

Appendix J: Appointment card, reminder insert, and refrigerator magnet

Appendix K: First Interview (English)

Appendix L: Follow-up Letter/Check-in Follow-up Letter

Appendix M: Participant Tracking Form

Appendix N: Gift Card Insert

Appendix O: Check-in Tracking Form

Appendix P: Check-in Follow-Up Letter

Appendix Q: Second Interview Checklist

Appendix R: Third-Eleventh Interview Checklist

Appendix S: Second Interview (English)

Appendix T: Interview 3-11 (English)

Appendix U: Reporting and Referral Form

Appendix V: Irregular Incident/Protocol Violation Form

## REFERENCES

1. Fontana, A. and Frey, J. *From Structured Questions to Negotiated Text*. In Collecting and Interpreting Qualitative Methods, 2<sup>nd</sup> (2003). Ed. Norman Denzin and Yvonna S. Lincoln. Sage Publications, Thousand Oaks, CA.
2. Patton, M.Q. Qualitative Research & Evaluation Methods 3<sup>rd</sup> Ed. (1990). Sage Publications, Thousand Oaks, CA.
3. Weiss, R. Learning From Strangers (1994). The Free Press, New York, NY.