Project Title: Improving Reproductive Health for Women in Opioid Medication-Assisted Treatment (OMAT)

Principal Investigator: Deborah Rinehart, PhD, MA

Version: 4

Date: 3.9.18

I. Hypotheses and Specific Aims:

Developing effective reproductive health interventions for women in treatment for substance use disorders has tremendous potential to improve the health of women and children. In the US nearly half (51%) of all pregnancies are unplanned (L. B. Finer & Zolna, 2014). A recent study of pregnant women entering opioid medication-assisted treatment found much higher proportions – 86% described their current pregnancy as being unintended and about a third of these pregnancies were described as being unwanted (Heil et al., 2011). Women with unintended pregnancies had higher rates of recent substance use and almost all (90%) had a history of prior treatment for substance use disorders. Thus, substance use treatment programs are promising venues for addressing contraception.

Although there is a paucity of interventions specifically focused on preventing unintended pregnancies among women with substance use disorders, prior research from the addiction treatment and reproductive health fields provides relevant guidance for selecting key intervention elements. The addiction treatment field has an established history of using peers to support recovery (White, 2004). Peers have been used in effective HIV prevention interventions with vulnerable and hard to reach populations(Kelly, 2004; Kelly et al., 1991) and with adolescents (Brindis, Geierstanger, Wilcox, McCarter, & Hubbard, 2005; Key, Gebregziabher, Marsh, & O'Rourke, 2008). Involving individuals with similar life experiences may foster trust in intervention programs and increase sensitivity to the perspectives of the individuals in the target population. Thus, we propose to involve peers in a contraceptive and reproductive health education among women in treatment settings.

Long-acting reversible contraceptive (LARC) methods, such as intrauterine devices and subdermal implants, are considered the most effective method of reducing rates of unintended pregnancies (American College of Obstetricians and Gynecologists Committe Opinion no 450, 2009; Trussel et al., 2009; Trussell, 2012). Yet little is known about LARC use among women who use substances. LARCs are likely to be acceptable among this population as national data indicate similar rates of LARC use among low income women (6.1%) and women on Medicaid (6.7%) compared to all women using contraception (5.6%) (Kavanaugh, Jerman, Hubacher, Kost, & Finer, 2011). Furthermore, a recent Colorado Initiative promoting LARC use found an increase in uptake (5%-19%) among young low-income women (Ricketts, Klingler, & Schwalberg, 2014) and another

study among women seeking contraception found high rates (70%) of LARC acceptance (Mestad et al., 2011).

This study proposes to draw upon behavioral theory and prior evidence-based interventions to develop an innovative brief peer-led intervention to increase LARC uptake for women of child-bearing age entering opioid medication-assisted treatment (OMAT). The Health Belief Model HBM (Rosenstock, 1974) will be used to guide intervention development. HBM is a multidimensional social cognitive framework that focuses on modifiable factors related to decision making and behavior and was recently operationalized specifically to support current contraceptive research and practice.(Hall, 2012).

The study will utilize a mixed methods approach and involve two phases. The first phase will be a formative evaluation that will include individual qualitative interviews and focus groups with women in OMAT; the resulting information will be coupled with prior evidence and theory to develop the structure of the intervention. The second phase will involve the piloting and implementation of a peer-led sexual health intervention with women in OMAT. Women (150) will be recruited from two clinic sites and randomized to usual care (N=80) or intervention (N=80).

Aim 1. To develop a brief theory-based peer-led intervention to prevent unintended pregnancies among women entering opioid medication-assisted treatment.

a. Conduct up to 30 individual qualitative interviews to better understand: pregnancy desires/motivation and perceived susceptibility and severity; and contraceptive knowledge, perceived benefits/barriers, self-efficacy, social norms, behaviors and access to contraception and family planning services, especially related to LARCs.

b. Combine information from the qualitative interviews with HBM theory and results of prior research to specify the peer-led intervention.

c. Assess acceptability and feasibility of the intervention in two focus groups and refine.

d. Pilot the intervention with 10 women and finalize.

Aim 2. To assess acceptability, feasibility and the initial efficacy of the behavioral intervention (*n*=75) as compared to usual care in substance use treatment (*n*=75).
Aim 3. To conduct exploratory analyses to identify HBM constructs that are the most influential on LARC use
Hypothesis 1. Participants randomized to the intervention will be more likely to follow-up with a family planning clinic visit.
Hypothesis 2. Participants randomized to the intervention will be more likely to initiate Long Acting Reversible Contraceptive (LARCS) methods.

II. **Background and Significance**:

Unintended pregnancies and public health. Reducing unintended pregnancies is an important public health concern and is a national health goal that has been identified by the U.S. Department of Health and Human Services', *Healthy People 2020* campaign. In 2008, about half (51%) of the pregnancies in the US were unintended (L. B. Finer & Zolna, 2014). Additionally, disparities in unintended pregnancy rates exist for low income women, women with less than a high school education and minority women (L. B. Finer & Zolna, 2014). Unintended pregnancies have both financial and public health impacts. It is estimated that unintended pregnancies cost US taxpayers approximately $11 billion

dollars a year (Sonfield, Kost, Gold, & Finer, 2011). This is most likely a conservative estimate as costs were limited to public insurance costs for pregnancy and first-year infant care. Additionally, unintended pregnancies can lead to unintended childbearing, which is associated with adverse maternal behaviors before pregnancy is known, such as delayed or inadequate prenatal care, and/or substance use during pregnancy (L. B. Finer & Henshaw, 2006).

Unintended pregnancies in women who use substances. Studies suggest that unintended pregnancy rates are much higher among women with substance use disorders than in the general population. A seminal study of the reproductive health needs of women with opioid dependence demonstrated higher rates of lifetime pregnancies and abortions compared to national averages, suggesting that many pregnancies in this group were unintended (Armstrong, Kennedy, Kline, & Tunstall, 1999). A small study of pregnant women in methadone maintenance found that 67% did not plan their current pregnancy (Selwyn et al., 1989). In a more recent multi-site study of 946 pregnant women in treatment for opioid use disorders, 86% reported that their current pregnancy was unintended, of which 40% reported it was mistimed, 31% reported it was unwanted and 30% reported being ambivalent (Heil, et al., 2011). These numbers underscore the importance of targeting this population and developing effective interventions that bridge the gap between pregnancy desire and contraceptive behavior. Additionally, women with unintentional pregnancies had significantly more substance use in the past 30 days compared with women with intentional pregnancies. Women often do not find out they are pregnant until after the fourth week of pregnancy, well into a critical period for fetal development (Floyd, Decoufle, & Hungerford, 1999). Thus, women with substance use disorders, even those in recovery, may be at a much higher risk of having a substance-exposed pregnancy especially if the pregnancy is unintended. Continued substance use during pregnancy has been associated with immediate and long-term effects on exposed children ranging from premature delivery and low birth weight to developmental deficits that affect behavior and cognitions over the life course (NIDA., 2011). Additionally, the recent national increases in neonatal abstinence syndrome and antepartum maternal opioid use (Patrick et al., 2012), suggest that contraceptive interventions are particularly important for women with opioid use disorders.

Substance use treatment settings: a missed opportunity for prevention of unintended pregnancies. Reproductive health is an important issue among women in treatment for substance use disorders but is often not adequately addressed (Armstrong, Kenen, & Samost, 1991). While most treatment venues include sexually transmitted infection (STI) testing and education, most do not include a contraception focus or adequate connection to reproductive health services. In Heil's (2011) study with pregnant opioid-dependent women, almost all of the women (90%) in the study had a history of prior treatment for substance use disorders with an average of three or more treatment episodes. This finding strongly supports the idea that treatment programs are a vital setting for engaging at-risk women and empowering them to take control over their reproductive health. Treatment is a time of change and self-evaluation. Integrating a peer-led contraception intervention into this setting may provide women with additional resources that contribute to greater self-efficacy, empowerment and future stability in their lives and that in turn positively support their recovery.

The potential role of peers in prevention for women with addiction. Within the mental health and addiction fields, there is a history of using peer-based recovery support groups and recovered/recovering peers in service and support roles (White, 2004). Peers have also been used in health promotion and HIV prevention with hard to engage populations (Kelly, 2004; Kelly, et al., 1991) and adolescents (Brindis, et al., 2005;

Jemmott, Jemmott, & Fong, 1998; Key, et al., 2008; Siegel, Aten, Roghmann, & Enaharo, 1998). The definitional clarity and diversity of interventions that fall under the umbrella of "peer education" has hindered the evaluation of the value of this method (Shiner, 1999). In a study among adolescents receiving family planning services at a community health clinic, patients whose clinic services were augmented with a peer intervention were more likely to report consistent and effective contraceptive use at follow-up (Brindis, et al., 2005). However, in a sexual health school-based study that utilized peer-educators in group settings, differences were not found between students in the intervention and control groups (Mason-Jones, Mathews, & Flisher, 2011). The proposed study will rigorously operationalize and measure a peer education intervention that will include peers not only in the delivery of the intervention but also in the development of the intervention. Peer education has been more heavily promoted in projects working with vulnerable and hard to reach populations. The premise is that individuals may be more likely to personalize health messages if they are delivered by someone who understands and is facing similar concerns and pressures. Using peers who have experienced past substance use problems, provides participants with successful real-life role models. This may be particularly helpful in developing trust, ensuring the intervention incorporates the cultural context surrounding substance use, and empowering substance-using women to engage and take control over their reproductive health.

The opportunity provided by increased availability of Long-Acting Reversible Contraceptives. LARCSwhich include intrauterine devices (Mirena®, ParaGard®, Skyla®) and subdermal implants (Nexplanon®), are considered to be safe, cost-effective methods to reduce the rates of unintended pregnancies (American College of Obstetricians and Gynecologists Committe Opinion no 450, 2009; Trussel, et al., 2009; Trussell, 2012). By requiring little user participation to avoid pregnancy, their failure rates are very low (less than 1%) (Hatcher et al., 2007; Kost, Singh, Vaughan, Trussell, & Bankole, 2008; Trussel, et al., 2009). Rates of LARC use have continued to increase over the last decade in the US (L. Finer, Jerman, & Kavanaugh, 2012) and LARCs appear to be acceptable methods of contraception among low-income women and women on Medicaid (Kavanaugh, et al., 2011) A recent Colorado Family Planning Initiative focused on increasing LARC use among young low-income women observed a population increase in LARC use from 5% to 19% as well as a decrease in observed fertility rates, high-risk births, abortion rates and infant enrollment in WIC (Ricketts, et al., 2014). Another recent project promoting LARC use among women seeking contraception found that 70% of the women chose a LARC method as compared to a non-LARC method when the barrier of cost was removed and when counseling on the effectiveness of LARC methods was provided (Mestad, et al., 2011). Implementation of the Affordable Care Act and greater Medicaid coverage decreases financial barriers in accessing these methods. Women entering treatment often have multiple life issues to address and providing contraceptive options, especially LARC methods, may be particularly attractive and effective in reducing unintended pregnancies.

Theory to inform the study. Recent contraceptive interventions have not relied as heavily on theory as HIV prevention interventions. In a review of theory-based contraception interventions, the most heavily used theoretical basis was social cognitive theory (SCT) (Lopez, Tolley, Grimes, Chen, & Stockton, 2013). HBM is a social cognitive framework that applies a multidimensional approach to decision making and heavily relies on modifiable cognitive factors (Rosenstock, 1974). HBM will be used to guide the overall framework for operationalizing intervention content and measurement. HBM consists of 6 constructs that influence individual health related decision making and behaviors: perceived susceptibility (chance of getting a condition); perceived severity (seriousness of

the condition and it consequences); perceived benefits (ability of the preventive behavior to reduce risk); perceived barriers (the cost of the preventive behavior); cues to action (internal and external signals that trigger action) and self-efficacy (confidence in one's ability to take action). Self-efficacy, a component of HBM and an essential construct in Social Cognitive Theory(Bandura, 1986), has been utilized in many health studies and has been found to be an important predictor of safer sex behaviors (Brien, Thombs, Mahoney, & Wallnau, 1994; Goldman & Harlow, 1993; Longshore, Stein, & Chin, 2006; O'Leary, Goodhart, Jemmott, & Boccher-Lattimore, 1992; Sikkema et al., 1995; Wulfert & Wan, 1993). Thus, contraceptive self-efficacy will be a specific focus in the intervention. A recent conceptual review of primary research articles applying HBM to family planning, consolidated past work to specify a contraception specific HBM framework to be used to guide future research, measurement and practice (Hall, 2012).

Motivational Interviewing (MI) is an empirically supported intervention method and style that is effective in a number of health issues within short time frames (Lundahl et al., 2013; Martins & McNeil, 2009) MI has been extensively used in the addiction field and has been shown to be effective in brief interventions targeting alcohol use and contraception behaviors (Ingersoll, Ceperich, Hettema, Farrell-Carnahan, & Penberthy, 2013). It is a directive but client-centered approach focused on increasing patient motivation to change behaviors through exploring and resolving ambivalence (Miller & Rollnick, 2002). Structured elements of MI will be incorporated into the intervention, specifically providing personalized feedback on current contraception methods, developing discrepancy between contraception behaviors and pregnancy intentions, and goal setting.

Summary. Gaining a better understanding of the contraceptive and reproductive health needs of women struggling with addiction is an important public health issue. This study will develop a brief peer-led intervention that can be integrated into the substance use treatment setting and may prove to be a significant contribution to the public health effort of both reducing unintended and substance-exposed pregnancies. Additionally, empowering women to take control over their reproductive health may also create more long-term stability in their lives and positively support their recovery.

III. Preliminary Studies/Progress Report: None

IV. Research Methods

A. Outcome Measure(s):

Phase I Data collection. Because of the potentially sensitive nature of reproductive health behaviors, individual interviews were chosen as the first step to better elucidate and explore the issues related to pregnancy desires and contraceptive behaviors. The table below outlines the topics we will explore.

Level	Topics to Explore in Individual Qualitative Interviews
Individual	➢ Pregnancy desire/motivation, perceived susceptibility/seriousness of an unintended pregnancy (impact on woman biologically, financially/economically) ➢ Contraceptive knowledge, perceived benefits/barriers (effectiveness, side effects) internal cues for using contraception (past counseling experience, biological issues), overall attitude toward contraception ➢ STI knowledge, behavior, condom use and relationship to

	contraceptive behaviors
Social/relationship	➢ Perceived partner's knowledge and involvement in contraceptive decisions ➢ External cues to action - ongoing support and reinforcement for contraception ➢ Issues specific to different types of partners ➢ Familial, peer and cultural norms that influence contraception
Community	➢ Characteristics of family planning and STI services, past experience, media messages, access and utilization of services
Intervention specific	➢ Feedback on the core components of the intervention, specifically the role of a peer-educator and connection to services, and recommended intervention frequency/duration and suggested engagement methods

Information from the individual interviews will be combined with evidence from the literature to further specify the intervention. The intervention will then be operationalized by creating a manual as well as a detailed outline that will be used to solicit feedback in the focus groups. We will then conduct two focus groups with the primary aim of obtaining women's feedback on the intervention and their thoughts on the most important aspects of HBM as related to contraception decision making and behavior. Focus groups are a strong addition to our formative methods, as they provide a cost-effective method of collecting information and a social forum to further evaluate the intervention. The social forum helps to identify salient issues and weed out extreme views that may have been obtained in the individual interviews (Agar & MacDonald, 1995). It also allows participants to interact and respond to each other's ideas. This synergy will provide valuable information in further refining the intervention. After each focus group, suggestions will be reviewed and needed modifications will be made to the intervention content and structure. Additionally, during this time, processes will be explored and put in place for referral to family planning services.

B. *Phase II*. We will then recruit 160 women in OMAT to participate in this phase of the study. Quantitative study data will be collected through participant surveys at baseline, 3 months, and 6 months follow-up. We will collect baseline data on a tablet, and 3 and 6 months follow-up using RedCap. A copy of this survey is included in this application and the content is as follows:

- Demographic data: Age, religion, sexuality, living situation, partnership status, previous pregnancies length of time in treatment and number of unique episodes
- Psychosocial: Knowledge of contraceptive methods and pregnancy risk; stage of change and level of motivation to prevent unintended pregnancies, attitudes towards different contraceptive methods, self-efficacy regarding condom and birth control use, ability to engage in preventive behaviors, partner communication, pregnancy desires
- Current behavior: In last 30 days and most recent: number of partners, number of vaginal sex acts, times used contraceptives, times used condoms, partner perceptions of contraceptives and condoms, risk behaviors.

When possible, we will supplement survey data with clinical data from DH's data warehouse, including pregnancy and STI history, number of clinic visits, family planning visits, and contraceptive changes for the six month study.
Additionally, we will collect biological urine and test for pregnancy at baseline. Once the biological sample is tested, all clinic guidelines related to testing and follow-up will be conducted by appropriate clinic staff.

Description of Population to be Enrolled:

Study inclusion/exclusion criteria: Phase I: being female; 18-35 years of age; being in opioid medication-assisted treatment at one of our two clinic sites; not currently pregnant or trying to become pregnant; and have no known medical reason that would prevent pregnancy (e.g., hysterectomy, tubal ligation), having sex or intending to have sex with biological male (at risk of pregnancy) . Individuals who are not able to complete the interview in English, or who are intoxicated or impaired mentally to the point that they cannot voluntarily consent to participate in the project and/or respond to the interview will also be excluded.

Phase II: being female; 18-44 years of age; being in opioid medication-assisted treatment at one of our two clinic sites; not currently pregnant or trying to become pregnant; and have no known medical reason that would prevent pregnancy (e.g., hysterectomy, tubal ligation, menopause), having had sex or intending to have sex with biological male (at risk of pregnancy), and not currently using a LARC . Individuals who plan to move out of the area in the next 6 months, have a pending incarceration, and/or are not able to complete the interview in English, or who are intoxicated or impaired mentally to the point that they cannot voluntarily consent to participate in the project and/or respond to the interview will also be excluded.

C. Study Design and Research Methods

. This study will be completed in two phases The first formative phase (Aim 1) will include individual qualitative interviews with women in OMAT. These interviews will be used to elucidate and explore the barriers to effective contraceptive use and STD prevention. Findings from these interviews in conjunction with prior literature and evidence based models will be used to develop the intervention. Focus groups will then be conducted to obtain feedback on the developed intervention and a final intervention will be developed. The developed intervention will then be piloted with 10 women who are in OMAT. The second efficacy phase (Aim 2-3) will randomize subjects to the intervention or the usual care and assess outcomes 3 and 6 months post-baseline.

Phase I qualitative and intervention development. Individual interviews (up to 30) and 3 focus groups (n=20) will be conducted with women in OMAT of reproductive age. Purposeful convenience sampling is considered most appropriate for formative research (Patton, 2002; Schensul, 1999). Women will be recruited from two treatment centers. *Outpatient Behavioral Health Services (OBHS)* is a stand-alone substance use treatment clinic located on the Denver Health Medical Center campus in central Denver and has dispensed methadone (ORT) and provided substance use and mental health treatment for over 30 years. *Addiction Research and Treatment Services (ARTS)* is in the Division of Substance Dependence, Department of Psychiatry, University of Colorado School of Medicine. ARTs began in 1971 as a federally funded methadone maintenance program and currently has four outpatient clinics. The Denver Clinic will serve as a treatment clinic for this study and is also located in central Denver. Clinic providers will be

asked to identify and refer eligible women to the research assistant. Participation will also be solicited from flyers hanging in the clinics. Additionally, participants may be recruited in person by the researcher. We will attempt to include representation across different ages, ethnicities, women with and without prior non-condom contraception use, and women with and without children.

The content of the individual interview has been described above and will explore salient issues related to reproductive health among women in OMAT. We will combine information from the individual interviews with evidence from the literature to develop a preliminary intervention and proposed content. We will then conduct focus groups to obtain more targeted feedback from the women on the developed intervention. The intervention will be finalized and tested in the second phase which will be submitted as an amendment.

All formative qualitative interviews will be audio-taped and transcribed into Word. The qualitative interviews will be transcribed by a consultant who is not part of the research team (used in prior studies). The digital files will be saved on (www.box.com) for the transcriptionist to access. This is an encrypted storage site that also provides audit logs of who accessed the files. No names will be associated with the digital recordings or transcribed files. Once the transcribed file is received, all digital recording will be removed from www.box. The transcriptionists have also signed all Denver Health confidentiality paperwork. Once transcribed the word files will be transported into Atlas.ti for analysis. Once transported into Atlas the digital recording will be erased from the Denver Health server. All Atlas.ti files will contain a unique study id and no identifying information.

Focus group data will be audio-taped and the co-facilitator(s) will take extensive notes. The digital files will be reviewed and information will be added to the notes. These data will be used primarily to modify the intervention and all digital recordings will be erased after the intervention has been finalized.

Phase II Efficacy Evaluation This study will be conducted at the DH Outpatient Behavioral Health Services clinic (OBHS), and at the University of Colorado's Addiction Research and Treatment Services clinic (ARTS). Potentially eligible patients will be identified by the research staff through screening the clinic schedule, and by clerical clinic staff. Patients identified as potentially eligible will be approached at the clinic during dosing hours or before/after group sessions, and asked if they would like to participate in the study. Additionally, providers will be asked to refer potentially eligible participants to the research staff. Flyers will also be hung at the clinics. All identified/referred patients will be screened for final study eligibility by a trained researcher in a confidential setting, and if eligible invited to participate in the study. If deemed eligible and interested, the participant will be consented and will complete the baseline interview electronically.

Research staff will obtain informed consent from all participants by allowing them to review the consent form, and by highlighting particularly important aspects. The baseline interview will be collected using a computerized tablet using ACASI software. ACASI is a computer/tablet-based interview and data collection instrument that automatically enters and stores the data, eliminating the data entry process. In addition, this software allows the interview to be set up so that participant simultaneously reads the questions on a tablet, and hears the questions on headphones. This method decreases problems with low literacy levels and provides increased anonymity, especially with sensitive questions. All tablets will have headphones so that each participant can hear the questions privately. A researcher will also be there to answer any questions, or help if there are any technical problems with the survey. The survey data will be associated with a study id and initially stored in an encrypted file on the tablet as the participant is completing the interview. At

the completion of the interview, the researcher will retrieve the tablet, copy the interview to a secure Denver Health network drive, and erase the file from the tablet. The researcher will then pay the participant for her time. The three and six month interview will be done online using RedCap, a secure software that is regularly used in research. A spreadsheet will be developed to manage all aspects of study data. After the baseline interview, the research assistant will assign participants into study groups based on pre-defined randomization based on study ID.

For the first 10 patients recruited, we will ask them to provide feedback on the baseline survey and intervention and this information will be used to further refine the study survey and intervention. Depending upon the changes made, data from these initial participants may be excluded from the final analyses.

Study Condition

Usual Care. All participants will be in active OMAT at one of the two clinics. The current standard of care is to administer the state mandates Infectious Disease Behavioral screen. If women screen at risk for HIV, they are referred to the Colorado department of Public Health and Environment or Denver Public Health for further evaluation and follow up. At this time, neither program has standard work in place to assess pregnancy desire, contraception use and/or to provide information on contraception methods or referral to services. Standard care varies depending on the length of time a patient has been in treatment, but all are connected to a counselor and a treatment provider. The intention of this study is not to impact the care provided in OMAT, but to support reproductive behaviors and connection to a family planning visit.

Peer-Led Reproductive Health Intervention. After randomization, if the participant is assigned to the study intervention condition the researcher will introduce them to the peer navigator (PN) immediately after the baseline interview. The timing of each session is listed in the table below followed by a short summary of core objectives of each session. The PN intervention is specified in the Peer Navigator Handbook included with this submission.

Intervention Components		
Session	**Timing**	**Duration**
Session I	Immediately post-baseline	15 minutes
Session II	2-4 weeks post-baseline	20 minutes

Session One: The PN will conduct session one as outlined in the Peer Navigator Handbook. Core objectives of this session include engaging the patient in the intervention, assessing pregnancy intentions and current behaviors, advising patients on birth control options and summarizing the session and preparing for next steps. Motivational interviewing techniques will be used throughout the sessions. The primary goal of the first session will be to assess interest and readiness to connect to a family planning provider and to schedule a same day appointment for those patients who are ready to take action. It is estimated to take approximately 15 minutes.

- **If the participant is interested** in connecting to a family planning visit**:** The PN will make an appointment with an identified health educator (HE). A HE is a Denver Health employee who specializes in family planning education. All attempts will be made to make the appointment on the same day as session one.

- **If the participant is not interested** in connecting to a family planning visit: The PN will use the Topics (aka bubble sheet) and Values Worksheet (included in this submission) to determine if there are other areas or issues that the participant would like to discuss. If the participant is interested in being connected to a general practitioner, the PN will work to schedule an intake appointment from a list of identified DH providers who are experienced and interested in working with women in recovery. The PN will also have additional referral resources to provide the participant if there are other needs and/or concerns (outlined in the Peer Navigator Handbook).
- Session Two: The PN will attempt to conduct session two in person; however, participants will have the option of conducting session two over the phone. This session is expected to take approximately 20 minutes. The core content of this session will vary based on the results of the first session. If needed, motivational interviewing techniques will be used to continue to elicit self-change talk and increase motivation for a family planning provider visit. For participants who had a family planning visit, the PN will discuss any side effects or concerns the participant has with their birth control method. If the participant did not attend the appointment, the PN will facilitate the scheduling of a new appointment.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

Risks consist of potential embarrassment or discomfort in responding to sensitive questions. Participants may feel discomfort or embarrassment responding to questions about sensitive topics such as their knowledge and attitudes about reproductive health, STIs, pregnancy, and contraception. We believe this risk is low. Participants can choose not to response to questions they are uncomfortable with. Additionally, if they are upset by the survey or have additional health related questions, we will refer them to a clinician on site (either behavioral health consultant or primary care provider/nurse). We will also provide an informational brochure at the end of the interview or focus group. The brochure will outline contraceptive methods and clinic locations.

There is a risk of loss of confidentiality but we believe this risk is low. All study data will be collected in a confidential setting and will be associated with a study ID and not with identifying information. Confidentiality cannot be assured in the focus groups participants will be informed of this risk.

As part of the study, we will collect a urine sample to test for pregnancy at baseline. If the participant received a positive pregnancy screening, they will be referred to the appropriate clinic staff, and excluded from participating in the study.

E. Potential Scientific Problems:

In the qualitative formative work, we will use purposeful sampling, which will not be representative of all women in OMAT. However, these data will be used to inform the development of an intervention that will be tested in a second phase (to be submitted once finalized).

Participants may not represent all women in treatment in Denver. We will make every attempt to understand and correct any recruiting biases, and recruit and enroll all eligible women receiving treatment at ARTS or OBHS during the time of the study.

Retention of participants for the second session, and for the three and six month follow-up interview is the biggest potential scientific problem. We intend to ask all participants for relevant contact information so that we can find them for their follow-up session and interviews.

These data are self-reported, which comes with limitations. However, several mechanisms are being put in place to reduce this bias, including: conducting the interview in a confidential setting; ensuring data is stored in a secure location; and using software so that participants can directly enter their answers into the computer. Literacy levels may also be a concern, but we will use survey software that will allow participants to hear and see the questions simultaneously. Additionally, a researcher will be available during the interview to address any comprehension concerns.

F. Data Analysis Plan:

Phase I Qualitative Data Analysis. All qualitative data will be digitally recorded and in written notes. The tapes from the individual interviews will be transcribed (and translated when necessary), verbatim, directly after the interview. Coding will begin immediately and will be ongoing so that subsequent interviews can be used to clarify emerging themes.

Individual interviews that have been transcribed will be imported into ATLAS.ti for coding. A grounded theory approach will be used to inductively code and analyze the individual transcripts. Coding for the first 3 interviews will take place as a team (the PI and research assistant). The team will immerse themselves in these interviews starting with reading each interview transcription several times to begin to identify meaningful themes. The team will code the three interviews, labeling as many concepts as emerge, and meet to jointly develop and operationalize codes that will be used in coding subsequent interviews. The team will code the remaining interviews, meeting weekly to discuss problems or questions with current codes and make modifications as needed. Analysis will be an ongoing iterative process. Relevant themes/categories and topics will be extracted for use in the development of the intervention and focus group interview guide.

The intent of the focus groups is to provide feedback on the intervention developed. Therefore, the focus groups will be digitally recorded and reviewed after the group meeting. Notes from these groups will be summarized and the intervention will be modified based on the findings. Following completion of the analysis and intervention development, the recordings will be destroyed.

Phase II Quantitative Data Analysis. Multivariate regressions will be performed to assess statistical differences between the intervention group and usual care group from baseline to follow-up with respect to:

Hypothesis 1. Participants randomized to the intervention will be more likely to follow-up with a family planning clinic visit.

- Participants with a family planning visit will show an increase in knowledge, self-efficacy, and perceived benefit of birth control.

Hypothesis 2. Participants randomized to the intervention will be more likely to initiate Long Acting Reversible Contraceptive (LARCS) methods.

Prior to conducting the primary analyses, group differences in baseline measures will be evaluated to ensure that the group assignment was even. We will also inspect the

distributions of continuous variables (e.g., frequency condom use) for departures from normality. Variables that exhibit non-normal distributions will be subjected to normalizing transformations prior to analysis. If those transformations are unsuccessful, analysis will proceed using non-parametric tools. In addition, the rate of attrition between baseline and follow-up interviews will be evaluated to ensure that it is relatively constant across intervention conditions, and that there are no systematic differences in the variables of interest between participants who completed the study and those lost to follow-up. Missing data due to item non-response or loss to follow-up will be handled using the most appropriate method, depending on the amount of missing data, the assumptions of the missing data (completely at random, at random or non-ignorable) and the assumptions of the method of handling missing data. For example, for small amounts of missing data that are assumed to be missing at random, listwise or pairwise deletion (the default in most statistical packages) will be sufficient. Variables that differ significantly between those who returned for follow-up and those who did not can also be controlled for in regression analyses. Where appropriate, we will use statistical models that employ maximum likelihood techniques of parameter estimation, allowing us to use participants with incomplete data and avoid the potential bias caused by listwise deletion. These techniques are robust under conditions of missing at random so comparisons of groups will not be biased as long as missing data is ignorable. The number of planned comparisons will be limited based on a priori hypotheses, therefore the per comparison error rate of .05 will be used to evaluate significance of the specific aims. Exploratory or secondary analyses will be adjusted for multiple comparisons using the Bonferroni test.

Many of the variables will be either summary index scores or latent variables that assess the psychological, behavioral and biological constructs of interest. For example knowledge will be a summary score representing the number of variables the participant correctly endorsed, while motivation will be a mean score across multiple variables representing the underling latent construct. The variable related to use of LARCs will be a dichotomous variable representing current use or no current use of a LARC method (IUD or Implanon), as will attending a family planning visit during the study period.

Separate analyses will be conducted for each of the hypothesis to understand differential change over time. This includes looking at change scores as well as analysis of variance. The expectations for hypotheses 1 and 2 are that they will significantly increase in the intervention group. Differences will be assessed from baseline to follow-up period for each analysis.

Additional regression analyses will be conducted to identify significant predictors of differential change over time in birth control method and family planning visit. This analysis will determine if the intervention condition is a significant predictor of change. The regressions will account for any important statistically significant differences between groups at baseline. These differences may include variables pertaining to demographics, psychosocial factors, and behavioral variables. Generalized estimated equations (GEE) will be used to account for the within-subject correlation of repeated measures by individual patients. Group designations for the outcome analyses will adhere to the intention to treat threshold. All Statistical analyses will be performed using SAS (version 9.1 or later, SAS Institute Inc, Cary, NC) software.

Engagement variables. We will collect and analyze engagement with the PN and attendance to each session. These analyses will be used to assess intervention fidelity and to describe the amount of intervention each participant received to understand acceptability of the intervention as well as the relationship of intervention dose to study outcomes. These data will include, intervention activities covered and descriptive information such as the number of sessions attended, and the number of interactions with

the PN.

We will also record intervention sessions with the PN to determine the fidelity in which each session has been administered.

Study Statistical Power. Power analyses were done to assess the minimum detectable improvement needed for LARC uptake. A sample of 75 per group, using ITT approaches and assuming outcome if failure (dichotomous only) for patients who do not respond to follow-up surveys will provide 80% power to detect 23% difference between usual care and intervention patients on dichotomous outcomes, assuming an average success rate of 50% for maximum variability. For continuous outcomes, a follow-up sample size of 60 per group will provide 80% power to detect a .55 SD difference between usual care and intervention patients, or a medium linear effect over time (correlational structure CS with rho=.5).

G. Summarize Knowledge to be Gained:

This study will provide innovative information on the reproductive issues relevant to women in OMAT. It will use qualitative methods to develop a reproductive health intervention that can be delivered within the context of treatment. It will also provide information on the feasibility of this type of intervention. A randomized control trial in the second phase will provide important efficacy information on the impact of the intervention on participants' knowledge, family planning visits, and LARC uptake.

H. References:

Agar, M., & MacDonald, J. (1995). Focus groups and ethnography. *Human Organization, 54*(1), 78-86.

American College of Obstetricians and Gynecologists Committe Opinion no 450. (2009). Increasing use of contraceptive implants and intrauterine devices to reduce unintended pregnancy. *Obstetrics and Gynecology, 114*, 1434-1438.

Armstrong, K. A., Kenen, R., & Samost, L. (1991). Barriers to family planning services among patients in drug treatment programs. *Family planning perspectives, 23*(6), 264-266, 270-261.

Armstrong, K. A., Kennedy, M. G., Kline, A., & Tunstall, C. (1999). Reproductive health needs: comparing women at high, drug-related risk of HIV with a national sample. *Journal of the American Medical Women's Association, 54*(2), 65-70, 78.

Bandura, A. (1986). *Social foundations of thought and action: a social cognitive theory*. Englewood Cliffs, NJ: Prentice Hall.

Brien, T., Thombs, D., Mahoney, C., & Wallnau, L. (1994). Dimensions of self-efficacy among three distinct groups of condom users. *Journal of American College Health, 42*, 167-174.

Brindis, C. D., Geierstanger, S. P., Wilcox, N., McCarter, V., & Hubbard, A. (2005). Evaluation of a peer provider reproductive health service model for adolescents. [Evaluation Studies Research Support, Non-U.S. Gov't]. *Perspectives on sexual and reproductive health, 37*(2), 85-91.

Finer, L., Jerman, J., & Kavanaugh, M. (2012). Changes in use of long-acting contraceptive methods in the United States, 2007-2009. *Fertility and Sterility, 98*(4), 893-897.

Finer, L. B., & Henshaw, S. K. (2006). Disparities in rates of unintended pregnancy in the United States, 1994 and 2001. *Perspect Sex Reprod Health, 38*(2), 90-96.

Finer, L. B., & Zolna, M. R. (2014). Shifts in intended and unintended pregnancies in the United States, 2001-2008. *American journal of public health, 104 Suppl 1*, S43-48.

Floyd, L., Decoufle, P., & Hungerford, D. (1999). Alcohol use prior to pregnancy recognition. *American Journal of Preventive Medicine, 17*(2), 101-107.

Goldman, J., & Harlow, L. (1993). Self-perception variables that mediate AIDS-preventive behavior in college students. *Health Psychology, 12*, 489-498.

Hall, K. S. (2012). The Health Belief Model can guide modern contraceptive behavior research and practice. [Research Support, N.I.H., Extramural

Research Support, Non-U.S. Gov't
Review]. *Journal of midwifery & women's health, 57*(1), 74-81.
Hatcher, R., Trussell, J., Nelson, A., Cates, W., Stewart, F., & Kowal, D. (2007). *Contraceptive technology, 19th revised ed*. New York: Ardent Media.
Heil, S. H., Jones, H. E., Arria, A., Kaltenbach, K., Coyle, M., Fischer, G., et al. (2011). Unintended pregnancy in opioid-abusing women. *Journal of substance abuse treatment, 40*(2), 199-202.
Ingersoll, K. S., Ceperich, S. D., Hettema, J. E., Farrell-Carnahan, L., & Penberthy, J. K. (2013). Preconceptional motivational interviewing interventions to reduce alcohol-exposed pregnancy risk. [Randomized Controlled Trial
Research Support, N.I.H., Extramural]. *Journal of substance abuse treatment, 44*(4), 407-416.
Jemmott, J. B., 3rd, Jemmott, L. S., & Fong, G. T. (1998). Abstinence and safer sex HIV risk-reduction interventions for African American adolescents: a randomized controlled trial. [Clinical Trial
Randomized Controlled Trial
Research Support, U.S. Gov't, P.H.S.]. *JAMA : the journal of the American Medical Association, 279*(19), 1529-1536.
Kavanaugh, M. L., Jerman, J., Hubacher, D., Kost, K., & Finer, L. B. (2011). Characteristics of women in the United States who use long-acting reversible contraceptive methods. *Obstet Gynecol, 117*(6), 1349-1357.
Kelly, J. A. (2004). Popular opinion leaders and HIV prevention peer education: resolving discrepant findings, and implications for the development of effective community programmes. [Research Support, U.S. Gov't, P.H.S.]. *AIDS care, 16*(2), 139-150.
Kelly, J. A., St Lawrence, J. S., Diaz, Y. E., Stevenson, L. Y., Hauth, A. C., Brasfield, T. L., et al. (1991). HIV risk behavior reduction following intervention with key opinion leaders of population: an experimental analysis. [Research Support, U.S. Gov't, P.H.S.]. *American Journal of Public Health, 81*(2), 168-171.
Key, J. D., Gebregziabher, M. G., Marsh, L. D., & O'Rourke, K. M. (2008). Effectiveness of an intensive, school-based intervention for teen mothers. [Comparative Study
Evaluation Studies]. *The Journal of adolescent health : official publication of the Society for Adolescent Medicine, 42*(4), 394-400.
Kost, K., Singh, S., Vaughan, B., Trussell, J., & Bankole, A. (2008). Estimates of contraceptive failure from the 2002 National Survey of Family Growth. *Contraception, 77*(1), 10-21.
Longshore, D., Stein, J., & Chin, D. (2006). Pathways to sexual risk reduction: gender differences and strategies for intervention. *AIDS and Behavior, 10*(1), 93-104.
Lopez, L. M., Tolley, E. E., Grimes, D. A., Chen, M., & Stockton, L. L. (2013). Theory-based interventions for contraception. [Research Support, N.I.H., Extramural
Research Support, U.S. Gov't, Non-P.H.S.
Review]. *The Cochrane database of systematic reviews, 8*, CD007249.
Lundahl, B., Moleni, T., Burke, B. L., Butters, R., Tollefson, D., Butler, C., et al. (2013). Motivational interviewing in medical care settings: a systematic review and meta-analysis of randomized controlled trials. *Patient education and counseling, 93*(2), 157-168.
Martins, R. K., & McNeil, D. W. (2009). Review of Motivational Interviewing in promoting health behaviors. [Review]. *Clinical psychology review, 29*(4), 283-293.
Mason-Jones, A. J., Mathews, C., & Flisher, A. J. (2011). Can peer education make a difference? Evaluation of a South African adolescent peer education program to promote sexual and reproductive health. [Evaluation Studies
Research Support, Non-U.S. Gov't
Research Support, U.S. Gov't, P.H.S.]. *AIDS and behavior, 15*(8), 1605-1611.
Mestad, R., Secura, G., Allsworth, J. E., Madden, T., Zhao, Q., & Peipert, J. F. (2011). Acceptance of long-acting reversible contraceptive methods by adolescent participants in the Contraceptive CHOICE Project. [Research Support, N.I.H., Extramural
Research Support, Non-U.S. Gov't]. *Contraception, 84*(5), 493-498.
Miller, W., & Rollnick, S. (2002). *Motivational interviewing: preparing people for change.* (2 ed.). New York: NY: Guildford Press.

NIDA. (2011). *Topics in Brief: prenatal exposure to drugs of abuse-May 2011*.
O'Leary, A., Goodhart, F., Jemmott, L., & Boccher-Lattimore, D. (1992). Predictors of safer sex on the college campus: a social cognitive theory analysis. *Journal of American College Health, 40*, 254-263.
Patrick, S. W., Schumacher, R. E., Benneyworth, B. D., Krans, E. E., McAllister, J. M., & Davis, M. M. (2012). Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009. *JAMA : the journal of the American Medical Association, 307*(18), 1934-1940.
Patton, M. Q. (2002). *Qualitative Research & Evaluation Methods. 3rd ed*. Thousand Oaks, CA: Sage Publications.
Ricketts, S., Klingler, G., & Schwalberg, R. (2014). Game Change in Colorado: Widespread Use Of Long-Acting Reversible Contraceptives and Rapid Decline in Births Among Young, Low-Income Women. *Perspectives on sexual and reproductive health*.
Rosenstock, I. (1974). The health belief model and preventive health behavior. *Health Education Monographs, 2*, 354-385.
Schensul, S. (1999). Ethnographic sampling. In S. Schensul (Ed.), *Essential ethnographic methods: observations, interviews, and questionnaires (Ethnographer's Toolkit)* (pp. 231-269). Walnut Creek, CA: Altamira Press.
Selwyn, P. A., Carter, R. J., Schoenbaum, E. E., Robertson, V. J., Klein, R. S., & Rogers, M. F. (1989). Knowledge of HIV antibody status and decisions to continue or terminate pregnancy among intravenous drug users. *JAMA : the journal of the American Medical Association, 261*(24), 3567-3571.
Shiner, M. (1999). Defining peer education. [Review]. *Journal of adolescence, 22*(4), 555-566.
Siegel, D. M., Aten, M. J., Roghmann, K. J., & Enaharo, M. (1998). Early effects of a school-based human immunodeficiency virus infection and sexual risk prevention intervention. [Comparative Study
Research Support, U.S. Gov't, P.H.S.]. *Archives of pediatrics & adolescent medicine, 152*(10), 961-970.
Sikkema, K., Koob, J., Cargill, V., Kelly, J., Desiderato, L., Roffman, R., et al. (1995). Levels and predictors of HIV risk behavior among women in low-income public housing developments. *Public Health Reports, 110*, 707-713.
Sonfield, A., Kost, K., Gold, R. B., & Finer, L. B. (2011). The public costs of births resulting from unintended pregnancies: national and state-level estimates. *Perspectives on sexual and reproductive health, 43*(2), 94-102.
Trussel, J., Lalla, A., Doan, Q., Reyes, E., Pinto, L., & Gricar, J. (2009). Cost-effectiveness of contraceptives in the United States. *Contraception, 79*, 5-14.
Trussell, J. (2012). Update on and correction to the cost-effectiveness of contraceptives in the United States. [Comment
Letter]. *Contraception, 85*(6), 611.
White, W. (2004). The history and future of peer-based addiction recovery support services. paper developed for the Consumer Direction Initiative Summit, held by the Substance Abuse and Mental Health Services Administration.
Wulfert, E., & Wan, C. (1993). Condom use: a self-efficacy model. *Health Psychology, 12*, 346-353