PROTOCOL TITLE:

A quasi-experimental, interrupted time series study to evaluate the effectiveness of "SexHealth Mobile" on uptake of contraception in women with substance use disorder

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1.0 Study Summary

Study Title	A quasi-experimental, interrupted time series study to evaluate the effectiveness of "SexHealth Mobile" on uptake of contraception in women with substance use disorder
Study Design	A quasi-experimental study design using an interrupted time series (i.e., usual care [control] then intervention care) to compare uptake of contraception before and after implementing the "SexHealth Mobile" intervention.
Primary Objective	To improve access to highly effective contraception among women with substance use disorder (SUD) with our pilot program "SexHealth Mobile".
Secondary Objective(s)	To explore intervention feasibility
Research Intervention(s)/ Investigational Agent(s)	Our study intervention consists of "SexHealth Mobile" which integrates two existing services in our community: a mobile medical unit (MMU) operated by Swope Health Services, and "SexHealth" a point-of-care contraception counseling service that our research team developed for Children's Mercy Hospital's emergency department (ED).
IND/IDE #	N/A
Study Population	Study population includes women with substance abuse disorder (SUD) with an unmet need for contraception who are accessing health, recovery, or community services recovery sites committed to our community partner, Swope Health Services. We will also enroll staff and clinicians from Swope Health who will perform tasks (including contraceptive counseling) relevant to health care delivery in the mobile medical unit.
Sample Size	Total sample size is: Women with SUD = 160 (We need 160 with evaluable data at end of index visit with 80 in each time period so will request to enroll up to 170 if needed) – Usual Care [control]: up to 85 – SexHealth Mobile intervention: up to 85 Staff/Clinicians from Swope Health Services = 10
Study Duration for Individual Participants	Women with SUD = Total study duration will be 3 months for all participants. Follow-ups will be conducted at 2-weeks, 1-month, and 3-month post-enrollment. Staff/Clinicians from Swope Health Services = 18 months
Study Specific Abbreviations/ Definitions	SUD: substance abuse disorder OUD: opioid use disorder MMU: Swope's medical mobile unit ED: emergency department

Objectives and Hypotheses

1.1 **Our primary objective** is to improve access to highly effective contraception among women with substance use disorder (SUD) with our pilot program "SexHealth Mobile".

- **Our primary hypothesis** is that current use of highly effective contraception (includes *sterilization, subdermal implant, intrauterine device, injectable, pill, patch, or ring*) will be greater at 1-month post-enrollment among women recruited during the intervention period (i.e., "SexHealth Mobile") compared to those recruited during the usual care period. We will also compare current use and discontinuation rates at 2-weeks and 3-months among all participants.

1.2 **Our secondary objective** is to explore intervention feasibility.

2.0 Background

2.1 Scientific Background and Prior Experiences

Women with SUD experience higher rates of pregnancy complications including miscarriage, placental previa/abruption, and stillbirth. Substance-exposed infants, including those with neonatal abstinence syndrome (NAS) and fetal alcohol spectrum disorders (FASD), are more likely than non-exposed infants to be born preterm, have low birth weight, and require intensive care hospitalization [1]. SUD in pregnancy is common; about one in four pregnant women report substance use (including tobacco) [1]. And the national prevalence of women presenting in pregnancy specifically with opioid use disorder (OUD) increased by 333% from 1999 to 2014 [2].

Most pregnancies among women with SUD are unintended [3], often due to contraception non-use or misuse resulting from a confluence of patient- provider- and system-level barriers. In particular, OUD is growing problem among pregnant women in the U.S. Midwest, is as rates of neonatal abstinence syndrome have grown by 270 percent in the state of Missouri over the past decade [2]. Meta-analyses have estimated the prevalence of contraceptive use among women with SUD at only 55% [4], highlighting the urgent need for effective patient-centered interventions that increase access to contraception for women with SUD by integrating contraceptive counseling into existing recovery resources or other points of contact.

Many women with SUD never learn about contraceptive options as they often avoid seeking routine health care. Limited data suggests that when women with SUD use contraception, they most commonly use methods with lower rates of efficacy (i.e., oral contraceptive pills and condoms) and often make errors, rendering these methods even less effective than usual [4]. Identifying novel points of contact where women with SUD may be receptive to learning about and/or obtaining the most effective methods is key to reducing opioid-exposed pregnancies.

2.2 Formative Research and Preliminary Data

We conducted in-depth interviews with women who abused substances (e.g., opioids, alcohol, methamphetamines) throughout Missouri. Though many wanted to avoid pregnancy, women reported infrequent use of effective contraception. Due to their current financial/health/relationship instability, most were very receptive to receiving contraceptive care, including long-acting reversible contraception (LARC), in non-traditional settings such as mobile medical units and treatment or recovery centers. We also interviewed professionals who provide care or treatment for this population (e.g., treatment center managers, physicians). Providers agreed that access to contraception could be an important harm reduction strategy but identified barriers that interfere with delivery of this care. Most clinics and recovery centers do not actively identify unmet reproductive needs among this high-risk population. Further, many prescribing clinicians had limited experience in providing contraception directly, preferring to refer women to traditional clinic settings for this care.

Previously, our team developed and pilot-tested an intervention (SexHealth) to bring point-of-care sexual risk reduction counseling and sexual health services (e.g., contraception, condoms) to adolescents visiting the emergency department. In a randomized controlled trial (N=81), the intervention was acceptable to 95% of adolescents and feasible (mean length of session was 24.5 minutes). Compared to controls, intervention participants were more likely to complete ≥1 service (69% vs. 90%, p=0.028).

1. Forray A, Foster D. Substance use in the perinatal period. Current psychiatry reports. 2015 Nov 1;17(11):91.

2. Haight SC, Ko JY, Tong VT, Bohm MK, Callaghan WM. Opioid use disorder documented at delivery hospitalization—United States, 1999–2014. Morbidity and Mortality Weekly Report. 2018 Aug 10;67(31):845

3. Heil SH, Jones HE, Arria A, et al. Unintended Pregnancy in Opioid-abusing Women. J Subst Abus Treat. 2011;40(2):199-202.

4. Terplan, M. Hand, D.J. Hutchinson, M. Salisbury-Afshar, E. Heil, S.H. Contraceptive use and method choice among women with opioid and other substance use disorders: a systematic review. Prev Med. 2015; 80: 23–31

3.0 Study Endpoints

3.1 Primary Endpoint: Study will end data collection when the estimated sample size has been enrolled to show statistically significant effects for women with any type of SUD, including those with OUD.

4.0 Study Intervention and Drug Handling

4.1 Description:

Our study intervention consists of “SexHealth Mobile” which integrates two existing services in our community: a mobile medical unit (MMU) operated by Swope Health Services, and “SexHealth” a point-of-care contraception counseling service that our research team previously developed for Children’s Mercy Hospital’s

emergency department (ED). Using a menu of adaptive services, "SexHealth Mobile" will bring contraceptive care to women with SUD (including a subset of women with OUD), if they wish to receive it, at targeted recovery sites Swope currently partners with.

4.2 Drug Handling: All drugs and devices being dispensed are standard of care treatments. Swope Health will have sole responsibility of all study medications which includes storage, handling, and dispensing of drugs and devices (i.e., subdermal implants). Upon receipt by the designated person at Swope (Rachel Melson, DNP), devices and medications would be logged and accounted for then appropriately stored in secured location. Devices and medications would be labeled for the individual patient upon receipt of clinician order. The Swope staff members will responsible for filling individual patient containers and labeling the containers following their established procedures. The Swope staff will be responsible for keeping accurate records of the clinical supplies, the amount dispensed to and returned by the patients, and the disposition at the end of the study.

4.3 The contraceptive medications and/or subdermal implant that may be used in this study are not investigational as this study does not aim to evaluate the safety or effectiveness of these therapies.

5.0 Procedures Involved

5.1 **Study Design:**

A quasi-experimental study with an interrupted time series (i.e., usual care [control] then intervention care) to compare the uptake of contraception before and after implementing the "SexHealth Mobile" intervention. Participants recruited will be women with SUD/OUD with an unmet need for contraception who are accessing health, recovery, or community services at centers where Swope Health already provides clinical care (but not contraception). The recovery centers include: Healing House, ReDiscover, Journey to a New Life, and Amethyst Place. We are partnering with Swope Health Services to integrate the "SexHealth Mobile" model into their existing MMU that currently provides limited clinical services.

5.2 **Research Procedures:**

Usual care: Study staff will work with a point person at each of the recovery sites to facilitate recruitment logistics according to the site's COVID- related restrictions. Recruitment will continue until the target sample size has been reached (up to 6 months). Staff will work with recovery sites to reach and identify women that may be interested and meet eligibility criteria.

Study staff will distribute recruitment information virtually to the sites in the form of electronic recruitment document. We will also create a video with recruitment information for the sites to distribute.

Interested participants may be given options to meet in-person or call-in information for a TEAMS meetings that will serve as recruitment sessions. Women will speak to a member of the study staff, complete eligibility, informed consent, and the baseline survey. In-person recruitment may also occur. In this case, we will use our approved COVID-19 contingency plan to minimize risk of COVID transmission, including using outdoor spaces, wearing masks, maintaining social distance, and sanitizing all materials. We will also adhere to participating sites COVID-19 safety guidelines during this time.

During recruitment, women will complete an eligibility screen, informed consent, and baseline survey via REDCap surveys. All participants will be assigned a unique patient identifying number through REDCap.

If a participant is eligible and has agreed to consent, she will complete the baseline survey and provide contact information for the designated follow-up surveys and reminders that will be completed at 2-weeks, 1-month, and, 3-months after baseline. Study staff will then provide information about contraceptive services according to referral procedures followed at the specific recovery site where recruitment is taking place. The usual care referral document will be reviewed and sent to the participant electronically via TEAMS or email, and hard copies will also be mailed or dropped off to each participant at the site along with their Greenphire payment card.

If participant is not eligible, study staff will provide a referral on where they can access more information on contraception and care.

Follow-up survey reminders will be sent via email and text messages for participants to call study staff. Text message reminders will be sent via Twillo on REDCap.

Intervention (“SexHealth Mobile”): After usual care sample has been reached, Swope Health will begin integrating “SexHealth Mobile” into their health care services for women. These services include the MMU with in-person visits with a Swope health care provider. Study staff will work with recovery sites to disseminate information about the “SexHealth Mobile” and build interest in the intervention. This will be focused on raising awareness about the clinical service, not direct recruitment for the research study. Recovery site leaders will be instructed to direct any questions pertaining to the research study to the study team.

At the start of the “SexHealth Mobile” intervention, study staff will continue to recruit women virtually or in-person with the sites to participate in surveys about their experience and the care provided. If permitted, we will use similar procedures to conduct in-person recruitment using our approved COVID-19 contingency plan. At the end of the baseline survey, women who are interested in obtaining services with SexHealth mobile will be given an appointment for

virtual counseling and/or mobile health on-site services (depending on Swope's clinical care procedures at the time).

We estimate the research team will need 4-6 months in order to recruit the target sample of "SexHealth Mobile" patients.

Participants will complete an eligibility screen and informed consent with study staff via TEAMS or in-person. If a participant is eligible and has agreed to consent, she will complete the baseline survey on an iPad via REDCap. All participants will be assigned a unique patient identifying number through REDCap. Participants will also provide secure contact information for the designated follow-up surveys and reminders that will be completed at 2-weeks, 1-month, and, 3-months after baseline.

After completing the baseline, study staff will ask participants if she would like to be seen for contraceptive counseling. Women who are interested in obtaining services with SexHealth mobile will be given an opportunity to acquire an appointment for virtual or in-person counseling on the MMU or on-site services (depending on Swope's clinical care procedures at the time).

Swope providers will be given an audio recorder to record visits with participants to assess for intervention fidelity. If participant wishes to not be recorded, they will be given the option to turn off the recorded at any time during their visit.

After the visit is completed, participants will complete a brief post-intervention survey over the phone or in-person with study staff and be provided a referral to follow-up.

If participant does not want to be seen or acquire an appointment with a healthcare provider after baseline, study staff will provide a referral virtually or in-person on where they can access more information on contraception and care.

If participant is not eligible, study staff will provide a referral virtually or in-person on where they can access more information on contraception and care.

Follow-up survey reminders will be sent via email and text messages for enrolled participants to call study staff. Text message reminders will be sent via REDCap through Twilio or other CM approved messaging.

5.3 **Procedures for lessen risk:**

Data and safety will be monitored on multiple levels. Drs. Miller and Hurley, the lead Research Coordinator and research staff will meet at least weekly to review study progress, safety issues, recruitment progress, and data quality. The entire research team will meet quarterly to review study progress. The Research Coordinator will produce quarterly reports describing recruitment milestones, adverse events, and data quality. We will report any adverse events as directed by the institutional IRB and adverse event (AE) reporting policies. Events will be reported promptly to the PIs and the lead Research Coordinator who will make provisions to

respond appropriately, ensuring referral to medical/professional resources, as needed. All data collected will be stored and secured on REDCap on password protected computers. Access will only be granted to study staff. Contact information will be marked as “identifiers” in the secure REDCap project, stored on a REDCap instrument separate from the other study data, and not downloaded along with the dataset for analysis.

In addition, participants interested in birth control will be given verbal and printed evidence-based information about the method (these information sheets are publicly available at reproductiveaccess.org). This includes information about possible side effects and risks associated with the medication.

For participants who start a medication, we will ask about common (expected) adverse events at each follow-up survey. The vast majority of medication side effects are mild and often don't require any intervention or care. Participants will be given guidance (anticipatory) for side effect management at enrollment and also if side effects are disclosed during survey follow-up. Participants will be instructed to contact Swope Health for mild side effects and this number will be provided to participants (written and verbally). For more concerning side effects, (i.e., chest pain, trouble breathing, weakness or numbness on part of the body, bad headache, or leg swelling/redness/pain), participants will be directed to seek care at the nearest emergency department or to call 911.

5.4 **Data collection:**

Our multi-disciplinary team developed the assessment tools, based on national surveys and a review of the pertinent literature including validated items where applicable. At baseline, we will assess for high-risk sexual behaviors, substance use, relationship status, health care access and utilization, health history (e.g., pregnancies, mental health), and demographic information. Follow-up surveys will assess for contraception use (including condoms), healthcare utilization, health history, intervention satisfaction and feasibility.

Baseline information will be collected directly from participants on an iPad recorded on REDCap. Follow-up surveys will be completed after enrollment and recorded in REDCap.

See our measure tools to know what demographic, baseline, and follow-up data will be collected.

6.0 Data and Specimen Banking

6.1 All information will be stored in REDCap via a Children’s Mercy secured iPad or laptop onto a secure Children’s Mercy server by granted study staff.

7.0 Sharing of Results with Subjects

7.1 All information collected will be deidentified before sharing results. We will have a short write up of the data for each recovery site to distribute to their clients.

8.0 Study Timeline

8.1 The duration of this study is estimated to be at 18 months to reach our target sample size. We estimate we will need approximately 6 months to recruit and enroll participants in the usual care period, and approximately 6 months during the intervention "SexHealth Mobile" period. There are 3 months included before recruitment for preparation (securing ethical approval, creating intervention and research tools, developing a manual of operations) and 2 months at the end for analysis.

8.2 The duration of the study for each participant will be 3 months.

	Month																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Preparation																		
Usual Care				Recruit					Follow-up									
Intervention									Recruit					Follow-up				
Analysis																		

9.0 Inclusion and Exclusion Criteria

9.1 Swope staff/clinician as a participant:

- is a current employee of Swope health services
- Practice or tasks are relevant to intervention

9.2 Inclusion Criteria for client participants

Participants will be eligible if they:

- are between the ages of 18-40 years
- are biological females
- have an unmet need for contraception (sexually active, able to become pregnant, not consistently/currently using these contraception methods [sterilization, subdermal implant, intrauterine device, injectable, pill, patch, or ring]
- have current or recent (within the past year) problematic patterns of substance use (according to the CAGE-AID self-assessment

9.3 Exclusion Criteria for subjects

Participants will be ineligible if they:

- have previously enrolled in the study
- are unable to provide informed consent
- are pregnant at index (recruitment) visit

10.0 Vulnerable Populations

10.1 Women with active addiction or in recovery may be vulnerable to undue influence because of unique challenges involving housing, relationships, and health. We will use these strategies to avoid situational vulnerability among potential participants: 1) provide written and verbal information about the study that is easy to understand (e.g., layman's terminology, no higher than 8th grade reading level); 2) provide clarifications and answer all questions about participation; 3) allow as much time as needed for prospective participants to make their decision about participation. We will build support from trusted community members who can facilitate research understanding (including voluntary nature). We will assist with referrals for women interested in learning more about contraception but who do not want to participate in our study.

11.0 Local Number of Subjects

11.1 We anticipate enrolling up to 170 new participants to reach out target sample size of 160 with evaluable data (up to 85 during the usual care period, and up to 85 during the intervention period). This is in addition to the 31 recruited in the first attempt to being the study before COVID-19, meaning a total of 201 women will be enrolled in the study. Additionally, we will recruit up to 10 Staff/Clinicians from Swope Health Services.

12.0 Screening and Recruitment Methods

12.1 For the usual period, recruitment will occur through recovery sites at certain weekly rotations throughout the 6-month period. Participants will be presented with a recruitment flyer (virtually or in person) and ask if they are interested in participating by study staff. We will have a peer outreach coordinator at each site to help elicit participation interest. If a participant is interested, study staff will screen the participant for eligibility on REDCap via a tablet, their personal mobile device, or a computer available at their site.

12.2 During the intervention period, study staff will recruit at the recovery sites based on the mobile clinic's stop schedule. If MMU is not available, study staff will recruit based on certain weekly rotations that are provided by Swope's health care provider. Participants will be presented with a recruitment flyer (virtually or in person) and ask if they are interested in participating by study staff. We will have a peer outreach coordinator at each site to help elicit participation interest. If a participant is interested, study staff will screen the participant for eligibility via a tablet on REDCap.

12.3 All identifying information will be collected after participant has been screened and consented

13.0 Reimbursement, Payment and Tangible Property provided to subjects

13.1 Participants will be compensated up to $70 for their time. Participants will receive $20 at the recruitment visit. They will

receive $15 for completing the two-week follow-up survey, another $15 for completing the one-month follow-up survey, and $20 for completing the three-month follow-up survey. There are no plans for the collection of SSN from participants.

14.0 Withdrawal of Subjects

14.1 Participants may withdrawal themselves from the study at any time. When a participant withdraws from a study, data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. Discussion of enrolled participants will be held weekly to ensure they meet our inclusion and exclusion criteria.

15.0 Risks to Subjects

As with any study, there is potential for loss of confidentiality. Information security is top priority for both the investigators and the hospital. We believe that all identifying and clinical information will be secure, and a security breach is highly unlikely to occur. We acknowledge, however, should a security breach occur, it would have several serious consequences for the participant, including identity theft and loss of privacy.

There is potential for emotional distress while discussing sensitive material related to sexual health. Participants may skip a question or stop the study at any time. Due to the sensitive nature of some of our survey questions, we will offer printed resource material to all participants.

Risk of emotional distress: Women will receive detailed information about this study to minimize the risk of physical and emotional harm to study participants. Participants may experience increased stress over survey questions asking about sexual risk behaviors. However, we feel this risk is minimal and will include information in the consent process that reminds participants that they are not required to answer questions that make them feel uncomfortable. At each recovery site and at Swope Health, there are advocates available for patients and families, if needed. Clinical counseling sessions will be recorded and continuously reviewed for research quality purposes. In this study setting, if a participant expresses a concern or need that is outside of the scope of this project, we will refer those participants back to their SUD treating team, as is our standard practice. During the consent process, we will inform participants that most of the information they share during the study will be kept confidential except in rare cases where their safety is at risk or mandated reporting is in effect.

Risk of device removal: Participants who choose to start a subdermal contraceptive implant during the study and need removal of the implant within one year of placement, the cost of the implant removal will be paid for by the study. If participant has an expired implant or IUD that needs to come out and chooses to have the device removed at enrollment, the cost for removal of the expired implant will be paid for by the study. Swope staff members will be responsible for removing devices at enrollment on the medical mobile unit.

16.0 Potential Benefits to Subjects

16.1 There may be no direct benefit to participating in the study as the SexHealth intervention is not a research intervention. Participants may benefit from the additional monitoring that will occur as part of the follow-up survey visits.

17.0 Investigator Assessment of Risk/Benefits Ratio: **(IRB makes the final determination)** *Based upon your response in Sections 17.0 and 18.0, please provide your assessment of risk and benefits in below table.*

Select as applicable:	**Pediatric Risk Category:**	
	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (45 CFR §46.405 and 21 CFR §50.52)
	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
X	Not Greater than Minimal Risk	
	Greater than Minimal Risk	

18.0 Data Management and Confidentiality

18.1 **Statistical Methods:**

Demographic variables collect from both control and intervention participants will be summarized and compared. Categorical variables will be reported as frequencies and percentages; whereas, continuous variables will be reported as means with standard deviations or medians with interquartile ranges depending on which is more appropriate. Fidelity will be assessed through analyzing recordings using a checklist developed for the delivery of the training. Differences between groups regarding the usage of highly effective contraception at 1-month post enrollment will be compared using a Fisher's Exact Test. We will also compare contraception usage at 2-weeks and 3-months post enrollment. Baseline and follow-up survey data will also be summarized and compared. Likert-scale items will be compared using Wilcoxon Mann Whitney tests. To assess the primary outcome, logistic regression models will be fit to investigate potential predictors for utilizing highly effective contraception at the post enrollment time points.

All statistical tests will be conducted at the alpha = 0.05 level. Statistical analysis will be done using The SAS software v 9.4 (Copyright, SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA) and R statistical software (R Core Team (2015). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL http://www.R-project.org/).

18.2 **Multiplicity:**

We are powered to test our primary hypothesis for both the entire sample as well as the subsample of women with OUD in both the usual care and interventional groups. Survey responses collected at baseline and follow-up will have multiple items which will be compared and adjusted for multiple comparisons using a Bonferroni correction.

18.3 **Power/Sample Size:**

This n is based on Fisher's exact test assuming uptake of 20% in the baseline period and 76% in the intervention period (based on studies showing uptake of point-of-care contraception among active drug users [66%] and women in recovery [85%]). Assuming 90% power and an error probability of α =0.05, this calculation gives us starting sample size of 32. Because we want to show statistically significant effects for both women with any type of SUD including those with OUD, and estimating that 30% of the study population will have OUD (according to estimates from our partner sites), we want to finish with 107 women with in total (30% of this is 32), To protect against attrition with this highly transient population, we will oversample our total by 50%, bringing our total N=160 (107x1.5).

18.4 **Data Management:**

To minimize risk of possible breach of confidentiality, data will be entered and stored into REDCap by study staff. Data will be stored on a CM secure network via CM encrypted password protected tablet and laptop. Participants will be assigned a unique REDCap ID number for management of their data collection. Online consent forms will minimize risk of transporting PHI back to CM from the recruitment sites.

18.5 Our research is covered by a Certificate of Confidentiality

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 To protect participant's privacy interest, study staff will ensure all data collected will be secured and encrypted on a CM server. At the end of the study, all data collected will be de-identified and reported as a summary to partners and for dissemination.

To ensure participants feel at ease with the research study, women will be recruited in a quiet, private and secluded area at the recovery site. In addition, women who are treated in the mobile medical unit will have privacy with the nurse practitioner for their clinic visit and

exams. Audio recordings will be de-identified when stored on a secure server.

19.2 *P*HI obtained from participant will include name, phone number, and email. This information will be obtained after participant has completed informed consent. All information will be stored REDCap on password protected serves.

19.3 Full written HIPAA Authorization will be wrapped into the consent form.

20.0 Economic Burden to Subjects

20.1 There is no economic burden by participating in this project. There are no costs of participating in the research study.

21.0 Consent Process

21.1 Informed consent to participate in research will be obtained via eConsent for all participants who wish to be enrolled in the study. There will not be any waiting period to consent since all participants will be asked on site before the baseline survey is conducted. When a person is eligible, informed consent will be presented. Blank paper copies of the consent form will be available with study staff for participants to have.

22.0 Process to Document Consent

22.1 Informed consent through a signature from participant will be collected and stored electronically via REDCap

23.0 Setting

23.1 Research procedures will be conducted at recovery centers Swope Health Services currently partner with. These centers include Healing House, Hope City, ReDiscover, and Amethyst place for both the usual care and intervention period. Contraceptive counseling will be conducted on the MMU. Study staff will ensure all settings have private rooms for participants to complete procedures. Permission to conduct research procedures at these centers will be sought out.

24.0 Resources Available

24.1 Swope Health is our community partner and they provide accessible, high-quality, comprehensive patient care. Swope Health provides primary health care and behavioral health services throughout Greater Kansas City. They are a patient-centered medical home, nationally recognized for their commitment to an integrated model of health care. The mobile medical clinic (MMU) currently serves adults experiencing homelessness and other disadvantages. They visit sites in the Kansas City metro every week. Services include blood tests, urgent care for non-emergencies and immunizations. The Swope Mobile features two exam/treatment rooms staffed with a full-time nurse practitioner, a registered nurse, and a certified medical assistant.

24.2 If any participant requires medical or psychological resources as a result of an anticipated consequences of the human research, they will be referred to our community partner, Swope Health (described above). Further, if a participant elects to receive a subdermal implant and then desires early removal of the device (i.e., within one year of placement), we have received contingency funds from Merck Inc to pay for the removal procedure. Finally, each site that is visited by the mobile medical unit also has extensive support services that participants can access.

24.3 Based on our previous work as well as discussion with Swope Health staff, we anticipate women at each site will be eager to volunteer as participants as the interest in reproductive health is high. During the intervention period, we estimate that up to four women will be enrolled during one clinic session. The number of clients attending a clinic session can vary between 2-14. We will utilize peer liaisons at each site to increase awareness of the study and opportunities for participation.

24.4 The research study team has received funding support from Merck Inc, which allows for adequate time to conduct the research (Dr. Miller and Dr. Hurley are devoting 0.15 FTE, the research coordinator is dedicating 0.5 FTE).

24.5 Research coordinator has been working with PIs to develop protocol for research procedures. Coordinator will refer to protocol and PIs weekly during implementation to ensure procedures and functions are being met.