**PROTOCOL TITLE:** Providing Expanded Continuous Labor Support to Pregnant Women in New Mexico with Substance Use Disorders
NCT03808909

## PRINCIPAL INVESTIGATOR:

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## VERSION: ClinicalTrials.gov

## VERSION DATE: 07/12/2018

## Contents

# 1.0 Objectives

*1.1 Specific Aims.*

This study will determine the feasibility of offering expanded continuous labor support by trauma- and addiction-trained medical paraprofessionals (i.e. doulas) at no cost to pregnant women receiving care for substance use disorders (SUD). The long-term goal of this transdisciplinary multilevel intervention is ultimately to reduce a major existing behavioral health disparity in the state.

Pregnant women with substance use disorders (SUD) disproportionately have low socio-economic status and co-occurring mental health problems, especially trauma-related disorders.[1–4] Additionally, women of color experience behavioral health disparities in care and higher rates of poor maternal and infant behavioral and medical health outcomes.[5–13] Women with prenatal SUD are consistently under-resourced and are at high risk for homelessness, loss of child custody, incarceration, loss of parental rights, birth defects, stillbirth, infant death, and child abuse and neglect. There is high long-term postpartum morbidity among women with deliveries complicated by alcohol or drugs, including higher rates of mental, viral, and bacterial illness and requiring an increased need in more medical and social services.[9,14] These women are 38 times more likely than controls to die within 9 years of giving birth.[14] SUD relapse rates during pregnancy are high, often around 50%,[15,16] with uniquely high risks in this population. Many women with prenatal SUD have extensive trauma histories, and are at increased risk of postpartum PTSD, SUD relapse, postpartum depression, poor mother-infant attachment, and of development or aggravation of PTSD from traumatic birth experiences.[11,17–21]

Paraprofessional continuous labor support may offer a low-cost method of improving these outcomes.[22] ‘‘In this proposal, the term “doula” refers to a person trained to provide continuous labor support. A recent Cochrane report found that continuous labor support was associated with less emotionally traumatic birth outcomes (i.e., adverse events that can happen during childbirth that might be emotionally traumatic for a woman giving birth, such as cesarean section, instrumental vaginal birth, or extended labor).[23] Two states, Minnesota and Oregon, in the U.S. already allow Medicaid reimbursement for doula services.[24] In New Mexico doulas are not covered by Medicaid. This creates a behavioral health disparity, by which women with high economic status predominantly have access to these supportive services. This pilot study is intended to explore the feasibility of offering access to trauma and SUD trained doulas at no cost to women in the XXX program at XXX.

This cross-campus multi-disciplinary collaboration, is in partnership with Young Women United (a research and policy organization in NM) and doulas of the UNM Birth Companion Program. Through this partnership, women receiving combined OB/SUD treatment at the XXX Program at UNMHSC will be offered expanded doula services.

*1.2 Hypotheses*

This is a feasibility study; therefore, the aims are to determine the feasibility of this research design in this context. Our overall hypothesis is that this study will be feasible in this population. We plan to also use this pilot data to calculate effect sizes to conduct power analyses for future research on this topic.

**Aim 1. Feasibility** – (a) Develop and refine participant recruitment and retention methods, (b) Develop and refine doula trauma and SUD training with input from a group

of prior XXX Program patients (who gave birth with an SUD), (c) Estimate patient interest, satisfaction, and knowledge about doula services, (d) Estimate doula retention, satisfaction, and increased knowledge about SUD and trauma, and (e) Estimate patient attrition and follow-up rates.

**Aim 2. Estimate behavioral health outcomes** – (a) Traumatic birth outcome, (b) breastfeeding uptake, (c) SUD relapse and postpartum mental health change from baseline, (d) Estimate effect sizes of all theorized relationships.

## 2.0 Inclusion and Exclusion Criteria

*How individuals will be screened for eligibility*

Recruitment and screening will be by the RA or Dr. Sanjuan at the XXX Clinic or in some cases at CASAA (e.g. if a participant hears about the study via word of mouth and calls our recruitment line, or if a participant is interested but is unable to be screened at the XXX Clinic) using a study specific screening form attached. See section 21 for more information on recruitment methods.

*Inclusion/Exclusion Criteria*

Inclusion Criteria: Participants must be at least 18 years old, able to participate in informed consent, able to read, write, and speak English, gestation of at least 26 weeks at baseline (necessary because of short duration of study), and plan to give birth at XXX.
Exclusion Criteria: Participants will be excluded if they are actively psychotic or are currently incarcerated. Additionally, patients identified by medical staff as unable for medical reasons to currently participate in the study will not be approached for screening. Finally, only patients who indicate they are interested in participating in a study on doula support will be screened for the study.

*Special Populations*

Rationale for the involvement of special vulnerable populations: We will be recruiting only pregnant women, and thus from a special vulnerable population. The justification for this is that substance relapse during pregnancy is a unique and relatively underexamined problem that is different than relapse to substance use in other populations because of (1) the high risk involved, (2) the role of pregnancy hormones in emotional dysregulation, (3) the high rates of PTSD in this population, and (4) the powerful social stigma towards substance use during pregnancy. Specially trained doulas who provide continuous labor support and postpartum follow-ups may be a pregnancy-specific intervention for these women. High risks of substance relapse among pregnant women with SUD include death from overdose, damage to the developing fetus, miscarriage, stillbirth, premature birth, involvement of child welfare, loss of parental rights, and incarceration. Additionally, pregnant women with SUD are at high risk of postpartum relapse, PTSD, and depression, resulting in a high rate of morbidity for this population. Gaining knowledge that can lead to targeted SUD treatments for pregnant women is critical to reduce the suffering and social costs resulting from prenatal substance use and postpartum problems. The risks to pregnant women and their fetuses from participation in this study are minimal, and there may be some small incidental benefits to all the women (doula and control group) and their fetuses from such

participation (e.g. assessment reactivity could reduce their chances of relapse). Moreover, the women who are provided a doula may benefit from this added level of psychosocial support. Thus the involvement of pregnant women in this research is justified.

Additional protections for pregnant women, human fetuses and neonates are outlined under #16 below.

## 3.0 Study-Wide Number of Subjects

We plan to enroll 34 women in order to have a final number of 30 who complete the study.

## 4.0 Study Timelines

*4.1 Describe:*

- *The duration of an individual subject's participation in the study.*
  Between 4 weeks to 20 weeks, dependent upon fetal gestational age at baseline.

- *The duration anticipated to enroll all study subjects.*
  12 months from the funding date

- *The estimated date for the investigators to complete this study (complete primary analyses)*
  July 1, 2020

## 5.0 Study Endpoints

Primary Outcomes
Relapse will be defined as percent drinking or drug use days postpartum and by drug screen at hospital admission results.
Postpartum PTSD severity – PTSD Checklist score
Postpartum depression severity – Edinburgh Postpartum Depression Scale Score
Breastfeeding Uptake
Neonatal Abstinence Syndrome
Length of NICU Stay
Secondary Outcomes
Social Support – NIH Toolbox
Labor and Delivery Autonomy
Participant Satisfaction
Doula Satisfaction

## 6.0 Procedures Involved*

We will offer doula services at no cost to the 15-17 women (G1) who screen into the study and have a comparison group of 15-17 women with no doulas (TAU).

We will recruit 30-34 pregnant women (to have a final sample size of 30 women) at the XXX Program. Women in G1 will be assigned a doula. The 2nd group (G2

Treatment as Usual) will be asked if they would potentially be interested in doula care, but will not be assigned a doula. We will conduct baseline (covariates/ dependent variables) and postpartum (outcome variables) behavioral health assessments, as well as a chart review (outcome variables and covariates).

Assessment. All questionnaires are well-validated and will be administered electronically (e.g. Qualtrics) or on paper. Baseline assessment will immediately follow screening and consent at the XXX Clinic, unless participants request more time to review the consent form or can't stay at the Clinic that day. In this case, a follow-up appointment will be made to conduct consent and/or assessments, which may then occur at the XXX Clinic or at XXX. Follow-up outcomes will be assessed at postpartum follow-ups (PPFU), ideally in the XXX Clinic, but when necessary at XXX, via the telephone, or via an online form and also by chart review. See Chart Review section below for details. Additionally, doulas will fill out a doula satisfaction survey online following each 2-week postpartum doula visit. Participants will be asked to provide a list of "locators" – people who will be able to help us find them if we lose contact before the PPFU visit. We will use a "Locator" form developed by XXX for this. This information will be stored with PII, separate from all PHI and ID numbers.

| **Table 1. Purpose – Measure** | Baseline | 2-wk PPFU |
|---|---|---|
| Screener – Study specific form | X | |
| Traumatic Life Events – Life Events Checklist - 5[38] | X | X |
| Prenatal PTSD – PTSD Checklist - 5[39] | X | X |
| Perinatal Depression – Edinburgh Postpartum Depression Scale[40] | X | X |
| Substance Use Disorders – Structured Clinical Interview for DSM5-E[41] | X | |
| Demographics – Study specific form | X | |
| Current substance use – Timeline Followback[42] | X | X |
| Social Support – NIH Toolbox[43] | X | X |
| Labor & Delivery Autonomy- Mother's Autonomy in Decision | | X |
| Participant Satisfaction – Study specific form | | X |
| Breastfeeding intent/uptake – Study specific form | X | X |

Psychosocial Intervention. There will be 3 Doula visits: 1) a prenatal visit at home/clinic, 2) continuous labor support, and 3) a 2-week postpartum follow-up visit at home/clinic. Continuous labor support will occur at the hospital, but may begin at the XXX clinic or homes.

## 7.0 Data and Specimen Banking

No specimens will be collected.

Data will be stored initially in a secure electronic survey (e.g. Qualtrics, which is an ISO 27001 certified secure server, see https://www.qualtrics.com/security-statement/) server

and ultimately at XXX on the secure server. This data will all be stored in a de-identified state. See 11.3 for more data security information. Some data cannot easily be collected electronically (e.g. SCID5, Timeline Followback) and these paper forms will be identified only by a unique randomly generated ID number, stored in locked file cabinets in a locked room at XXX. All data will be destroyed 7 years after the final publication from the study. Paper forms will be shredded at this time. Digital/electronic data will be deleted at this time as well. Identifiers will be stored in locked file cabinets in locked rooms. Links between identifiers and the study ID number will only exist in a database stored on the XXX secure server at XXX. Identifiers and links between identifiers and PHI will be destroyed at the close of the study with the IRB.

Doulas and medical staff will not identify patients as participants in this study in any of their notes or medical records nor will they record study ID numbers.

## 8.0 Data and Specimen Management

*Data Analysis*
Given the small scale of the pilot study, statistical analyses are intended to detect a signal rather than between-group differences. Preliminary analyses will focus on the distributional characteristics of the primary outcomes, in addition to conducting analyses for group baseline equivalency and participant attrition. Preliminary analyses will also examine group differences in demographics (e.g. age, education, gestation) at baseline. We will examine distributions using standard tests to detect outliers. For outcomes only measured at a single time point, analyses will consist of ANOVAs and Chi Square tests. For between-group contrasts (df=1) for measures expected to change over time (measured at baseline and PPFU) we will utilize the ANCOVA analog using multilevel modeling with outcome measures separately entered as a level 1 variable and group membership entered in level 2, with no protection for type 1 error. Meta analytic techniques[45] using mixed-model regressions will be used to determine overall impact of the intervention (all dependent variables entered into 1 distribution). The Q statistic will then be used to examine the homogeneity of the observed effect sizes associated with outcomes. Finding of heterogeneity will indicate that, on average, one or more outcomes are more sensitive to detecting treatment effects than others. Thus, we will identify those outcomes which provide the strongest signal. Given the nature of this rich dataset, many important analyses not directly tied to aims will be conducted (e.g. temporal patterns of relapse).

*Power Analysis*
Given the novelty of this pilot study, meaningful estimates of between group differences cannot be reasonably obtained or calculated. In fact, the objective of this study is to derive those estimates necessary for a future sufficiently powered R01 proposal.

*Steps that will be taken to secure the data to maintain confidentiality*
Most data will be collected electronically through a survey tool, such as Qualtrics. Some data are difficult to entirely collect this way (e.g. Timeline followback, SCID5) and will thus need to have values extracted from paper questionnaires or notes. Electronic data

will be stored on a secure database. Paper records will be locked in a file cabinet in the locked offices of the PI or RA at XXX, which are co-located in a locked suite. Papers with participant names or any PII will be stored separately (in a folder for consent forms and locator forms) from other data in locked file cabinets in the PI or RA offices. These paper forms with identifying data will not contain ID numbers. The only link between ID numbers and identifying data will be on the XXX secure server in a password protected file separately from any other XXX data. Only study staff will have access to this folder. All files with ID-coded de-identified data will be password protected.

*11.4 Quality control of collected data*

All data not entered directly into the survey tool (i.e., collected on paper) will be double-entered into an electronic database by two different individuals by study team members listed on the study team member page and reconciled by a third person also a study team member (e.g. Dr. Sanjuan, or the RA). Data collected on paper or by the electronic survey tool will be reviewed by the RA with the participant to ensure all items are answered. All data collected will be reviewed visually at least every three months by senior staff (e.g. Dr. Sanjuan) to ensure quality.

## 9.0 Withdrawal of Subjects

All participants will be informed of the right to withdraw from the study at any time and still receive full compensation for their time. Participants can withdraw from the study at any time and withdraw their consent for us to use their PHI at any time, by notifying us in writing. Participants have been notified in the consent document that the research team will not be required to destroy or retrieve any of their or their baby's health information that has already been used or shared before their withdrawal is received. Participants will be withdrawn from the study if it becomes apparent that their participation in the study is endangering their safety or if they are found to no longer meet eligibility criteria. Failure to complete the baseline assessments may also result in withdrawal from the study. However, failure to complete follow-up assessments or changing their mind about having a doula will not be cause for withdrawal, but will be tracked as a feasibility outcome in the study file. Participants who leave the XXX program, but who do not withdraw from the study will still be contacted to complete a final assessment, so that we can evaluate factors involved in this outcome as part of feasibility testing. Participants have given us contact information at baseline and agreed that we can contact them for follow-up assessments. This is also in the consent form. (See locator form and consent form.) Unless participants withdraw consent at the time of being withdrawn from the study, their data may still be used in analyses. Data from participants who have withdrawn consent will be destroyed if it has not already been used.

## 10.0 Risks to Subjects

The primary risk posed by the assessment battery is fatigue or anxiety. Some of the assessments may stir negative memories. RAs are trained to recognize when a participant is significantly disturbed by the assessment, and will gauge participant distress by observation of outward signs (e.g. crying, shaking, pacing) and by querying the participant directly about their level of distress. Should any participant become

significantly disturbed by the assessment (expected to be a rare or non-occurring event) they will meet with the PI or another licensed therapist (per XXX protocol) immediately following the incident to be evaluated for risk and de-escalated. (We had no instances of this with our prior study where we screened 60 participants at the XXX Clinic and conducted substantially more comprehensive and stressful baseline assessments with 33 participants.) Any participants reporting significant distress will be evaluated for suicide ideation. Any participants who indicate suicidal or homicidal ideation (expected to be a rare or non-occurring event) during an assessment and who are deemed to be in need of emergency care will be escorted to the XXX Psychiatric Emergency Room, to their counselors across the parking lot at XXX, or to XXX triage in accordance with XXX and XXX Clinic Policy.

Loss of confidentiality of sensitive information is also a risk to subjects. Participants could possibly experience social stigmatization or legal action by authorities if their answers became known outside of the research study.

It is unlikely that this research could increase social stigmatization of this greater population as a whole. In fact, it would be more likely to find results that contradict the current negative social stereotypes of pregnant women with SUD.

Physically invasive procedures are not proposed in this study. There are no known risks to having a doula provide support. There will be no financial cost to participating in the study.

*Protections Against Risk*

Every effort will be made to protect the confidentiality of participant records. A Certificate of Confidentiality will be automatically granted by the Federal government, because we are asking participants about the use of illegal drugs. Unfortunately, complete confidentiality can never be absolutely guaranteed because records may be examined by personnel from the XXX XXX and because accidents or other unforeseen circumstances sometimes occur despite the best protections put in place. Participants will be informed of this possibility prior to signing any consent forms for this study. All records will be kept strictly confidential and will not be inspected by any other agency except if required by law. Only research staff and staff of the XXX XXX will have access to PHI. Signed consent forms will be kept separately from any documents containing PHI or participants' unique ID numbers. The database linking ID numbers to participants' identity will be kept separately from all PHI and ID numbers and only the PI and research staff on this study will have access to this link. All hard copies of data (paper records) will be kept double-locked in rooms designated for the storage of PHI. Data will be destroyed 7 years after the last publication. The results of this research may be presented at meetings or in publications; but participants' identities will not be disclosed. All files with PII will be encrypted and password protected. Identifiable individual PHI will not be shared with non-study treatment providers.

Support will be available to manage any anxiety or fatigue associated with the assessment for this study. Any participants reporting significant distress (expected to be rare or non-occurring) will be evaluated for suicidal ideation. Research assistants will always have a list of licensed psychologists and the number for XXX triage to call in the event of an emergency, as part of XXX policy. If a participant discloses suicidal or homicidal intentions or ongoing child or elder abuse, the research assistants will notify an available licensed psychologist who will evaluate the participant for risk and follow the state law regarding mandated reporting. In the unlikely event of significant suicide or homicide risk, XXX emergency procedures will be followed. Research assistants will disclose these limits of confidentiality to participants during the consent procedure. All participants will be informed of the right to withdraw from the study at any time and still receive full compensation for their time.

Additional Protections for Pregnant Women, Human Fetuses and Neonates are listed below.

## 11.0 Potential Benefits to Subjects

Participants in G1 with a doula may experience this as a benefit of increased perinatal social and emotional support. We expect this resource to benefit at least some of the participants. We expect this benefit to be enduring beyond the immediate postpartum phase, especially if it reduces the risks of postpartum SUD relapse, PTSD, or depression. However, one of the goals of this study is to test this hypothesis, thus we could find that there is no benefit associated with the doula support.

There is no direct benefit to the participants in G2 (control group) outside of the compensation provided for the study. All participants may however, benefit indirectly from the assessment session (assessment reactivity), although this is not expected to be the case for most participants. Participants will already be engaged in treatment through the XXX program. Participants may feel good about the possibility that involvement in this research may help others or themselves if in similar situations in the future.

## 12.0 Vulnerable Populations

Additional Protections for Pregnant Women, Human Fetuses and Neonates:
(a) Preclinical studies are not scientifically appropriate to this research as there is no pre-clinical model of doula support. Still, prior research has been conducted using substance use, social support, and mental health assessments with pregnant women with addiction, and these indicate that the risks from this type of research are minimal. Moreover, research has been conducted providing doulas to other populations of high risk women with positive results and no identified risks.
(b) Women who are in the doula group may benefit from having the services of a doula. There is no other prospect of direct benefit to the woman or fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important psychosocial knowledge which cannot be obtained by any other means.
(c) Any risk in the research is the least possible for achieving the objectives of the research.

(d) The research holds some preliminary prospect of benefit for the woman, the risk to the fetus is not greater than minimal, and the purpose of the research is the development of important psychosocial knowledge that cannot be obtained by any other means, therefore the consent of the pregnant women will be obtained in accord with the informed consent provisions of subpart A of 45 CFR 46 (46.116 General requirements for informed consent and 46.117 Documentation of informed consent).
(e) The father's consent is not required as there is no direct benefit to the fetus.
(f) Each individual providing consent under paragraph (d) or (e) of this section will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.
(g) Children are not recruited in this study. Information will be collected from infant medical records, however, and adult mothers will provide consent for this.
(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Women recruited into this study will already be at 26 weeks gestation, so termination of a pregnancy is highly unlikely.
(j) Individuals engaged in the research will have no part in determining the viability of a neonate. Women recruited into the study will already be at 26 weeks gestation, and neonatal viability is usually established earlier than this.

## 13.0 Community-Based Participatory Research

*Involvement of the community in the design and conduct of the research.*

XXX will be a key partner to this project. XXX leads policy change, research, place-based community organizing, and culture shift by and for women and people of color. Members of XXX who are listed on the IRB-approved study team in Click-IRB will have an active role in advising the design and conduct of the study and will collaborate with the team to interpret data and produce manuscripts and reports. Additionally, utilizing a community engagement framework in partnership with XXX, we will organize a small advisory group of women with an SUD who have recently given birth. They will inform the design of the doula training. These women will be individuals known to XXX and be contacted by them. Women in the advisory group will be paid $25 in gift cards for approximately 1 hour of advising our team. Any results of the advising from XXX that results in proposed changes to the protocol or consent will be submitted to the IRB for approval before being instituted in the conduct of the study.

## 14.0 Sharing of Results with Subjects

Individual subject results will not be shared with participants. Participants will be informed that they may contact the study following the end of the study period (after June 30, 2019) to request copies of any peer-reviewed and published results at that time. Participants will be informed of any significant new findings that become available during the course of the study that involve the risks or benefits resulting from participating in the research or new alternatives to participation that might change their mind about participating, however we consider this to be unlikely considering the effect

size we expect and the sample size for this pilot study. This would include findings in other research that are valid or changes in access to doulas (if they became available via Medicaid for example).

## 15.0 Setting

*Locations where the research team will conduct the research.*

*Where the research team will identify and recruit potential subjects.*
The research team will identify and recruit potential subjects from the XXX Clinic at XXX.

*Where research procedures will be performed.*
Screening, consent, and baseline assessments will occur at the XXX Clinic at HSC. In some cases, screening, consent and assessments may take place at CASAA. Pre- and postnatal doula visits will occur at either the XXX Clinic, the patients' homes, or the UNM Hospital. Births attended by doulas will occur at the UNM Hospital. Follow-up postpartum assessments will occur either at the XXX Clinic, the UNM Hospital, at CASAA, or via telephone.

## 16.0 Recruitment Methods

Participants will be recruited from patients being seen for appointments at the XXX clinic during regular clinic hours by study staff approved on the IRB who are not regular XXX clinic medical staff (e.g., Dr. Sanjuan or the RA). Study staff will first ask patients who are in private rooms if they are interested in being screened for the study. Some participants may hear about the study by word of mouth as well and call our recruitment phone number.

Participants will be patients at the XXX Clinic.

*Recruitment Methods*
Participants will be identified by the study staff as not currently inmates (this will be determined by the presence or lack thereof of correctional officers outside the clinic room door and also by whether or not the patient is wearing orange scrubs and handcuffs), Additionally, study staff will not approach patients who are identified by medical staff as being engaged in medical treatment that render them unable to participate. This is determined as follows: before entering any patient room, our study team asks medical personnel if this is a good time to speak with the participant. This is done so that our study protocol does not interfere with medical treatment. When appropriate, medical personnel will indicate that a particular patient will not be available for screening at all that day, because it would interfere with their medical treatment. Our team will not need any more information than this.

*Recruitment materials*

We will have a single flier that we will give to participants to have them contact us if when first approached they would rather contact us later. This flier will also be posted at the XXX Clinic.

*Payments*
Participants will receive a $25 gift card following each of the two assessments.

## 17.0 Number of Subjects

We will recruit up to 34 participants in order to have 30 who complete the study. We plan to recruit 17 participants for each group in order to have 15 who complete the study in each group.

## 18.0 Provisions to Protect the Privacy Interests of Subjects

Screening, consent, baseline assessments, and follow-up assessments will be conducted in private rooms. Additionally, as much as possible, study questions will be conducted on laptop computers, which allows for additional privacy. Doula visits will be conducted either in private rooms at the clinic or hospital, or at the patients' homes as appropriate.

Participants will always be informed that they have a right to not answer any questions or to quit being in the study at any time. They may also take breaks or ask questions as needed at any time. Study staff are trained in building rapport with and calming participants. The electronic administration of most study questionnaires is also expected to help participants feel more at ease, as this methodology can involve less social stress than other methods of data collection.

Research staff will conduct chart reviews as outlined under section number 27 Chart Review and in accordance with XXX policy and only after receiving training and with the written consent of the participant. Research staff will access PowerChart during recruitment/screening at the clinic to identify potential participants, as described above, being seen that day at the clinic.

## 19.0 Consent Process

Written informed consent will be obtained at the XXX clinic or sometimes at XXX following the screen prior to any testing and will be conducted in a private room. As part of the informed consent, participants will be informed that because the research is funded by NIH there is a Certificate of Confidentiality from the Federal government. Research assistants or the PI will provide each participant with a copy of the XXX-approved consent form to read. They will be given the choice to take the form home to review or to complete consent and baseline assessments that day. Study staff will then review the consent form page-by-page as trained and, at the end of each page, ask the participant if they have any questions. At the end of the consent form, research assistants will ask the participants if they still want to be in the study. If they answer "yes," the research assistant will ask them the following questions: "What are the possible risks and benefits of this treatment?" "Can you quit being in this study at any time if you want?" "Who do you need to talk to if you have a complaint about this study?" "What information do I

need to report if you share it with me?" The participants' responses to the questions will be recorded verbatim on a consent record form kept in their file (see attached). Participants will be informed of the limits of confidentiality as a part of the consent process. After participants consent to enrollment, they will sign and date the consent form and the research assistant will also sign the consent form as a witness. The participant will be provided a copy of this signed form to keep.

## 20.0 Chart Review

***X Retrospective Chart Review***

***Date range of the chart review*** 07/01/18 – 06/30/19

*Study Methods*

*a.* XXX PowerChart

*b.* Only participants who have enrolled in our study and consented to have their and their newborns' charts reviewed will have those charts reviewed.

*c.* Chart reviews will be conducted by XXX of the XXX Program, who is 100% faculty and is on the IRB approved study team and has Power Chart training. Data will be transferred by XXX to XXX study members via Qualtrics.

*27.3 Confidentiality of data*

Data collected from chart review will be directly entered into the secure electronic survey tool (i.e. Qualtrics) database. This data, identified only by a study ID number, will periodically be downloaded to the secure server. See resources above for more information about the XXX server. In the case of a loss of internet connectivity or inability to access the survey database, the data may be recorded on paper, also identified only by a study ID number. This paper document would be stored at XXX in a locked cabinet in a locked office until it was entered into the survey database. At that time the paper version of the data would be securely shredded by professional secure shredders under contract with XXX.

Only members of the IRB-approved team will have access to harvested patient data in Qualtrics, which will be labeled with only a study ID number when it is harvested.

ID-coded data will be stored initially in electronic survey (Qualtrics) servers and ultimately at XXX on a secure password protected drive where only team members have access. All data will be destroyed 7 years after the final publication from the study. Paper forms will be shredded at this time. Digital/electronic data will be deleted at this time as well. Identifiers and links between identifiers and PHI will be destroyed at the close of the study with the XXX and thus the team will no longer have access to the link.

The link noted above that links patient identifiers with ID numbers for the rest of the study will exist until the study is closed with the XXX.

De-identified data only will be shared with XXX contingent upon the signing of a Data Sharing Agreement between XXX and XXX and also contingent upon XXX approval of the resulting modification to this protocol and the consent form. The details of how this data will be shared will be clarified once this agreement is in place. No data will be shared outside of XXX without an agreement and XXX approval.

*Consent:*

By signing the consent form, subjects will give authorization to do this chart review.
*Risks and Benefits:*

The chart review portion of this study is not expected to add any risks or benefits that are not listed above for the other parts of this study. The main risk of chart review is breach of confidentiality, as mentioned above.

*Statistical Considerations*

a. *Proposed sample size:*
   34
b. *Proposed time period to be evaluated:*
   Initial prenatal visit to XXX Clinic for the current pregnancy through the postpartum visit.
c. *How data will be analyzed and by whom:*
   Data will be analyzed by study staff, primarily the PI. The analyses to be conducted are the same as detailed in the analysis section of this protocol for the rest of the study above.