PROTOCOL TITLE:

Piloting a MI Informed Shame Resilience Intervention

PRINCIPAL INVESTIGATOR:

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REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☐	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

The protocol is awaiting funding. An UNM HSC RAC Grant has been applied for.

CLINICAL TRIALS

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new

habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

1. Objectives

1.1 Shame is an emotion that can have significant negative impacts on health outcomes, including engagement in care. Feelings of shame are commonly experienced with stigmatized behaviors, such as substance misuse, and may be particularly strong among pregnant women who misuse substances. Rates of opioid misuse during pregnancy are dramatically rising, particularly in New Mexico, leading to negative health outcomes for mothers and fetuses. Shame has been found to decrease these patients' willingness to attend and engage in care. Although a theoretical model is available to guide interventions to reduce shame, it has not been tested empirically. In the current study, we seek to evaluate the preliminary effectiveness and feasibility of a brief Shame Resilience Intervention among women seeking care in UNM's Milagro program, a prenatal medical clinic for opioid using pregnant women. This research has the potential to significantly improve public health by generating a tool to reduce barriers to care.

The specific aims of this project are as follows:

Aim 1: Assess the feasibility of study methods (recruitment and retention), intervention fidelity, and treatment satisfaction.
We will track rates of participation in the study as well as retention at follow-up. All intervention sessions will be audio-recorded and rated using the Motivational Interviewing Treatment Integrity tool. Participants will provide quantitative ratings of treatment satisfaction. In addition, a random sample of ten participants will be invited to complete qualitative interviews on treatment satisfaction.
Hypotheses: The study sample will be recruited during the study timeline and a ≥85% follow-up rate will be attained. Coded intervention samples will meet benchmarks for proficiency on a validated treatment fidelity rating tool. Participants will report high satisfaction with the intervention.

Aim 2: Examine the preliminary effectiveness of the intervention on well-being, shame, shame resilience, and treatment attendance. We administer a battery of validated questionnaires at baseline and 1-month follow-up. We will analyze within-group changes in effectiveness outcome variables. Standardized measures of effect size will be calculated.
Hypotheses: The intervention will lead to significant improvements in well-being, shame, shame resilience, and treatment attendance.

2. Background

2.1 While the emotion of guilt entails "feeling bad" about a choice, shame involves the internalization of this emotion to a feeling of "I am bad."[1] While both emotions likely serve an adaptive function in helping individuals to modify behaviors,[2] because of its internalized nature, shame is also often associated with negative behavioral health outcomes,[3] and, based on our own preliminary data, lower overall well-being.[4]Specific to the current application, individuals who misuse substances have been found to have high levels of shame[5] and women often experience shame during pregnancy,[6] particularly when there is a history of sexual or other trauma.[7] The stigma associated with drug use during pregnancy is particularly high high[8]and leads to extensive shame among affected patients.[9]

Although it is difficult to estimate the prevalence of substance misuse during pregnancy because of the impact of shame on willingness to report accurately, available data suggests that more 5% of women report use drugs during pregnancy.[8]Nationally, more

than ten thousand infants are born to opioid addicted mothers each year.[10] New Mexico is among the highest with rates of pregnant opioid misuse exceeding 2.5 per 1000 deliveries.[11] The impact of substance use on the health of pregnant women and their fetuses is a significant public health concern.[9] Opioid use during pregnancy can lead to preterm births, poor fetal growth, longer hospital stays, and birth defects.[12] Opioid misuse during pregnancy can also lead to neonatal abstinence syndrome (NAS).[13] NAS is a drug withdrawal syndrome that affects opioid-exposed infants shortly after birth. NAS can lead to respiratory complications, feeding difficulties, and seizures and accounts for upwards of half of all neonatal intensive care hospital unit stays.[14]

Shame has been found to function as a major barrier to care across a range of health behaviors.[15]This effect is especially evident in populations of women dealing with stigmatized health issues, such as HIV/AIDS, depression, eating disorders, and domestic violence.[16] Shame has been found to decrease the chance that patients will attend care and disclose unhealthy behavior to practitioners.[10] For women who use substances during pregnancy, shame has been found to negatively impact participation and engagement in care, as it motivates efforts to avoid detection by not attending care, limits disclosure to providers, and decreases acceptance of front line recommended medication assisted treatments.[9,10]

Despite the well documented impacts of shame on health outcomes, little empirical work has investigated interventions that may minimize shame or its negative impacts on health. Intervention development and evaluation could be guided by the prominent Shame Resilience Theory.[17] Shame Resilience Theory posits that four behaviors may minimize the negative impact of shame on health outcomes, by improving understanding and encouraging vulnerability.[17] These include:

1) Seeking to Understand Shame - Shame is an emotion that is often mistaken for other emotions. Shame can be difficult to identify and process, as the feelings of shame is often misattributed to other emotional processes.[18] This behavior involved identifying shame as well as shame triggers.

2) Practicing Critical Awareness – This behavior serves to improve understanding and involves efforts to normalize and contextualize the thoughts coming from the shame response and process them.

3) Reaching Out – This behavior involves disclosing shame to others and asking for empathy from a support network.

4) Speaking Shame – This behavior involves speaking openly about the experience of shame and leading to desensitization and externalization.

Shame Resilience Theory was developed through qualitative interviewing techniques[17] and has not been translated into a replicable behavioral health intervention or qualitatively evaluated to determine its impact on health outcomes.

One means by which Shame Resilience Theory could be translated into clinical practice is through a widely utilized and evidence-based communication strategy known as Motivational Interviewing (MI).[19] [20] MI is a collaborative, goal-oriented style of communication with particular attention to the language of change. It is designed to strengthen personal motivation for and commitment to a specific goal by eliciting and exploring a person's own reasons for change within an atmosphere of acceptance and compassion.[21] MI is often implemented as a brief intervention in medical settings.[22] In the current study, we seek to use MI as a

communication strategy to encourage behaviors thought to minimize the impact of shame on health as posited by Shame Resilience Theory. The goal of the current research is to evaluate the feasibility and preliminary effectiveness of an MI-Guided Shame Resilience intervention with pregnant, opioid misusing women attending UNM's Milagro Treatment Programs. Identifying an effective and scalable intervention for managing shame in these settings, holds promise for significantly improving engagement in care, and consequent mother and fetus outcomes.

2.2 The PI has dedicated her career to the development and evaluation of brief applications of MI, including a clinical trial focused on risky alcohol use in a recently completed K23 award (K23 AA020865;) and another soon to be completed multi-site clinical trial focused on unintended pregnancy prevention from an R01 level grant (TP2AH000028;). The current proposal bridges the PI's background in addictions and pregnancy and targets a new health behavior in shame resilience. Pilot data demonstrating feasibility and initial efficacy will be needed in order to secure a larger grant. Co-Investigator Leeman is the Medical Director of the Milagro Clinic. He will shortly be conducting a sabbatical at X in which he will be focusing on treatments for shame and trauma with this clinical population. He has previously worked on treating infants who were exposed to substances during pregnancy as well as researching treatment programs of pregnant women with past trauma and substance abuse. Project Coordinator, Cade Arnink, also has extensive experience relevant to shame resilience and motivational interviewing, making him ideal to carry out the study intervention and evaluation aspects of the proposal. Mr. Arnink recently graduated with honors from UNM's psychology department, where his senior thesis, which is currently under review for publication[4] found a significant association between shame resilience and well-being, providing support for the theoretical mechanisms underlying shame resilience theory. Mr. Arnink has worked extensively with the PI for the past year and is skill MI interventionist.

2.3. Mr. Arnink recently graduated with honors from UNM's psychology department, where his senior thesis, which is currently under review for publication[4] found a significant association between shame resilience and well-being, providing support for the theoretical mechanisms underlying shame resilience theory.

2.4. Based on the existing literature this research is the next reasonable step in establishing the efficacy of the shame resilience theory. To our knowledge this is the first shame resilience intervention to be established and examined. This project will add to the current literature by expanding our knowledge of shame and by providing quantitative evidence to the leading theory of managing shame. Continuing research with a pilot study is important to evaluate and formulate the intervention as well as how the intervention is administered. Participant feedback will be important in finalizing the intervention for a future clinical trial. A smaller group will allow for both quantitative and qualitative data. Allowing us to incorporate measurable changes and participant suggestions.

3. Study Design

3.3. This project will use a mixed methods research design to determine the feasibility and impact of a brief, MI-Guided Shame Resilience intervention on well-being, shame intensity, shame resilience, willingness to communicate, and

treatment attendance. Data will be collected in person by survey and interview at baseline and either in-person or over the phone at 1-month follow-up. Although a controlled, between group design was considered for the current study, in consultation with Co-Investigators and Milagro providers and staff, we elected to conduct a within groups evaluation, to maximize our ability to refine and investigate the acceptability of the intervention. Within group changes in outcomes can be used to estimate effect sizes for a larger trial.

4. Inclusion and Exclusion Criteria

4.3. 20 Milagro participants will be recruited to participate in the intervention and follow-up. Participants will be screened and consented during regular medical visits at the South-East Heights clinic and the Family and Community Medicine (FCM) Clinic at 2400 Tucker Ave. NE. During recruitment, all patients attending the clinic for standard services will be approached by a research team member in the waiting or exam room. The research team member will ask the patient if they are interested in learning whether they are eligible to participate in a study.

4.4. Inclusion criteria: Study participants will be Milagro patients, engaged in medication assisted treatment, at least 18 years of age, can read and speak English, are willing to be contacted for follow-up, are not incarcerated, and are within the first or second trimester of pregnancy

4.3 We will be including pregnant women in the sample.

4.5. Exclusion criteria: The study will not enroll non-English speaking Milagro patients, patients with obvious cognitive impairments, or those with the inability to provide informed consent.

5. Number of Subjects

5.1 This is not a multi-center study.

5.2 We will recruit participants at the South-East Heights Clinic and the FCM Clinic

We will recruit 20 participants for the pilot study.

5.3 The sample size for this pilot study is based on the criteria set forth by Dr. Richard Browne in 1995. The South-East Heights and FCM clinics provides health services to the Milagro population.

6. Study Timelines

6.1 Individual participants will participate for a duration of one month. After the initial encounter we will follow-up with participants at the end of a one-month period. The duration for enrolling all subjects will be ten months, the duration for investigators to complete the analysis will be twelve months.

7. Study Endpoints

7.1 The primary endpoint for the study is December 2020, the secondary endpoint is February 2021

7.2 There are no safety endpoints to report.

7.3. There are no exploratory endpoints to report.

8. Research Setting

8.1 Research will be conducted in University of New Mexico South East Heights Family Medicine Clinic and the FCM Clinic.

8.2 Potential subjects will be identified and recruited at the South East Heights Clinic and FCM Clinic. As described in section 4.1, recruitment strategy 1 will involve inviting patients at the clinic to complete an eligibility screening form.

Research procedures will be performed at the South East Heights Clinic and FCM Clinic. Including: recruitment, screening, consent, baseline assessment, and completion of brief intervention. Follow-up interviews will be conducted either via telephone or in person. Analysis will be conducted in offices at the University of New Mexico Health Sciences Center.

8.3. We will not have a formal community advisory board, although throughout the project period, we will engage community groups and advocacy organizations for their support and input.

8.4. NA, no research will be conducted outside of UNM HSC or its affiliates.

9. Resources Available

9.1 The PI and study staff have extensive experience which prepares them to conduct the proposed study.

Principal investigator Jennifer Hettema, PhD, is an associate professor in the department of family and community medicine. She works closely with the research management team and is currently the PI on the TEMPO study, and as such has experience managing a multidisciplinary research team delivering a brief intervention using motivational interviewing. This research question is of high clinical relevance to her and will lay the groundwork for future research into establishing programs of care. Dr. Hettema will supervise all study activities.

Lawrence Leeman, MD, MPH, will serve as a co-investigator and clinic liaison. Dr. Leeman is the medical director of the maternal child health program for the department of family and community medicine. Dr. Leeman has a proven track record for the coordination and care of maternal health research and patients. He has been the lead investigator on several studies that promote maternal health. Dr. Leeman will be responsible for medical-related issues should they arise.

Cade Arnink, BS, will serve as research coordinator for the current project. Mr. Arnink is a research coordinator in the Department of Family and Community Medicine at the University of New Mexico Health Science Center. Mr. Arnink has a proven track record in the coordination, data collection, and analysis of shame research. He has participated in several studies that recruit, provide a brief intervention, and follow-up participants. Mr. Arnink currently serves as a research coordinator on the TEMPO study. This brief intervention research study includes motivational interviewing and multiple follow-up surveys, both telephone and in-person. Mr. Arnink has also mentored family medicine residents in the UNM Department of Family and Community Medicine in motivational interviewing related activities.

9.2 All medical procedures will be conducted as part of standard care by site clinicians. However, Dr. Leeman is a licensed physician and will be responsible for any emergent medical decision-making associated with the project.

9.3 Recruitment Feasibility: There are 250 potential subjects within the Milagro population. We need to recruit 8 percent over a ten-month period.

Time Committed: The project is anticipated to take one year to complete.

Facilities: The University of New Mexico Health Sciences Center (HSC) is the largest academic health complex in the state of New Mexico and has the only medical school in the state. With its internationally recognized track record for conducting cutting-edge and community engaged health research, the UNM HSC is an ideal setting for a research project of this size and scope. The UNM HSC provides extensive support for the management of projects including infrastructure, grants and contract management, IT and library service, and educational opportunities for faculty and staff. The project offices will be housed in the HSC Department of Family and Community Medicine (FCM). FCM is currently ranked 3rd nationally in federal funding among all departments of Family Medicine. The department is known for our commitment to increasing strategies to eliminate barriers to health equity. FCM will provide office space, desktop computers, grants management and other administrative support to facilitate the success of the project. The Department Chairman, David Rakel, MD is highly supportive of this project.

Availability of Medical or Psychological Resources: All participants will have full access to all standard care services at South-East Heights Clinic.
Process to Ensure Protocol Knowledge among Study Personnel: All study staff and investigators, will be asked to read this IRB proposal in its approved form. Weekly team meetings will be held for staff to review study procedures. All study personnel will complete required CITI training.

10 Prior Approvals

10.1 We obtained a letter of support from Dr. Lawrence Leeman, the Medical Director of the Milagro population. Which will be included with our supporting documents.

10.2 We have included the Departmental Review Form with our supporting documents

10.3 Ionizing radiation is not included in this study.

10.4 Biological specimens and drug attachment are not included in this study.

11 Multi-Site Research

11.1 This is not a multi-site research project.

11.2 Adverse events, problems, interim results, data and safety monitoring reports and study closure will be reported to the UNM HSC IRB

11.3 This is not an FDA regulated trial.

12 Study Procedures

12.1 There are no collaborating sites or investigators in this project.

12.2 The study procedures are described thoroughly below:

Recruitment: Milagro patients presenting at the Southeast Heights and FCM Clinics will approached in the waiting room or an exam room following triage and asked if they would like to voluntarily screen for a confidential study. Patients who meet eligibility criteria will be informed about the study and their option to voluntarily participate in the study. Screening will be done through REDCap and completed screening forms will be maintained with other confidential study forms.

Consent: Informed consent will be obtained from each participant before completing any research procedures. Each participant will read a document outlining the purpose and content of the research. Participants will fully understand what is expected of them throughout the research process. Participants will be made aware of potential risks, benefits, and incentives for participating in the initial meeting as well as the follow-up. During the consent process, phone numbers and other forms of contact information will be collected to perform the follow-up data collection.

Baseline Assessment: Data will be entered directly into REDCap (Research Electronic Data Capture) software via a tablet device. REDCap is a secure, web-based application designed to support data capture for research studies providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources. REDCap is secure and HIPAA compliant and available for use to all UNM HSC faculty and staff.

Baseline Assessment Questions can be found in the section on study forms. Questions are self-report and may be completed individually by participants or with the support of a study staff member. Questions will include demographic variables, including age and ethnicity. Contact and locator information will be gathered.

Brief-Intervention: Twenty participants will receive a brief, MI-Guided Shame Resilience intervention. Participants will attend a one-on-one intervention with the research coordinator. The intervention will be 20-30 minutes and will be conducted in style consistent with MI. Participants will be invited to discuss their own experience with shame and how it affects them before moving into a collaborative discussion in which shame resilience strategies are introduced and practice. The interventionist will help guide the conversation and incorporate shame resilience into the participants' own life.

All participants will receive the brief-intervention as there currently no alternative treatments or procedures for issues of shame.

Follow-up Data Collection: Telephone or in-person follow-up surveys at one month after receiving the intervention. In-person follow-ups will occur at a patients' scheduled visit to the clinic. Data collection will be surveys completed on a tablet device for privacy and security. If follow-up occurs over the phone, the interventionist will work with the participant to establish an adequate time, during the initial visit.

12.3 We are not collecting existing or prospective data.

12.4 Participant recruitment, consent, baseline measurements, and intervention will occur at the South East Heights clinic. Participant follow-up will occur over the phone or at the South East Heights Clinic. Data analysis will occur at the department of Family and Community Medicine.

12.5 After completing the informed consent process participants will complete five instruments before the intervention to measure the preliminary effectiveness of the intervention. Participants will complete the instruments again during the 1-month follow-up phone call.

1. The *Measure of Subjective Well-Being*[3031] is short, five-item survey with Likert response options for subjective quality of life based on positive mood, vitality, and general interest. The tool was developed by the World Health Organization and has strong psychometric characteristics.

2. The *Shame Inventory* [32,33] is a two-part survey that looks measures an individual's past month experience of shame. It provides an empirical measure for the extent and severity of overall shame experience and the severity of several possible shame events. Questions include items such as: How often do you typically experience shame? What is the intensity or severity of the shame you typically experience? To what extent does shame negatively affect your life? Response options are all on a 5-point Likert scale.

3. The *Shame Resilience Measure* is a psychometrically valid measure examining healthy shame behaviors in response to potentially shame inducing events. Participants are asked to select from response options that are more or less consistent with the Shame Resilience Theory, including communication and self-compassion, negative self-talk, and avoidance, on a 4-point Likert scale.[34]

4. The *Willingness to Communicate about Health*[34,35] is a survey made of 10 items that are rated on a 5-point Likert scale. It assesses individual's willingness to communicate to both providers and non-providers about their health. High scores indicate a greater willingness to communicate. This scale is based off the Willingness to Communicate scale (WTC), a previously standardized scale, and demonstrated a Cronbach reliability coefficient of .91.

5. The *Trauma Checklist Adult*[39] *(Modified)* is a three part – self-report measure of symptomatic distress in adults arising from traumatic experiences. It measures aspects of post-traumatic stress as well as other symptoms found in some traumatized individuals.'s children and their families. In our analysis we are only interested in patient symptoms and are not asking them to report specific traumatic situations. Our modified checklist only includes the second and third part which asks about symptoms.

13 Data Analysis

13.3 Descriptive statistics will be used to calculate rates of recruitment and retention, treatment fidelity scores, and quantitative treatment satisfaction. Detailed process notes regarding any unexpected study complications will be kept and analyzed using standardized qualitative methods. Our qualitative analytic approach for open ended satisfaction questions will follow Gläser and Laudel's framework for theory-driven qualitative content analysis to identify categories and patterns related to the main domains of the questions asked.[36] Notes will be reviewed for systematic themes and

subthemes, and coded inductively. The extractions will be reduced, refined, summarized, and catalogued. To further explore patterns within each theme or sub-theme, data will be examined and organized for coherence, and further interpretations will be developed.

To address Aim 1: We will conduct a qualitative analysis to assess the feasibility of providing brief shame resilience training to the Milagro population. The feasibility of study methods and satisfaction with the intervention will be measured using the following measures.

1. *Recruitment Feasibility* will include the number of patients approached, the proportion who agree to be screened, eligibility rates, and consent rates.

2. *Retention Feasibility* will include rates of baseline completion, intervention completion, and follow-up rates at 1-month.

3. *Treatment Fidelity:* Fidelity to the intervention will be measured by the MITI 4.2.1.[28] MITI is a one-pass behavioral coding system designed to measure treatment fidelity for motivational interviewing. It can be used for clinician training or as a quality check in clinical trials. The instrument has proficiency cut-points for a range of interventionist behaviors.

4. *The Treatment Satisfaction Questionnaire* will measure treatment satisfaction using five, Likert style questions focused on quality and delivery.[29]

5. *The Treatment Satisfaction Interview* will include an open-ended, interview-guided discussion of treatment satisfaction. The interviews will be audio-recorded

6. *Treatment Attendance* will be measured by comparing changes in past month proportion of Milagro appointments attended prior to and after the intervention, based on a medical record abstraction.

To address Aim 2: Within group changes in targeted outcomes including well-being, shame, shame resilience, willingness to communicate about health, and treatment attendance. We will analyze the within-group data using one sample t-tests comparing baseline and follow-up means for each measure. In addition, we will calculate standardized effect sizes comparing baseline and follow-up scores, using Cohen's d.[37,38] Exploratory analyses will compare all measures using a correlation matrix at both baseline and follow-up, particularly looking at the interaction between shame resilience and each measure.

Fidelity and Quality: The research coordinator will meet with the study PI, a clinical psychologist, weekly for clinical supervision during the intervention phase of the study. All sessions will be audio-recorded and scored by the PI using an established MI fidelity rating tool called the Motivational Interviewing Treatment Integrity Scale 4.2.1.[26]

13.4 The main purpose of this Pilot is to assess feasibility for a future clinical trial. Data from this pilot will be used in a future power analysis.

14 Provisions to Monitor the Data to Ensure the Safety of Subjects

The research does not involve more than Minimal Risk to subjects, however the study investigators will conduct a periodic review of the findings to ensure that no unanticipated events have occurred. Safety data will be evaluated monthly. The study lead will review participant transcripts to review for unanticipated events.

Additionally scientific literature was reviewed to inform the safety and conduct guidelines of the study.

15 Withdrawal of Subjects

15.3 Subjects will only be withdrawn without their consent is if it becomes clear during other study procedures that the participant in fact did not meet inclusion criteria or if they fail to follow study instructions.

15.4 Termination or safe withdrawal is not applicable to the single session, brief, behavioral interventions that will be tested in the current study.

15.3 There are no procedures that participants could withdrawal from but collect other forms of data.

15.4 If a subject withdraws from the study and requests that their assessment data be withdrawn this will be possible. However, once aggregated data analysis is complete, it will no longer be possible for subjects to withdraw their data for that particular analysis.

15.5 Participants can withdraw participation at any time for any reason.

16 Data Management/Confidentiality

16.1 Data will not be transferred or shared with an external entity

16.2 The research team is only permitted to access any source of information about the subjects through secure UNM verified tools. Such as REDCap and Powerchart.

16.3 Identifiers will be collected including participants names, dates of birth, and medical abstracts.

16.4 The research does require access, use, and disclosure of Protected Health Information. Protected Health Information being collected includes participant names, dates of birth, and medical abstracts.

16.5 The data being gathered is not publicly available.

16.6 Data includes sensitive information about the occurrence of shame experiences. We describe the procedures for managing data and protecting confidentiality below.

16.7 A Certificate of Confidentiality will be sought immediately following UNM IRB approval.

16.8 Many steps will be taken secure the data. All study staff will receive extensive training and monitoring in study procedures and complete required ethics trainings. For all study procedures, identifying information will be kept separate from study data. The Locator Form, Informed Consent, and Participant Information forms will be the only forms with identifying information. All participants will be assigned a unique identifier. This number will be used to identify patients on assessment and medical abstraction data. Identifying data will be stored separately from assessment and medical abstraction data. A key linking participants to their unique identifier will be kept in a password protected file that is only accessible to study staff. Hard copies of data will be kept in locked offices in locked filing cabinets at the study sties or in UNM offices. Data will be transferred from the study sites back to UNM approximately weekly. Data

transfer will involve a direct trip from the study site back to UNM in a vehicle. All electronic study data and brief intervention audio sessions will be stored on a secure, encrypted server that also requires password access. Brief intervention audio sessions will be checked for the presence of identifying information and such information will be muted or 'beeped' out before the audio sessions are accessed for the intervention fidelity and quality coding. Data will only be accessible by study staff.

16.9 Assessment and medical record abstraction data will be coded with a unique identifier. A key linking participants to their unique identifier will be kept in a password protected file that is only accessible to study staff.

16.10 Intervention performance evaluations are measured by the MITI instrument. A percentage of all interventions will be evaluated for quality, and regular feedback will be given to the study interventionists. Weekly meetings will take place between the study interventionists and the evaluator to facilitate communication and quality improvement

16.11

- We will collect demographics, age and ethnicity. We will include data gathered from each measure.
- Data will be maintained and stored on REDCap with only necessary team members given access.
- Data will be collected and stored electronically through REDCap
- Data will be stored for six years following close of the study and will then be destroyed.
- Only members of the research team will have access to data.

16.12 Data will be collected, transmitted and stored via the internet, through use of secure software, REDCap. Data will be protected via a code to ensure participant data is not identifiable. This code will be kept in a secure file cabinet, separate from the data, with limited access via a single key controlled by the PI.

16.13 Data will be collected by audio recording during the intervention. The purpose of this recording is to measure interventionist fidelity. The recordings will not be transcribed. All electronic study data and brief intervention audio sessions will be stored on a secure, encrypted server that also requires password access. Brief intervention audio sessions will be checked for the presence of identifying information and such information will be muted or 'beeped' out before the audio sessions are accessed for the intervention fidelity and quality coding. Data will only be accessible by study staff.

16.14 The data will not include photographs.

16.15 Research records and consent documents will be maintained for six years after the studies completion, following HIPAA Requirements for collecting identifiable health information.

16.16 No minors will be included in the study.

17 Data and Specimen Banking

17.1 This study does not involve banking.

17.2 This is not a multi-center study.

18 Risks to Subjects

18. 1 Participants may experience discomfort when talking about engagement in a stigmatized behavior (shame surrounding opioid use) during intervention. In addition, potential psychological distress may also be caused by issues related to sexual health topics addressed. Lastly, inadvertent disclosure of confidential data to non-study staff could be damaging to patient's reputation. Extra care will be taken to protect information during waiting room recruitment. Researchers will make no mention of shame behaviors or screening results in the waiting room. During telephone assessments, we will encourage participants to complete the brief follow-up call in a private location and explicitly ask about ability / comfort to discuss sensitive issues prior to commencing each assessment.

18.2 We are not aware of any procedures with unforeseeable risks.

18.3 We are not aware of any procedures with risks to embryos or fetuses.

18.4 We do not anticipate risks to others who are not subjects.

18.5 Steps to ensure the confidentiality of data are described above. In the case that participants become psychologically distressed by participation in the study, referral to the clinic's behavioral health care providers is available. Additionally, participants will be given the information for the Agora Crisis Center, a free crisis hotline, which can provide further support and resources. If a participant does experience psychological distress we will follow up with them over the phone the following day to ensure they are alright.

19 Potential Benefits to Subjects

19.1 Participants involved in the study will receive a brief intervention in addition to standard care and may benefit from the effects of either. However, no proven direct health benefits will accrue to the research participants. If this research is successful, then the patients may benefit from new program developments based on the findings, but this is in the future.

20 Recruitment Methods

20.1 Recruitment methods are described extensively above. Briefly, during recruitment all patients attending the South-East Heights clinic for standard services will be approached by a research team member in the waiting or exam room. The research team member will ask the patient if they are interested in learning whether they are eligible to participate in a study. Interested patients will be given a brief self-administered screening instrument (see Screening Form) assessing inclusion criteria. Patients who do not meet inclusion criteria will be informed that they are not eligible and thanked for their willingness to be screened. Participants who do meet inclusion criteria will be informed they are eligible for participation. Patients will be informed of eligibility or ineligibility once they are in the exam room.

20.2 Potential subjects will be individuals who are attending the clinic for regularly scheduled medical visits or for behavioral health screening. No chart review or referral process will be used to recruit participants.

20.3 We have included a recruitment script in our submission with supplementary materials.

21 Provisions to Protect the Privacy Interests of Subjects

21.1 Potential subjects will be individuals who are attending the clinic for regularly scheduled medical visits or for behavioral health screening. No chart review or referral process will be used to recruit participants. No data collected as part of the study assessment or intervention will be shared with standard care providers.

21.2 With the exception of self-report written screening, all study procedures will take place in a private office space. In addition, measures to protect confidentiality are described above.

22 Economic Burden to Subjects

22.1 Participants are not expected to accrue any costs as a result of participating in the study. Standard medical services will be billed using standard procedures.

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Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
MI Guided Shame Resilience Intervention	20	☒	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐

Standard of Care Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐

22.2 There are not any costs to participants that are not described above.

22.3 Participants will not be charged for investigational drugs, devices, procedures.

22.4 No adverse events are expected however participants or their insurer will be responsible for all standard medical procedures.

22.5 Costs have been addressed in the consent.

23 Compensation

23.1 Participants will be reimbursed with $50 merchandise cards for their time at each assessment point. There will be two points of assessment so participants will receive $100 in total for their participation in the project. Each assessment point will last 20-30 minutes and will be incorporated into the participants regular schedule.

24 Compensation for Research-Related Injury

24.1 The research does not involve more that Minimal Risk to subjects.

25 Consent Process

25.1. We will be obtaining informed consent.

25.1.1 Study staff will be responsible for obtaining informed consent. These staff members have not yet been hired. All study staff will receive extensive training in research procedures including informed consent. For the purpose of screening we are requesting partial waivers of consent.

25.1.2 The consent process will take place in a private exam room.

25.1.3. The consent will emphasize the voluntary nature of research participation. The consent will highlight that decision to participate or not participate in the research trial will not affect the patients regular care at the clinic. Study staff will be trained in ethical consent procedures.

25.1.4. We anticipate that most participants will decide to participate or not during the initial study contact. However, participants can have as much time as needed to decide regarding participation. Participants who need more time to think will be provided with the study team contact information and asked to follow-up with any questions or to participate.

25.1.5 Participants will be provided with a copy of their consent upon signing. In addition, participants will be reminded at each follow-up that participation is voluntary. Comprehension quizzes will be administered following discussion and reading of the consent and, for any areas that potential participants are not able to answer correctly, additional time will be devoted to explanation to ensure comprehension.

25.1.6 The consent will be written at or below the sixth-grade reading level. Participants will be asked to read the consent, which will also be paraphrased by a study staff member.

25.1.7 To ensure that the prospective participant has sufficient knowledge and comprehension of all the elements of informed consent, a short open-ended quiz will be administered. Incorrect answers will be followed up with further explanation and the quiz will be re-administered.

Subjects not fluent in English

25.1.8 English is the only language proficiently spoken by study staff.

25.1.9 We will not enroll subjects with limited English fluency.

25.1.10 We will not use short-form consent documents.

Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally Authorized Representative

25.1.11 Adults with cognitive impairments that limits their decision-making capacity will not be enrolled.

25.1.12 *- 25.1.25* Not applicable.

26 Documentation of Consent

26.1. We will use a consent form, which is included in this protocol submission.

26.2. We will not be collecting and/or storing tissue samples.

26.3. We will use a standard HIPPA consent form.

27 Study Test Results/Incidental Findings

27.1. Individual Results: Baseline and follow-up assessment results are based on self-reported behavioral data and will not be reported to participants. Any testing done as part of standard care will be reported to patients per standard medical care practice procedures.

27.2. Incidental Findings: We do not anticipate any incidental findings.

28 Sharing Study Progress or Results with Subjects

28.1. We do not anticipate providing summaries of trial progress. Data analysis will likely not occur until the study is complete. The study findings will be shared with interested participants at once results have been analyzed. These results will be written into an accessible information sheet that will be shared with community stakeholders and participants who indicated an interest in receiving such findings.

28.2 Due to the confidential nature of the study, results will only be shared with participants who indicate a desire to receive them and then only via the channel of communication that they specify. Study results will also be presented in academic journals and at conferences.

29 Inclusion of Vulnerable Populations

29.1 Vulnerable populations are described below.

29.1.1 The research does not include students or employees.

29.1.2 The voluntary nature of the research will be made clear and reinforced across the informed consent process. The informed consent forms and process will emphasize that in no way will their decision to participate or not interfere with their receipt of services in their respective programs and medical staff will not have knowledge about their decision to participate.

29.1.3 Due to their history of opioid, participants from both sites may be considered educationally disadvantaged. The informed consent materials will be written at an accessible reading level and a quiz will be administered to ensure understanding.

29.1.4 The research does not include seriously or terminally ill patients.

29.1.5 The research does include pregnant women. The checklist is completed below.

29.1.6 The research does not involve neonates.

29.1.7 The research does not involve prisoners.

29.1.8 The research does not involve children.

29.1.9 The research does not involve cognitively impaired adults.

30 Community-Based Participatory Research

30.1 The Pilot Study will involve extensive engagement of the study population in the design of the research. In addition, as a research team, we will meet with relevant community members, advocacy groups, and site staff to ensure that our study methods remain sensitive to the needs of the community.

31 Research Involving American Indian/Native Populations

31.1 We do not anticipate Native American participants being largely represented in the Milagro population. If we do have a Native participant we will ensure that their feedback is incorporated and we seek out consultation of Native community groups to discuss the trial outside of the context of research aims.

32 Transnational Research

32.1 The study does not involve transnational research.

33 Drugs or Devices

33.1 The study does not involve the testing of drugs or devices.

34 Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of <u>de-identified data</u>**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy

document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**

3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.
4. **Alternate storage media** must be approved by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

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35 CHECKLIST SECTION

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

36 Partial Waiver of Consent for Screening/Recruitment

Complete this checklist if you are requesting a partial waiver of consent so that you can review private information to identify potential subjects and/or determine eligibility prior to approaching potential subjects for consent or parental permission.

A. Describe the data source that you need to review (e.g., medical records):

Date of birth, medical records

B. Describe the purpose for the review (e.g., screening):

screening

C. Describe who will conducting the reviews (e.g., investigators, research staff):

Research staff

D. Do all persons who will be conducting the reviews already have permitted access to the data source?

☒ Yes

☐ No. Explain:

i. Verify that each of the following are true or provide an alternate justification for the underlined regulatory criteria:

1. The activity involves no more than minimal risk to the subjects because the records review itself is non-invasive and the results of the records review will not be used for any purposes other than those described above.

☒ True

☐ Other justification:

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects because eligible subjects will be approached for consent to participate in the research and are free to decline. Further, the information accessed during the records review will not be disclosed to anyone without a legitimate purpose (e.g., verification of eligibility).

☒ True

☐ Other justification:

3. The research could not practicably be carried out without the waiver or alteration because there is no other reasonably efficient and effective way to identify who to approach for possible participation in the research.

   ☒ True

   ☐ Other justification:

4. Whenever appropriate, potentially eligible subjects will be presented with information about the research and asked to consider participation. *(Regulatory criteria: Whenever appropriate, the subjects will be provided with additional pertinent information after participation.)*

   ☒ True

   ☐ Other justification:

37 Partial Waiver of HIPAA Authorization for Screening/Recruitment

Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

   ☐ Yes. Describe:

   ☐ No

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

   ☐ True

   ☐ False

38 Waiver of Documentation of Consent

Complete this checklist if you intend to obtain consent verbally but will not be obtaining signatures from subjects on a consent form to document consent. Waivers of documentation of consent are commonly requested when using scripts, information sheets, or email or survey introductions to present the elements of consent instead of using a traditional consent form.

A. Are you requesting a waiver of documentation of consent for some or all subjects?

   ☐ All

☐ Some. Explain:

B. Provide justification for one of the following:

i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

ii. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

C. Do you intend to provide subjects with a written statement regarding the research in lieu of a traditional consent form?

☐ Yes. Please attach a copy to your submission in Click.

☐ No

39 Alteration of Consent

Complete this checklist if you intend to obtain consent but will be eliminating or altering one or more of the required elements of consent. Alterations of consent are commonly requested for research involving deception or for minimal risk research when an abbreviated consent is desired and one or more of the required element are not relevant to the research.

Note: FDA-regulated research is not eligible for an alteration of consent.

A. Which element(s) of consent do you wish to eliminate and why?

B. Which element(s) of consent do you wish to alter and why?

C. Provide justification for each of the following regulatory criteria:

i. The research involves no more than minimal risk to the subjects:

ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects:

iii. The research could not practicably be carried out without the waiver or alteration:

iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

40 Full Waiver of Consent/Parental Permission

Complete this checklist if you are requesting a full waiver of consent for all subjects or certain subject groups (e.g., retrospective cohort). Full waivers of consent are commonly requested when the research does not include any opportunity for interaction with subjects (e.g., chart review).

Note: FDA-regulated research is not eligible for a full waiver of consent using these criteria. If you believe that your FDA-regulated research may be eligible for a waiver under another mechanism, such as planned emergency research, contact the HRPO for assistance in determining what information to provide to the HRRC.

A. Are you requesting a waiver for some or all subjects?

☐ All

☐ Some. Explain:

B. Provide justification for each of the following regulatory criteria:

i. The research involves no more than minimal risk to the subjects:

ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects:

iii. The research could not practicably be carried out without the waiver or alteration:

iv. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:

41 Full Waiver of Consent/Parental Permission (Public Benefit or Service Programs)

Complete this checklist if you are requesting a full waiver of consent for all subjects or certain subject groups (e.g., retrospective cohort) and the research involves the evaluation of a public benefit or service program.

A. Are you requesting a waiver for some or all subjects?

☐ All

☐ Some. Explain:

B. Provide justification for each of the following regulatory criteria:

i. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs:

ii. The research could not practicably be carried out without the waiver or alteration.

42 Full Waiver of HIPAA Authorization (Checklist)

Complete this checklist if you are requesting a full waiver of the requirement to obtain HIPAA authorization for all subjects or certain subject groups (e.g., retrospective cohort). Full waivers of HIPAA authorization are commonly requested when the research does not include any opportunity for interaction with subjects (e.g., chart review).

A. Are you requesting a waiver of authorization for some or all subjects?

☐ All

☐ Some. Explain:

B. Describe your plan to protect health information identifiers from improper use and disclosure:

C. Describe your plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so):

D. Describe why the research could not practicably be conducted without the waiver or alteration:

E. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

☐ True

☐ False

43 Other Waiver Types (Checklist)

If you are seeking another waiver type (e.g., Planned Emergency Research, Waiver of Parental Permission to Protect Child Participants, Enforcement Discretion for In Vitro Diagnostics, etc. contact the HRPO office for assistance in determining what information to submit for the HRRC's consideration.

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44 Vulnerable Populations (Checklist)

A. Adults with Cognitive Impairments

Complete this checklist if the subject population will include adults with cognitive impairments.

This checklist does not need to be completed if the research doesn't involve interactions or interventions with subjects and will be conducted under a waiver of consent.

1. Describe why the objectives of the study cannot be met without inclusion of adults with cognitive impairments.

2. Describe how capacity to consent will be evaluated.

3. If subjects may regain capacity to consent, or if subjects may have fluctuating capacity to consent, describe your plans to evaluate capacity to consent throughout the research and to obtain consent to continue participation if capacity is regained.

4. Describe your plans, if any, to provide information about the research to subjects and the steps you will take to assess understanding.

5. Describe your plans to obtain assent, including whether assent will be obtained from none, some, or all subjects.

6. Describe why risks to subjects are reasonable in relation to anticipated benefits to the subjects.

7. If this study involves a health or behavioral intervention, describe why the relation of the anticipated benefit to the risk of the research is at least as favorable to the subjects as that presented by alternative procedures.

8. Describe your plans for monitoring the well-being of subjects including any plans to withdraw subjects from the research if they appear to be unduly distressed.

B. Children

Complete this checklist if the subject population will include children.

1. Select the category of research that you believe this research falls within and provide justification for any associated criteria. If there are different assessments for different groups of children or arms (e.g., placebo vs. drug), include a memo to provide an assessment for each group.

☐ Research not involving greater than minimal risk. *(Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)*

☐ Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

Provide justification for each of the following criteria:

(1) The risk is justified by the anticipated benefit to the subjects:

(2) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches:

☐ 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.

Provide justification for each of the following criteria:

(1) The risk represents a minor increase over minimal risk:

(2) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations:

(3) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition

C. Pregnant Women and Fetuses

Complete this checklist if the subject population will include pregnant women and fetuses.

This checklist does not need to be completed if the research is both minimal risk and is not conducted, funded, or otherwise subject to regulation by DHHS, DOD, EPA, or VA.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.

2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; ***or***, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.

3. Any risk is the least possible for achieving the objectives of the research.

D. Neonates of Uncertain Viability or Nonviable Neonates

Complete this checklist if the subject population will include neonates of uncertain viability.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

3. Individuals engaged in the research will have no part in determining the viability of a neonate.

4. The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, ***or***, the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research

E. Nonviable Neonates

Complete this checklist if the subject population will include nonviable neonates.

Provide justification for each of the following:

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

3. Individuals engaged in the research will have no part in determining the viability of a neonate.

4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Verify each of the following:

5. Vital functions of the neonate will not be artificially maintained
   - ☐ True
   - ☐ False

6. The research will not terminate the heartbeat or respiration of the neonate
   - ☐ True
   - ☐ False

7. There will be no added risk to the neonate resulting from the research
   - ☐ True
   - ☐ False

F. Biomedical and Behavioral Research Involving Prisoners

Complete this checklist if the subject population will include prisoners.

Note: Minimal risk for research involving prisoners is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

1. Select and justify which allowable category of research involving prisoners this research falls within:

   ☐ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

   ☐ Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects

   ☐ Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults)

   ☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject

   ☐ Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than Minimal Risk and no more than inconvenience to the subjects, and Prisoners are not a particular focus of the research.

2. Provide justification for each of the following regulatory criteria:

   a) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired

b) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers

c) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless justification is provided, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project

d) The information is presented in language which is understandable to the subject population

e) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole

f) When appropriate, adequate provision has been made for follow up examination or care after research participation, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact

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45 Medical Devices (Checklist)

Complete this checklist if the research evaluates the safety or effectiveness of a medical device. If more than one medical device is being evaluated, provide the requested information for each.

A. Device Name:

B. Manufacturer:

C. Does the research involve a Significant Risk Device under an IDE?

☐ Yes. Include documentation of the FDA approval of the IDE with your submission. *Acceptable methods of documentation include: (1) FDA letter noting IDE number and approval status; (2) Industry sponsor letter noting IDE number and FDA approval status; or (3) FDA-approved industry sponsor protocol with IDE number noted*

☐ No

D. Is the research IDE-exempt?

☐ Yes. Include a FDA letter with your submission noting the determination that the research is IDE-exempt or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is IDE-exempt*.

☐ No

E. Does the research involve a Non-Significant Risk (NSR) Device?

☐ Yes. Include a FDA letter with your submission noting the determination that the research is NSR or a letter from the sponsor (or sponsor-investigator) justifying why they believe the research is NSR**.

☐ No

* This FDA guidance includes a description for when a device study is exempt from the IDE requirements:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf

**This FDA guidance includes information on how to differentiate between Significant Risk and Non-Significant Risk device studies:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf

46 Export Control (Checklist)

Indicate if there will be export control concerns (i.e., select agents or select toxins involved in the project, collaboration with foreign institution or foreign nationals, publication restrictions, foreign travel, etc.). If so, please upload and complete Export Control Exclusion Screening Form.

EC-Screening-Form-FILLABLE 12-1-14.pd

47 Data Transfer/Sharing (Checklist)

Complete this checklist if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will data be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒ No. **The remainder of this section does not apply.**

B. Indicate if the data is incoming and/or outgoing:
C. Provide the name of the entity that data will be transferred/shared with:
D. Provide the contact name, email and phone number with whom data is being transferred/shared with:
E. Who is responsible for transmission of the data?
F. Who is responsible for receiving the data?
G. Describe how the data will be transferred/shared. Please note data cannot be transferred/shared without assistance from UNM HSC IT. **Requesting HSC Central IT Transfer is detailed on the Sponsored Projects website:**

H. For data being transferred/shared with outside locations or entities, describe the following:
    - Where is data storage and how will it be maintained in a secure manner (i.e. encryption, password protection, use of Qualtrics or REDCap, etc)?
    - What is method in which data will be collected and stored (i.e. electronic, hard copy, etc)?
    - How long will the data be stored?
    - Who will have access to data?

I. Please list all specific data elements, variables, etc. to be sent out and/or received. Indicate if the data contains identifiers and health information. Please note that identifiers that MUST be removed to make health information de-identified are as follows: Names, All geographic subdivision smaller than a State, All elements of year (except year), Telephone, Fax numbers, E-mail addresses, Social Security, Medical record number, Health plan beneficiary, Account numbers, Certificate/license numbers, Vehicle identifiers and serial numbers, Device identifiers and serial numbers, Web URLs, IP address numbers, Biometric identifiers, full face photographic images, and Any other unique identifying number, characteristic or code.)

J. If the research requires the access, use, or disclosure of any of the 18 individually identifiable protected health information (PHI) identifiers that can be used to identify, contact, or locate a person (e.g., name, medical record number, etc.), are the subjects going to consent to or authorize the disclosure of their individually identifiable health information?
    a. ***Or*** is HIPAA authorization altered or waived?

K. What is the classification of the data (de-identified, limited data set, protected health information, other).

L. Does the request to transfer/share data include clinical data that belongs to the UNM Health Systems?

M. Does the data to be transferred/shared include information about patients seen at external health system or at a third party medical provider?

N. Is the external entity a “covered entity”?

O. Is the data that is going to be transferred/shared owned or partially owned by another party or have any type of restrictions including regulatory restrictions (i.e. HIPAA, FERPA, etc.)?

P. Is the data publicly available? If yes, please provide details:

Q. Does the data include information about substance abuse treatment, sexually transmitted diseases, genetic testing results, HIV/AIDS testing results, and/or mental health?

48 Specimen Transfer/Sharing (Checklist)

Complete this checklist if the research involves transferring/sharing of specimens with an external entity (institution, company, etc.).

A. Will specimens be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒ No. **The remainder of this section does not apply.**

B. Indicate if the specimens are incoming and/or outgoing:

C. Provide the name of the entity that specimens will be being transferred/shared with:

D. Provide the contact name, email and phone number with whom specimens are being transferred/shared with:

E. Who is responsible for sending out the specimens? Please note specimens cannot be sent out without a fully executed material transfer agreement.

F. Who is responsible for receipt of the specimens? Please note specimens cannot be received without a fully executed material transfer agreement.

G. For specimens being transferred/shared with outside locations or entities, describe the following:

- *Where is specimen storage and how will it be maintained in a secure manner?*
- *What is method in which specimens will be collected and stored?*
- *How long will the specimens be stored?*
- *Who will have access to the specimens?*