Document Coversheet

Study Title: Social Media HIV Prevention Intervention for High Risk Rural Women

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	3/3/2023 (protocol); 9/13/2021 (ICF)
NCT Number:	NCT03456453
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Coversheet created:	3/20/2023

PROTOCOL TYPE (VERSION 4)

Which IRB

◉ Medical ○ NonMedical

Protocol Process Type

○ Exemption
◉ Expedited (Must be risk level 1)
○ Full

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after saving this section. If you select the wrong IRB or Protocol Process Type, you may need to create a new application.

See below for guidance on these options, or refer to ORI's "Getting Started" page. Please contact the Office of Research Integrity (ORI) at 859-257-9428 with any questions prior to saving your selections.

Which IRB

The **Medical IRB** reviews research from the Colleges of:

- Dentistry
- Health Sciences
- Medicine
- Nursing
- Pharmacy and Health Sciences
- and Public Health.

The **Nonmedical IRB** reviews research from the Colleges of:

- Agriculture
- Arts and Sciences
- Business and Economics
- Communication and Information
- Design; Education
- Fine Arts
- Law
- and Social Work

Note: Studies that involve administration of drugs, testing safety or effectiveness of medical devices, or invasive medical procedures must be reviewed by the **Medical IRB** regardless of the college from which the application originates.

Which Protocol Process Type

Under federal regulations, the IRB can process an application to conduct research involving human subjects in one of three ways:

- by exemption certification
- by expedited review.
- by full review;

The investigator makes the preliminary determination of the type of review for which a study is eligible. Please refer to ORI's "Getting Started" page for more information about which activities are eligible for each type of review.

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i)*

Check the appropriate categories that apply to your research project:

☑ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements.
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☐ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may qualify for Exempt review. This listing refers only to research that is not exempt.)
(Note: If submission includes materials previously collected for either non-research or research purposes in a protocol for which IRB approval expired, you may check Category 5. However, a separate category must also be selected for prospective collection of data/specimens obtained solely for research purposes)

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

Social media HIV prevention intervention for rural women drug users

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

Social media HIV prevention

Anticipated Ending Date of Research Project: 1/31/2024

Maximum number of human subjects (or records/specimens to be reviewed) 193

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

- (●) (Risk Level 1) Not greater than minimal risk
- ( ) (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ( ) (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ( ) (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

*****For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).*****

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 99

Study Population:

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider these resources:
NIH Diversity Policy
FDA Diversity Guidance

Gender disparities faced by Appalachian women call for the critical need for prevention services for this high-risk population. Research indicates that women drug users, in general, are more likely to have injecting intimate partners, and with fewer economic resources to buy drugs, they are more likely to engage in sex exchange to obtain drugs. Studies of rural women drug users are challenging because recruitment of this high-risk population can be limited by the lack of formal treatment opportunities, travel distances to study sites, and the general protective nature of rural social networks (Friedman, 2003). This study will utilize local rural jails as venues for screening and recruitment of high-risk women drug users, followed by targeted prevention efforts in the community post-release. Eligibility criteria for this study includes: 1) NM-ASSIST indicators of high-risk drug use during the 6 months before jail (including injection); 2) engagement in at least one sexual risk behavior in the past 3 months; 3) no evidence of cognitive impairment (GAIN, Dennis, 1998), 4) no evidence of active psychosis (currently experiencing hallucinations), 5) no self-reported current symptoms of physical withdrawal from a recent episode of drug use; 6) self-reported HIV negative status; 7) projected jail release date within 3 months; 8) active Facebook user prior to entering jail (defined as having a Facebook account that was checked at least once a week); and 9) reside in a rural, Appalachian county prior to incarceration. This R34 pilot study proposes to enroll 20 rural women and 10 stakeholders in the focus group phase (n=30) and 60 rural women from the two proposed jail sites during the pilot phase. It is expected that participants who meet eligibility criteria and enter the study will be about 33 years old, mostly white (98%, reflecting the central Appalachian region), about a quarter will be single (24%), and have a high school diploma or GED (27%). The majority will report a history of poly-drug use including prescription opioid misuse, marijuana, and cocaine. Dates of study enrollment are projected to be 4/1/18 - 3/31/21.

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:	0	0		
Asian:	0	0		
Black/African American:	0	5		
Latinx:	0	0		
Native Hawaiian/Pacific Islander:	0	0		
White:	0	355		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:	0	0		

If unknown, please explain why:

N/A

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☑ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☐ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☐ Patients
- ☑ Appalachian Population

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see also the E-IRB Research Description section on this same topic]
- International Citizens [DoD SOP may apply]
- Military Personnel and/or DoD Civilian Employees

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

Does this study focus on adult subjects with any conditions that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes and you are not filing for exemption certification, go to "Form T", complete the form, and attach it using the button below.

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

PRISONERS

0 unresolved comment(s)

SECTION 1.

For studies involving **prisoners** or people at risk of becoming involuntarily detained during the research (e.g., subjects with substance abuse history), respond to the following items. For information on restrictions and regulatory requirements, see ORI's Research Involving Prisoners web page.

For research involving prisoners, the definition of minimal risk refers to 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.

Select the category below that best represents your research and explain why your research meets the criteria.

Prisoner Categories

- (●) **Category 1: My research involves the study of possible causes, effects, processes of incarceration, and of criminal behavior.** (Processes of incarceration can be interpreted broadly to include substance abuse research, half-way houses, counseling techniques, criminal behavior, etc.)
- ( ) **Category 2: My research involves the study of prisons as institutional structures, or of prisoners as incarcerated persons.** (This category is usually used fairly narrowly – i.e., looking at prisoner diet, conditions of prison, etc.)
- ( ) **Category 3: My research involves the study of conditions particularly affecting prisoners as a class.** (This category is rarely used – e.g., vaccine trials, research on hepatitis, social and psychological problems such as alcoholism, drug addiction, sexual assaults. Minimal risk studies should not go under this category.)
- ( ) **Category 4: My research involves the study of practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.** (Rare for research involving placebo or control groups to fall in this category because of the difficulty in justifying improvement of the health or well-being of the subject being given placebo or in a control group.) Note: Contact the Office of Research Integrity at (859) 257-9428 for more information.
- ( ) **Epidemiologic Research Involving Prisoners [See also SECTION 3 below]**

Justify how the research presents no more than minimal risk and no more than inconvenience to the subjects:

Participants in this study will be incarcerated at the time of study enrollment, but intervention activities will take place upon their release to the community. In the community, the majority of the US population, including vulnerable, high-risk individuals, use social media - including Facebook. This been shown through our previous work with rural women transitioning from jail to the community. This study, therefore, poses no more than the minimal risk to study participants than the daily things that people experience when using technology. The procedures to be used by this study will involve conventional social science research methods that are routine in studies of this type. The potential risks will be discussed with participants during recruitment contacts and during the informed consent process to assist them in making a voluntary decision as to whether they wish to participate in the study protocol. Potential psychological risks are primarily related to being asked questions in the interview that they do not feel comfortable asking, and to the risk of a confidentiality breach through the Facebook intervention condition. Based on our experiences working with this population, such occurrences are rare. Participants will be assured that they do not need to answer anything they do not feel comfortable answering (either orally or through Facebook communication), and they will be given the opportunity to set up an additional FB account with password protection for purposes of the study only. These risks will be discussed with each potential study participant during the informed consent process, as well as safeguards in place to provide study protections.

SECTION 2.

When an IRB is reviewing a protocol in which a prisoner will be a subject, the IRB must find and document justification that six additional conditions are met. Describe in the space provided how each condition applies to your research.

NOTE: If your study **only** involves epidemiologic research, you may insert "N/A" in each of the text boxes in this section (Section 2). Your response to Section 3 will determine appropriateness for "N/A" answers here.

Condition 1. Advantages acquired through participation in the research, when compared to the prisoners' current situation, are not so great that they impair their ability to weigh risks.
Describe the possible advantages that can be expected for prisoner participants:

There are potential benefits of the proposed study, but they are not so great that they should impair a participant's ability to adequately weigh risks. First, study participants will have equal opportunity to be screened for risk behavior including substance use and risky sexual activity. Second, participants will have the opportunity to participate in HIV and HCV pre-test counseling and testing with results provided during the baseline. Third, the study interventionist will share important prevention intervention information with high-risk women during the transition from jail to the community with the overall goal of reducing risk behavior. Fourth, there will be significant potential benefits to science because the study will provide important information about the low-cost intervention delivery high-risk to women in rural areas who otherwise face enormous challenges to service utilization. The proposed study may also provide information which can be used to improve the reach and scope of evidence-based prevention interventions through a low-cost, easily accessible social media platform. Finally, the project will generate important information related to the feasibility of the intervention for rural female drug users, providing the formative work needed to advance social media interventions tailored to high-risk and underserved populations.

Condition 2. Risks are the same as those that would be accepted by non-prisoners.
Describe the possible risks that can be expected for prisoner participants and justify that they are the same as for non-prisoners:

The potential psychological risks will be discussed with participants during recruitment contacts to assist them in making an informed decision as to whether they wish to participate in a study protocol. These potential psychological risks are primarily related to being asked questions in the interview that they do not feel comfortable asking. There is also a risk that for participants assigned to the FB condition, there may be a breach of confidentiality of their study files or prevention intervention information. Every effort will be taken to ensure that this does not happen. No files – hard copy or electronic – will be stored in the jail. All risks will be discussed with each potential study participant during the informed consent process. It is also possible that a study participant may experience anxiety, emotional distress, or other negative reactions due to the content of the interview questions, HIV/HCV testing, and/or intervention. Based on our experiences working with this population, such occurrences are rare. However, with the participant's permission, they will be referred to the medical staff at the jail for additional help and support related to psychological distress. Participants will also be given a referral sheet for additional mental health and substance abuse services in the community.

Condition 3. Procedures for selection are fair to all prisoners and are immune from intervention by prison authorities in prisons; control subjects must be randomly selected.

a) Describe how prisoners will be selected for participation:

Consistent with strategies used in the current R01 trial (IRB protocol #12-0372), participant recruitment for the pilot study in each of the rural jails (Leslie County Detention Center and Kentucky River Regional Jail) will occur once a month based on a randomized schedule involving days of the week and times of the day. On each recruitment day, a targeted number of women offenders serving time in the jail will be randomly sampled from the daily census sheet. All women residing in the jail on the day of screening will have an equal opportunity of being selected, including minorities, as long as they are at least 18 years of age and not previously screened for the study. Following random selection, participants will be screened to identify rural women who have engaged in high risk drug use and HIV risk behaviors, and who are regular Facebook users. Eligibility criteria for this pilot study includes: 1) NM-ASSIST indicators of high-risk drug use during the 6 months before jail (including injection); 2) engagement in at least one sexual risk behavior in the past 3 months; 3) no evidence of cognitive impairment (GAIN, Dennis, 1998), 4) no evidence of active psychosis (currently experiencing hallucinations), 5) no self-reported current symptoms of physical withdrawal from a recent episode of drug use; 6) self-reported HIV negative status; 7) projected jail release date within 3 months; 8) active Facebook user prior to entering jail (defined as having a Facebook account that was checked at least once a week); and 9) reside in a rural, Appalachian county prior to incarceration.

b) Describe what measures will be taken to prevent intervention by prison authorities in the selection process:

Consistent with our current R01 (IRB protocol #12-0372), while jail staff may monitor participant entry and exit into the visitation room for the screening and interview process, no jail staff will be present for the screening administration and confidential baseline interviews.

Condition 4. Parole boards cannot take into consideration a prisoner's participation in research. Informed consent must state participation will not impact parole.
Describe what measures are in place to ensure parole boards are not influenced by prisoners' participation in research and how prisoners will be told their participation (or refusal or withdrawal from) will not impact parole:

Based on our current study, we anticipate that most of our participants will be on probation rather than parole. However, confidentiality issues will be stressed during informed consent and will include the description of a federal Certificate of Confidentiality. Participants will also be assured that their screening results, HIV/HCV test results, study participation, and study data will not be made available to any representative of the jail or criminal justice system. Jail officials and administrators will not be informed of participants who participate in the screening, eligibility data, or refusals in order to protect participant confidentiality. Consent form language reflects this emphasis on participant confidentiality.

Condition 5. For studies that require follow-up, provisions are made including consideration for the length of individual sentences; informed consent must reflect provisions for follow-up.
Describe what provisions have been made for follow-up and how this information will be relayed to the prisoner participants:

For this pilot study, follow-up data will be collected 3 months post-release from jail to assess feasibility and acceptability of the FB intervention, as well as self-report measures at 3 months to assess ratings of acceptability and feedback. In addition, measures are proposed for field testing during the 3 month follow-up to examine relevant covariates and participant characteristics which may influence intervention behavioral outcomes, as well as to examine integrity of our randomization procedures. To achieve a high follow-up rate, participants will also be asked to provide telephone numbers of the person who is most likely to know where they will be when they are released (usually a mother or grandmother). Locator information will also include Facebook, primary and secondary addresses, telephone numbers, hangouts, aliases, and contact information for close relatives, and friends. Once located, follow-up interviews will be face-to-face and will be conducted at a location mutually agreed upon by participants and the study coordinator. Participants will be informed about follow-up interviews and time intervals at the baseline interview, and they will be provided with incentives for completed interviews.

Condition 6. Information about the study is presented in a language understandable to prisoners.
Describe what efforts have been made to present information about the study in a language understandable to the prisoner population:

All questions in the required assessments are constructed to be understandable by individuals with an 6th grade education or less. Additionally, data is collected via a face-to-face interview by the UK research assistants, thus there will be an individual present to help provide clarification/prompts for any questions not understood by the participant.

SECTION 3. Epidemiologic Research Involving Prisoners
Only complete if applicable:

Effective June 20, 2003, DHHS adopted policy that allows waiver of the requirement for documenting applicability of a category (as found in Section 1 of this form) for certain epidemiologic research involving prisoners. This waiver applies to epidemiologic research on prisoners that presents no more than minimal risk and no more than inconvenience to the prisoner-subjects.

☐ Check this box if your research meets all three criteria listed below, then provide justification in the space provided.

1. I request a waiver for meeting the category conditions under Section 1 of this form.
2. My research involves epidemiologic research intended to describe the prevalence/incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease; **and**
3. Prisoners are not the sole focus of my research.

Justify how the research presents no more than minimal risk and no more than inconvenience to the subjects:

SECTION 4. Prisoners are not the targeted population
Only complete if applicable:

Although prisoners may not be the target population for your research, a subject could become a prisoner during the course of the

study (particularly if studying a subject population at high-risk of incarceration).

Note: If you did not receive IRB approval for involvement of prisoners, and a subject becomes a prisoner during the study, **all research activities involving the now-incarcerated participant must cease** until IRB approval has been issued for their continuation in the research. If you need IRB approval for a prisoner subject to continue participation in your research, select and complete the applicable category from Section 1, complete section 2 and this section, then submit for IRB review.

In special circumstances where it is in the best interest of the subject to remain in the research study while incarcerated, the IRB Chairperson may determine that the subject may continue to participate in the research prior to satisfying the requirements of Subpart C. However, subsequent IRB review and approval of this completed form is required.

☐ Prisoners are not a target population for my research, but a subject became a prisoner during the study and I am seeking IRB approval so the subject can continue participation in the research.

Explain the importance of continuing to intervene, interact, or collect identifiable private information during the participant's incarceration:

SECTION 5. Kentucky (KY) Department of Corrections (DoC) Approval

Review the following conditions and determine whether any apply to your study:

- active recruitment of participants from a correctional facility (prison, jail, or community corrections institution);
- active recruitment of individuals under community supervision from a state probation and parole office.

If any of the above conditions apply to your research, refer to the Kentucky Department of Corrections Policy and Procedures, Management Information and Research (Chapter 5) for information about submitting a proposal for DoC approval of research including the DoC approved Research Consent and Research Agreement (5.1.G.1).

If your research involves a certificate of confidentiality or the Department of Corrections is directly involved in the study as a sponsor (or otherwise), contact David Kinsella, Legal Counsel, at David.Kinsella@uky.edu, or 859-323-1161, for additional information.

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For creating your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and edit to match your research project.

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a “Reliance Consent Form” so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".
- It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.
- Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.
  Document Types that do NOT get an IRB approval stamp are:
  - "Highlighted Changes",
  - "Phone Script", and
  - "Reliance Consent Form",
  - "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form and/or translated short form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☐ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Reliance Consent Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☑ Stamped Consent Doc(s) Not Needed

Attachments

Informed Consent Process:

Using active voice, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)

- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Potential participants who are interested in the study will be asked to participate in the screening session at the jail with the UK research coordinator. Potential participants will be provided with informed consent prior to the collection of screener data. As part of the informed consent process, potential participants will be assured that: (a) Neither participation nor refusal to participate in a protocol will affect their legal parole status (if applicable); (b) No individual or identifiable data collected as part of a study protocol will be made available to any criminal justice authority including jail, parole, or community mandated treatment; and (c) If potential participants do NOT wish to participate, their parole or other legal status will not be affected. Potential participants who choose NOT to participate in the study protocol will not be identified in their records, and non-participation will NOT become a matter of official record in any file. For the focus groups, the consent procedure will only cover the focus group. For the pilot trial, informed consent procedures will cover participation in the screener, baseline interview, HIV/HCV testing,intervention participation, and follow-up interviews so that participants are fully aware of all possible study procedures before making a decision about entering the study.
Due to the sensitive nature of some of the questions asked in the interviews, confidentiality issues will be stressed during informed consent which will include a description of a federal Certificate of Confidentiality which provides an additional layer of human subject protection. Participants will also be assured that their screening results, study participation, and study data will not be made available to any representative of the criminal justice system. The research coordinator will keep detailed records on the number of interested participants who participate in the screening session and the number of refusals. Screening data will be examined as part of the implementation phase to examine characteristics of participants who enter the study compared to those who are not eligible.
Because of the short time frame between baseline and follow-up interview (3 months), consent procedures will not be repeated since no new procedures will be introduced.
The Kentucky Department of Corrections (DOC) requires us to provide the DOC with the study title and participant name of individuals under their supervision, including inmates, parolees, or individuals likely to be incarcerated by the DOC. This information is sent to: Cyndi Heddleston, Director of the Office of Research and Legislative Services for the Kentucky Department of Corrections.

**Due to COVID-19 restrictions in the jails, we are requesting a waiver of documented informed consent (described in detail in the Informed Consent page). Research staff will still review the consent in detail will potential participants and there will be a section added to the IRB-approved consent document for staff to verify that they reviewed the consent with the participant, answered any questions, that the participant agreed to participate in the study, and the participant's name. Once COVID-19 restrictions are lifted the previously approved process of documented informed consent will resume.
Participants will be encouraged to call the Principal Investigator if any questions arise during the course of the research. Phone numbers for the PI and the ORI are included in the consent form. It is expected that providing the phone number and contact information for the PI may offer a safe, confidential, and reliable channel for participants to express problems, concerns or questions, and obtain study information since the PI will not, on most occasions, be the person originally collecting the data.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting a waiver of the requirement for the informed consent process.

☐ I am requesting an alteration of the informed consent process.
If you checked the box for this item, describe which elements of consent will be altered and/or omitted, and justify the alteration.

SECTION 2.

Explain how each condition applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

☑ Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (e.g., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (e.g., a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk to the subject, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an English and a Spanish version.*

○ **Option 1**

Describe how your study meets these criteria:

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

◉ **Option 2**

Describe how your study meets these criteria:

a) The research presents no more than minimal risk to the participant:

There is no more than minimal risk to participants.

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

We also request a waiver of documented informed consent for some study participants who are unable to be met with in person to sign a consent form. Given the Kentucky governor's recent declaration of a state of emergency, we have advised our data coordinators to take extra precautions when collecting data from participants. Should either jail be placed on lockdown or UK staff deem it unsafe to do face-to-face interviews with eligible participants, we request that those who are unable to complete a face-to-face baseline interviews be granted a waiver of documented consent, and their interview will be completed over the telephone or HIPAA-compliant video conferencing (e.g., Zoom). Research staff will review the consent form in detail with the participant and answer any questions they may have. Verbal consent will be requested. Whenever possible, face-to-face interviews and documented informed consent will be preferred. No interviews will be administered without written or verbal consent.

○ **Option 3**

Describe how your study meets these criteria:

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

RESEARCH DESCRIPTION

0 unresolved comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section or under the Additional Information section to include supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

The Appalachian region has the highest rates of morbidity, disability, and impaired quality of life in the nation (ARC, 2017). Health disparities are attributed in large part to the opioid epidemic, which has significantly and disproportionately affected this region. KY ranks 2nd in the country for drug-related deaths (AHR, 2016), with rates highly concentrated in rural areas of Appalachia. These health disparities are compounded by a dearth of behavioral health treatment in the region, which contributes to a lack of opportunities for education and prevention among this vulnerable population. Thus, there is significant need for real-world strategies to increase access to HIV prevention resources in this underserved area, which has not been examined. This project addresses a critical, unmet need by adapting and feasibility testing an evidence-based prevention intervention (The NIDA Standard) for social media delivery using Facebook. The NIDA Standard has demonstrated reductions in risk behavior among drug users (e.g., Wechsberg et al., 2004), and is currently being examined in an ongoing trial with rural women drug users recruited from local jails with promising preliminary results (Staton, et al. 2017). However, our findings suggest that the majority of incarcerated women are released from jail to rural communities with limited access to HIV prevention education. This application proposes to leverage existing, available, and accessible social media to increase access to prevention services for this high-risk and underserved population following jail release.
Social media platforms have received attention in recent years in public health research, including HV prevention among high-risk urban men (Young, et al., 2012). Our current work with rural drug users in Appalachia suggests that the majority of rural women drug users use Facebook and maintain active Facebook accounts (Dickson, Staton-Tindall, et al., 2016). Considering the critical need for prevention among this group and the popularity of Facebook, this research team proposes to adapt the NIDA Standard for Facebook and to feasibility test the adapted intervention through a randomized pilot study with high-risk rural women drug users during the high-risk period of community re-entry. The following aims guide the proposed study: (1) Adapt an evidence-based HIV prevention intervention for delivery via social media. (2) Examine the feasibility and acceptability of the adapted Facebook intervention with high-risk rural women.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

Specific Aim 1: Adapt an evidence-based HIV prevention intervention for delivery via social media. Using the systematic ADAPT-ITT approach, the NIDA Standard will be adapted for social media (Facebook) through feedback from focus groups with rural women drug users, stakeholders, and topical experts in the field. The adapted Facebook intervention (individualized content, delivery strategies, frequency of contact, etc.) will be established and disseminated through publications.
Specific Aim 2: Examine the feasibility and acceptability of the adapted Facebook intervention with high-risk rural women. Participants will be recruited from jails, consented and interviewed, and randomized into two pilot groups for community re-entry: (1) NIDA Standard via Facebook, or (2) Re-entry services as usual (RSAU). The primary outcomes of this R34 pilot trial will be feasibility and acceptability of the intervention delivery methods. Results from this preliminary study will aid in the development of a larger R01 trial focused on prevention intervention effectiveness and sustainability.

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK

Research Registry Guidance.

During this 36-month R34 developmental pilot trial, our research team will adapt and feasibility test an evidence-based prevention intervention via Facebook with rural women re-entering the community from jail. The study will be accomplished through two specific aims. The first aim will focus on adapting an evidence-based prevention intervention for delivery via social media. Using the ADAPT-ITT model, a series of focus groups (n=30 participants) will assist in the adaptation of the NIDA Standard Intervention for delivery using Facebook including content and preferred delivery strategies. The second study aim will examine the feasibility and acceptability of the adapted social media intervention with high-risk rural women through a pilot trial that includes screening, recruitment, data collection, and random assignment to intervention with 60 high-risk rural women, recruited through local rural jails. All participants will complete a baseline interview in jail, be offered HIV/HCV testing, and be randomized to one of two re-entry study conditions: (1) NIDA Standard via Facebook, or (2) Re-entry services as usual. Study participants will be followed 3 months post-jail release in the community to examine primary study outcomes including feasibility and acceptability. See attached Research Strategy for additional details.

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

UK staff will recruit participants from each of the rural jails once a month based on a randomized schedule. On each recruitment day, UK research staff will randomly select women offenders serving time in the jail from the daily census sheet to participate in the screening sessions. Jail personnel are not involved in the random selection of cases, and they will only providing access to the daily census sheet. UK research staff will randomly select participants from all women residing in the jail on the day of screening who meet the time frame criteria of at least two weeks– three months incarcerated, and all women inmates will have an equal opportunity of being selected for inclusion in the screening process by the UK research team, including minorities, as long as they are at least 18 years of age and not previously screened for the study. Focus group recruitment will occur 1-2 times, depending on interest. Beginning in Month 13, approximately 5 women will be recruited into the pilot trial each month across both jails in order to maintain a manageable number of participants in the intervention conditions.

**During COVID-19 restrictions, we propose to change the recruitment to hang sign-up sheets (attached in the research procedures section) in the women's cells at both jails to allow women to volunteer for the study. All women who volunteer on the sign-up sheet will be contacted for screening. Once COVID-19 restrictions are lifted, study recruitment will return to previously approved methods. Advertising materials will not be used in this study.

Attachments

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

The revised procedure attachment only includes study methods for Phase 1 (Intervention adaptation) and for Phase 2 Pilot trial (screening, recruitment, data collection, intervention, analysis). All other text from the previous research strategy has been deleted. A letter reminding participants about the study, including that they will receive a Facebook friend request from the study account, will be left with the participant and placed with their belongings that will be returned to them at release (attached FB Reminder Letter). Participants may be mailed a letter (attached FB Follow-Up Letter) to remind them about the follow-up interview. These letters will be mailed to the address provided on the locator form (attached in the Data Collection section).

**During COVID-19 restrictions in the jails, we propose several temporary changes to the research procedures, which are outlined in the attached table. Face-to-face procedures will be conducted unless UK research staff are unable to physically meet with the participant due to reasons beyond UK research staff control (e.g., COVID-19 restrictions). As soon as the jail opens to visitors, we will resume normal IRB-approved protocol procedures.

Attachments

Attach Type	File Name
ResearchProcedures	COVID19 Revision Summary Table_v2-Changes Marked.pdf
ResearchProcedures	FacebookDirections.pdf
ResearchProcedures	Focus Group Procedure_TheaterTest.docx
ResearchProcedures	FocusGroupQuestions_6 19 18.pdf
ResearchProcedures	Research Procedures.pdf
ResearchProcedures	3rdFocusGroupQuestions_1 3 19.docx
ResearchProcedures	Facebook Pilot Trial SOPs_5-31-19.pdf
ResearchProcedures	Facebook Pilot Trial SOPs_5-31-19_marked and new.pdf
ResearchProcedures	Revised 3 mo research strategy.docx
ResearchProcedures	FB Reminder Letter.pdf
ResearchProcedures	Recruitment Sign Up Sheet.docx
ResearchProcedures	FB Follow-Up Letter.pdf

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

Primary outcomes of interest for this R34 developmental trial include feasibility and acceptability of our methods and intervention delivery as measured the 3-month follow-up interview following jail release (see Table 3, bottom of page 8 of the Research Strategy). Measures assessing feasibility and acceptability will be collected via secondary data analysis of the FB site at 3 months post-release (number initiating FB site, number of posts viewed, length of engagement, likes/shares, etc), as well as through self-report during the 3 month follow-up (usability of the site, acceptability of the site). In addition, measures are proposed for field testing at the baseline and 3 month interviews to examine relevant covariates and participant characteristics which may influence intervention behavioral outcomes, as well as to examine integrity of our randomization procedures. These measures include demographics (age, race, marital status, employment, education); substance use severity measured by the NM-ASSIST, injection drug use and sharing practices as measured by the Risk Behavioral Assessment for Women, risky sexual practices including unprotected sex and sex exchange as measured by the RBA-Women, mental health issues related to depression, anxiety, and/or trauma, and involvement in high-risk social networks. See attached for DRAFT measures, which is still under development.

Attachments

Attach Type	File Name
DataCollection	Rural Women Social Media 3 Month Follow Up Codebook 5-26-20-Marked.pdf

DataCollection	rural women grant Codebook.pdf
DataCollection	Appendix 3 Adult Case Report Form 2018_508.pdf
DataCollection	Appendix 4 Risk Factor Ascertainment.pdf
DataCollection	Appendix 6 Payment Receipt.pdf
DataCollection	Appendix 7 W9.pdf
DataCollection	Appendix 8 Institution Payment Receipt.pdf
DataCollection	Baseline Codebook 5 16 19 clean.pdf
DataCollection	FB Locator Form.pdf
DataCollection	FB Screener.pdf
DataCollection	HIV HCV Testing Forms.pdf
DataCollection	Facebook Data Collection Form_v2.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

The proposed study will use the approach established by our current R01 (IRB #12-0372) in Leslie County Detention Center and the Kentucky River Regional Jail. Across the jails, there is an average daily census of 105 women, and based on average length of incarceration, an average yearly population of 270 women. With the estimated prevalence of drug use, it is expected that the target number of high-risk women (20 focus groups, 60 pilot trial) with 3 month follow-ups is feasible. Because of our relationships with providers in the community, it is also feasible to recruit 10 stakeholders (health and behavioral health care providers), for a total of 90 subjects. Each of the jails provides medical services and will be available to respond to referrals for HIV/HCV testing procedures if needed. However, because many of the women in the study are expected to be re-entering the community, HIV/HCV referrals will also be made to local health departments and community based services as well.Additional available resources for this project include a Principal Investigator with experience in managing clinical research trials (R21-AA017937; R01-11030397), as well as a research staff who work on the current R01 trial with experience with substance using women in jails. Thus, the team has experience in specific IRB requirements related to the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results using data.
Dr. Christina Studts is a co-investigator and statistical and implementation consultant on this project. Dr. Studts is now at UC Denver.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

Among participants who are randomly chosen to participate in the Facebook group, one of the risks is a possibility that information may be seen by someone else (if someone gets on the phone or computer, for example). Because confidential information may already be available on participants' Facebook sites, this study poses no more than the minimal risk than the daily things that people experience when using Facebook. This study will be using a closed, confidential study Facebook site. Participants can only join the site when sent a friend request from our study team, and they can join under their current Facebook account or establish a new account. The designated closed Facebook site (Women's Health Study) will only allow access to participants who have been invited to join as a "Friend" and have accepted the request to view information posted on the study site. Any interaction on the closed study Facebook site will also not appear in the participants "Newsfeed", preventing any other friends or family members from seeing that they are engaged in the study. Participants will only be able to interact with the study interventionist through the closed, confidential site, not with

other study participants. The team will be working closely with study consultant Dr. Sean Young (UCLA) who has developed recommended confidentiality and human subjects protection guidelines for delivering prevention interventions via social media, particularly Facebook (Young, 2012).
In both study groups, there is also a risk of a breach of confidentiality of research materials and/or data obtained by the study team. Other potential risks may also be associated with being asked questions in the interview that they do not feel comfortable asking. It is possible, that a participant may experience anxiety, emotional distress, or other negative reactions due to the content of the interview questions, HIV/HCV testing procedures, and/or intervention participation. Participants do not have to answer any questions that they do not want to answer, and participants can stop answering questions or quit at any time. The study staff are making every effort so that the information provided is not available to anyone except specific study personnel. Also, participants may experience physical or psychological/emotional problems such as anxiety and depression should they learn that they have HIV or HCV. A member of the research staff will provide post-test counseling and will be able to refer to community services. There are also minor risks associated with the finger-prick blood draw that may include soreness, bruising, pain, bleeding, fainting and infection.
The proposed study has potential benefits. First, study participants will have equal opportunity to be screened for risk behavior including substance use and risky sexual activity. Second, participants will have the opportunity to participate in HIV and HCV pre-test counseling and testing with results provided during the baseline. Third, the study interventionist will share important prevention intervention information with high-risk women during the transition from jail to the community with the overall goal of reducing risk behavior. Fourth, there will be significant potential benefits to science because the study will provide important information about the low-cost intervention delivery high-risk to women in rural areas who otherwise face enormous challenges to service utilization. The proposed study may also provide information which can be used to improve the reach and scope of evidence-based prevention interventions through a low-cost, easily accessible social media platform. Finally, the project will generate important information related to the feasibility of the intervention for rural female drug users, providing the formative work needed to advance social media interventions tailored to high-risk and underserved populations.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

There are no alternatives to participation in this evaluation project except not participating.

Back to Top

Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate retention policies and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

Self-reported behavioral data will be collected at screening, baseline, and 3 months post-release from jail for follow-up interviews, along with HIV/HCV Orasure tests. The study interviewer will attend an intensive week-long training that covers topics including human subjects protection and issues that could arise during jail-based data collection. For example, training will be conducted on the importance of ensuring that all materials brought in to the jail are also taken out of the jail by the interviewers (e.g., pens, study materials, etc). A variety of behavioral data including demographic characteristics, past drug use, injection drug use, health and mental health problems, and service utilization will be collected through self-reports using Computer Assisted Personal Interviewing. administration with a portable computer (DELL notebook). During the CAPI portion of the interview, the trained interviewer will read the instructions, questions, and response categories from a laptop and directly enter the participant's response. The CAPI formatting will be programmed using Questionnaire Development System (QDS™) from Nova Research (http://www.novaresearch.com), and laptops are encrypted to protect the data. Data with the participant ID and all other identifying information (consent form, locator sheet, payment forms) will be stored separately. Consent forms, locator sheets, and payment forms will be managed on site. Security of the data will be maintained through regular computer server backups and CD Rom back-ups secured in fire-safe locked boxes. In addition, data to

assess feasibility and acceptability will be collected via secondary data analysis of the FB site at 3 months post-release (number initiating FB site, number of posts viewed, length of engagement, likes/shares, etc), as well as through self-report during the 3 month follow-up (usability of the site, acceptability of the site). No data will be provided to jail officials or any other criminal justice official.
Every effort will be made in the protection of human participants and issues relating to participant confidentiality. Because this study will involve individuals who are incarcerated, this study's human participants' protocol will comply fully with the special protections pertaining to behavioral research involving prisoners as participants.
A Certificate of Confidentiality will be obtained from the National Institute on Drug Abuse which, under federal statute PL 94 255, prohibits all data collected during the course of a study protocol from being used in any legal or criminal proceedings. Participants will receive a copy of the Certificate of Confidentiality. In addition, participants will be verbally informed and given a copy of the signed informed consent, which describes the study purpose and the confidentiality safeguards. As such, no self-reported data will be shared with anyone outside of approved key personnel. No criminal justice authorities will have access to the self-reported data collected in the interviews or to the clinical data collected during individual sessions.
All research data will be kept in locked file cabinets in the office of the Principal Investigator at the University Of Kentucky Department of Behavioral Science (141 Medical Behavioral Science Building, Lexington KY 40536). Each participant will receive a unique identifying number. All research data collection instruments will be identified by this number only. The master list matching identifiers to specific participants will be maintained in a locked file in the PI's office. Research data will be reported in aggregate form only.
Computer files will be retained and all electronic data will be password protected, stored on secure UK-maintained servers, and accessible only be the researchers on this study. In addition, no DOC personnel (including jail staff or personnel, probation/parole officers, etc) will be asked about participants information for locating and tracking for follow-up. The consent form includes a statement about access to state-maintained records including the KOMS system (Kentucky Offender Management System) which is standard for offender protocols at UK CDAR. Information on participants in the study should be available from those systems and through self-reported locator information.
All interviews will take place in private, confidential office setting in the jail setting. All data collected will be kept in password protected files on a secure server and under lock/key. Clients will also be reminded that their legal status will not be altered based on their participation in the study. As an additional safeguard to ensure protection of client confidentiality, a Certificate of Confidentiality will be obtained from DHHS.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Do you confirm that you will retain all IRB-related records for a minimum of 6 years after study closure?

◉ Yes ○ No

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review this guidance for more information on payments to subjects, including restrictions and expectations.

Focus group participants (n=30) in phase 1 will receive $10 for attending the one-time one-hour focus group. Participants in the pilot trial will receive $25 for taking part in the research interviews for study at baseline and at follow-up (3-months post release). Participants will be given an additional $25 bonus for completing both interviews. Pilot trial participants will have the opportunity to earn up to $75 over the 3 months.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is "standard" – and thus not covered by the sponsor/study – unless you tell them.

There is no cost to participants in the study.

Data and Safety Monitoring

The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research or NIH-funded/FDA-regulated clinical investigations.

- If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.
- If this is a non-sponsored investigator-initiated protocol considered greater than minimal risk research, and if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

Written data safety and monitoring procedures have been developed by the University of Kentucky, Center on Drug and Alcohol Research to ensure adequate protection of research subjects. This study protocol and all activities concerning human participants will be approved by the Institutional Review Board (IRB) in accordance with OHRP regulations for prisoner research and will include the following requirements: (1) All participants must understand, agree to, and sign a consent form before participating. (2) Strict adherence to a participant's right to withdraw or refuse to answer questions is maintained. (3) The data collection interview is completely confidential and no names will be associated with the interview. (4) Data will be secured in a lock box during transport. (5) At no time will a person who is not study staff be permitted to review identifying data. (6) Consent forms and identifying information will

be kept separate from the actual participant data. (7) All identifying information (consents, locator forms, payment forms) will be kept locked at all times. (8) All documentation of IRB approval including OHRP certification for prisoner research, original consents, Certificate of Confidentiality, human participants certification for staff, and other related study information will be filed and easily accessible to the PI and the Research Coordinator.
Additional data safety and monitoring procedures at the University of Kentucky Center on Drug and Alcohol Research include: (1) All staff must successfully complete the Protecting Study Volunteers in Research Certification or the CITI on-line human subjects training course. (2) Specific and clear protocols for adverse events and violations of study protocols are established. (3) Data reports including recruitment and interview reports, contact and tracking reports, no show/refusal reports, and session contacts will be prepared on a regular basis.
Any data collected in a jail will be secured in a lock box during transport. All identifying information (consents, locator forms, payment forms) will be kept locked at all times in file cabinets in the office of the Principal Investigator at the University of Kentucky Center on Drug & Alcohol Research. Each participant will receive a unique identifying number. All research data collection instruments will be identified by this number only. The master list matching identifiers to specific participants will also be maintained in a locked file in the PI's office. Research data will be reported in aggregate form only. Computer files will be retained, but computerized identifying information will be destroyed when data collection and file building is completed. Participants will not be identified by name in analytic data files. All documentation of IRB approval including OHRP certification for prisoner research, original consents, Certificate of Confidentiality, human participants certification for staff, and other related study information will be filed and easily accessible to the PI and the Research Coordinator.

Back to Top

Future Use and Sharing of Research Data

If the results of this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

Data will not be shared with anyone who is not included in key personnel and will not be used for other research.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations

- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the “Additional Information/Materials” section. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?
◉ Yes ○ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

HIV/HCV testing procedures are covered under Research Procedures. Testing procedures will be using FDA and CDC approved for ORAQUICK Advance® HIV and HCV Rapid Testing. Testing of subjects will be conducted on a voluntary basis at all interview contacts. As such, none of the subjects will be coerced in any way to submit to testing. They will also be asked to consent for release of any positive HIV screen to the state Department for Public Health in Frankfort knowing that a HIV care coordinator may be contacting them for additional follow-up. In addition: (a) HIV/HCV test results collected at the initial assessment points will be used for research purposes only and will not be made available to correctional or treatment program authorities; (b) all HIV/HCV testing will include pre- and post-test counseling following Centers for Disease Control and Prevention (CDC) protocols; (c) subjects testing positive for HIV/HCV infection will be given referral information as to the appropriate community resources for counseling and treatment, and assisted in contacting these agencies if they so desire it.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?
○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?
○ Yes ○ No

If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ○ Yes ◉ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

- ☐ HIPAA De-identification Certification Form
- ☐ HIPAA Waiver of Authorization

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any

applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer “no” above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor’s authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition of Significant Risk (SR) device?

- Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required Study Device Form, picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

Attachments

RESEARCH SITES

0 unresolved comment(s)

To complete this section, ensure the responses are accurate then click "SAVE".

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☐ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☐ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☑ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page), including:

- A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.
- Supportive documentation, including letters of support, can be attached below.
- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK

sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

List all other non-UK owned/operated locations where the research will be conducted:

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

Attachments

Attach Type	File Name
-Letter of Support & Local Context	LOS_Jail sites.pdf

B) Is this a multi-site study for which **you are the lead investigator or UK is the lead site**? ○ Yes ◉ No

If YES, describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

C) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

	For additional requirements and information:
☐ Academic Degree/Required Research	
☑ Alcohol/Drug/Substance Abuse Research	
☐ Biological Specimen Bank Creation (for sharing)	
☐ Cancer Research	
☐ CCTS-Center for Clinical & Translational Science	
☑ Certificate of Confidentiality	
☐ Clinical Research	
☐ Clinical Trial - Phase 1	
☑ Clinical Trial	
☐ Collection of Biological Specimens for internal banking and use (not sharing)	
☐ Community-Based Participatory Research	
☐ Deception	
☐ Educational/Student Records (e.g., GPA, test scores)	
☐ Emergency Use (Single Patient)	
☐ Gene Transfer	
☐ Genetic Research	
☐ GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)	
☐ Human Cells, Tissues, and Cellular and Tissue Based Products	
☐ Individual Expanded Access or Compassionate Use	
☐ International Research	
☐ Planned Emergency Research Involving Exception from Informed Consent	
☐ Recombinant DNA	
☐ Registry or data repository creation	
☐ Stem Cell Research	
☐ Suicide Ideation or Behavior Research	
☐ Survey Research	
☐ Transplants	
☐ Use, storage and disposal of radioactive material and radiation producing devices	
☐ Vaccine Trials	

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
- Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Specimen/Tissue Collection...")
- Gene Transfer
- HIV/AIDS Research (look up "Reportable Diseases/Conditions")
- Screening for Reportable Diseases [E2.0000] (PDF)
- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Waiver of Informed Consent*

  *For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use, storage and disposal of radioactive material and radiation producing devices

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☑ (HHS) Dept. of Health & Human Services
  - ☑ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Click applicable listing(s) for additional requirements and information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education
- (DoJ) Department of Justice or Bureau of Prisons
- (DoE) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist
- (EPA) Environmental Protection Agency

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

NIDA

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

Attach Type	File Name
GrantContract	Staton 3200001760 2018-03-27 #1.pdf

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP and DoD Summary for details)

○ Yes ◉ No

Using the “attachments” button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

Additional Information

- ☐ Institutional Biosafety Committee
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- Institutional Biosafety Committee (IBC) - Attach required IBC materials
- Radiation Safety Committee (RSC) - For applicability, see instructions and attach form
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

Data Analysis:

Social media platforms have received attention in recent years in public health research, including HV prevention among high-risk urban men (Young, et al., 2012). Our current work with rural drug users in Appalachia suggests that the majority of rural women drug users use Facebook and maintain active Facebook accounts (Dickson, Staton-Tindall, et al., 2016). Considering the critical need for prevention among this group and the popularity of Facebook, this research team proposes to ***adapt*** the NIDA Standard for Facebook and to ***feasibility test*** the adapted intervention through a randomized pilot study with 60 high-risk rural women drug users during the high-risk period of community re-entry. The following aims guide the study:

Specific Aim 1: Adapt an evidence-based HIV prevention intervention for delivery via social media. Using the systematic ADAPT-ITT approach, the NIDA Standard will be adapted for social media (Facebook) through feedback from focus groups with rural women drug users, stakeholders, and topical experts in the field. The adapted Facebook intervention (individualized content, delivery strategies, frequency of contact, etc.) will be established and disseminated through publications.

Specific Aim 2: Examine the feasibility and acceptability of the adapted Facebook intervention with high-risk rural women. Participants will be recruited from jails, consented and interviewed, and randomized into two pilot groups for community re-entry: (1) NIDA Standard via Facebook, or (2) Re-entry services as usual (RSAU). The primary outcomes of this R34 pilot trial will be feasibility and acceptability of the intervention delivery methods. Results from this preliminary study will aid in the development of a larger R01 trial focused on prevention intervention effectiveness and sustainability.

Primary outcomes and data analysis are anchored in Aim 2 of this R34 application to ***feasibility test*** an evidence-based intervention for Facebook delivery as an innovative approach to increasing access to prevention resources for high-risk rural women during community re-entry. According to the seminal work by Leon and colleagues (2011), pilot studies such as the one proposed here do not generally require extensive sample size calculations, and it is recognized that "effects" generated from pilot studies cannot be utilized to power the eventual larger trial due to the wide confidence intervals often obtained in small pilots (Leon et al., 2011; Thanbane et al., 2010). In this R34 application, our goal is not to conduct a fully-powered trial to detect significant differences in risk behavior based on the intervention; but rather a pilot study with "a sample size based on the pragmatics of recruitment and the necessities for examining feasibility" (Leon et al., 2011; p. 627).

Our proposed sample size was guided by several considerations. The target jail study sites have a combined daily average census of approximately 253 women. Based on our current trial, 90% are anticipated to meet the substance use criteria for the study (n=228), and 60% of those are expected to be regular Facebook users, for a possible daily population of 160 women. Based on recommendations for sample size considerations in pilot and feasibility studies (Moore et al., 2011; Thabane, et al., 2010), we based our planned sample size on the confidence intervals for number of participants needed to assess participation rate, a key aspect of feasibility. Previous Facebook intervention trials have demonstrated high participation rates ranging from 80%-95% (Naslund, et al., 2017; Young et al., 2013). With a confidence interval width of 10% and a population of 160, the proposed sample size of 60 participants will be sufficient to examine feasibility and acceptability of the NIDA Standard using Facebook (n=30) compared to re-entry services as usual (n=30) in this R34 pilot trial.

Descriptive statistics (frequencies and means) will be used to characterize the participants and describe ***feasibility*** indicators (e.g., proportion of women agreeing to enroll in the study, the number of participants who "friend" the closed study site, the number of posts viewed on the study site, length of time of engagement). Based on other Facebook trials and our previous work (e.g., Dickson et al., 2017; Young et al., 2013), the participation rate is expected to be high (90%) across these variables. Among participants who use Facebook in the proposed trial, ***acceptability*** of intervention delivery is also expected to be high as measured through engagement ("likes", "shares", etc), changes in HIV/HCV knowledge, and connections with new "friends". In addition, bivariate analyses (e.g., chi square tests, independent groups t-tests, and other parametric and

non-parametric analyses, as appropriate) will be used to examine potential differences in other *covariates* of interest (risky drug use and sexual practices) between the two study conditions.

IRB Approval
9/13/2021
IRB # 43727
IRB2

KEY INFORMATION FOR SOCIAL MEDIA FOR HIV PREVENTION: PILOT TRIAL
9.3.21

You are being invited to take part in a research study about using Facebook for HIV education as you transition from jail to the community.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?
There are two purposes for this research. First we hope to work with different people to design Facebook messages that will be helpful to reduce the risk for HIV. Second, we want to try the intervention to see if women who are transitioning from jail to the community will use it. By doing this study, we hope to learn if Facebook is a good way to increase access to prevention interventions to reduce HIV risk behaviors among rural women during a time of emerging and significant public health risk in Appalachia. Your participation in this research will last about 3 months.

WHAT ARE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
There are a few reasons you might volunteer for this study. First, study participants will have equal opportunity to be screened for risk behavior including substance use and risky sexual activity. Second, participants will have the opportunity to participate in HIV and HCV pre-test counseling and testing with results provided. Third, the study interventionist will share important prevention intervention information during the transition from jail to the community with the overall goal of reducing risk behavior. Fourth, there will be potential benefits to science because the study will provide important information about the low-cost intervention delivery high-risk to women in rural areas who otherwise face enormous challenges to service utilization. Finally, the project will generate important information related to the feasibility of the intervention for rural female drug users, providing the formative work needed to advance social media interventions tailored to high-risk and underserved populations.

WHAT ARE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
You should not participate in this study if you are not currently at least 18 years of age or do not want to participate in the study. This study is completely voluntary. You should also not participate in this study if you were not a regular user of Facebook before you were incarcerated, and have a good sense of how Facebook works (including the confidentiality issues). You also might not choose to volunteer for this study if you are not comfortable discussing sensitive, confidential information (such as drug use and sexual behavior). If you choose not to participate in this study, there are no alternative treatments.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you do not want to take part in this study, it won't affect your status with any criminal justice agency, treatment, parole, or other agency. If you are currently on probation or parole, the researchers will not disclose any information about you or your participation in the study to the parole board or to a parole officer to influence their decisions without your specific written authorization.

WHAT ELSE DO YOU NEED TO KNOW?
If you are under the supervision of the Kentucky Department of Corrections (DOC), (including prisoners, parolees, awaiting sentencing for felony convictions), then note that: The DOC requires researchers to provide the DOC with the name of participants and the title of the research study. By agreeing to be in the study, you are allowing the researcher to provide your name and the study title to the DOC. The information will be sent to the DOC's Director of the Office of Research and Legislative Services in Frankfort. The researcher will not share any of your research data or confidential information with the DOC. The DOC may ask you to sign a separate consent form that verifies that you are volunteering for a study that is not a part of the DOC. If you do not want to sign the DOC consent form, you should not choose to participate in this study, and if you chose not to sign the DOC consent we would have to withdraw you from this study.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?
The person in charge of this study is Michele Staton, Ph.D. of the University of Kentucky, Department of Behavioral Science. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is 859-312-8245.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You will not qualify for this study if you have not engaged in high risk behavior in the last 6 months you were on the street. You will also not qualify for this study if you were not a regular user of Facebook on the street. In addition, you will not qualify for this study if the researchers believe there is any evidence of cognitive impairment, hallucinations, or symptoms associated with active drug withdrawal. Other criteria that is necessary for entering the study is that you planning to be released from jail within 3 months, and living in a rural Appalachian county prior to incarceration.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The UK research team will ask you to complete a screening interview at the jail facility which will take about 30 minutes. This will help us understand your drug use in the past year and other possible risk behaviors. If you meet study guidelines, the research assistant will ask you to complete a face-to-face, phone, or video conference interview with a research assistant which will also be done in the jail. If the interview is conducted over the phone or video conference (e.g., Zoom) in the jail, it will be conducted over a confidential line. If we cannot guarantee the interview would be conducted over a confidential line, you will be given the option to discontinue and reschedule the interview. Video conference interviews will be conducted using a HIPAA-compliant software (e.g., Zoom). It will take about 1 - 2 hours and will include questions about your drug use, health, and related issues. The research assistant will also talk with you one more time three months after you are released from jail. It will be for a face-to-face, phone, or video conference (e.g., Zoom) interview at a place that is convenient for you, and it will also take about 1-2 hours. The total amount of time you will be asked to volunteer for this study is 2-4 hours over the next 3 months.

WHAT WILL YOU BE ASKED TO DO?

In the first session (screening), you will be asked to answer some questions to see if you are eligible for the study. The screening will include questions about your risk behaviors (drug use and sexual activity) and about your Facebook use. If you are eligible to participate in the study, you will be asked to answer more specific questions in a confidential face-to-face, phone, or video conference (e.g., Zoom) interview about your history of substance use, sexual activity, mental health, criminal justice involvement, need for treatment, and feelings/attitudes about treatment.

Following the interview, you will be randomly assigned to one of two groups: 1) Facebook HIV prevention or 2) services as usual. This random assignment will be determined by chance, similar to the lottery. That means that you will have a 50-50 chance of being assigned to either the services as usual group or the Facebook group. This means that your assignment to a group is based on chance rather than a decision made by the researcher. Within 2 days following your release from jail you will receive a “friend request” from the study interviewer. You will be notified about your group assignment in a Facebook message after you have accepted the “friend request” from the study interviewer. If you are randomly selected to be in the services as usual group, you will receive HIV/HCV pre-and post-test education prior to testing. If you are randomly selected to be in the Facebook group, in addition to the education session, you will receive an “invitation” from the study interviewer to join a private Facebook group called “UK Rural Women’s Health.” We will also give you a study information sheet with details on how to establish a new account with new password protections in case you choose to do so. Once you accept the invitation into the closed, confidential Facebook site, you will be invited to engage in weekly wall posts from the study staff about how to reduce HIV risk behaviors. In addition, you will have the opportunity to engage with the study staff through the FB Messenger function using open chats or audio calls if you choose to do so. Activity on the Facebook group and with the UK research team will be monitored, but we will not record your name, username, or other identifying information along with those data.

Both groups will be asked to take part in the baseline interview and follow-up interview at 3 months post-release from jail. Questions in the follow-up interview will be very similar to the earlier interview regarding drug use and related issues. However, it will also look at any personal changes the services that you receive. In order to stay in touch with you for follow-up, you will also be asked to give locator information. This includes the names, addresses, and phone numbers of individuals who would be most likely to know how to reach you. You are also asked to let the research team access information in state-maintained records (DOC KOMS files, behavioral health service records) including admission/discharge/termination dates of treatment services, number and kind of

services received, discharges, diagnosis/other relevant clinical information, court dates and actions, results of urine screens, time incarcerated, and other criminal activity in the study. The research team may also use other internet searches and social media sites like Facebook to try to find you for the follow-up.

During the baseline interview, you will also have the opportunity for free HIV and HCV testing. If we are unable to meet with you in person at the facility due to situations outside of our control (such as COVID-19 restrictions), we will invite you to meet us at our office after you are released from jail to do the HIV/HCV testing. The HCV test involves a finger-stick test that only requires a small amount of blood, while the HIV test requires an oral swab. Results from the HIV and HCV test results will be given to you at the time of testing. If you choose to voluntarily submit specimens for testing, you will be informed of the results of the tests, regardless of the results. When your results are given, an individual qualified to provide post-test counseling will provide the results and counseling when the result is given to you. It is very important that we provide these test results to you in person. If you are positive and do not learn your status, you may place yourself and others at increased risk. A referral list of HIV and HCV professionals in Kentucky will also be provided to all study participants. If you decline HIV testing at the time of the interview, we will not be able to enroll you in the trial due to the focus on HIV prevention and the eligibility criteria of being HIV negative. Please understand that your participation in any disease testing is completely voluntary.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

If you are randomly chosen to participate in the Facebook group, there is always a possibility that your information may be seen by someone else (if someone gets on your phone or computer, for example). Because confidential information may already be available on your Facebook site, this study poses no more than the minimal risk than the daily things that people experience when using Facebook. This study will be using a closed, confidential study Facebook site. You may join the site when sent the group invitation from our study team, and you can join under your current Facebook account or establish a new account. The designated closed Facebook site (UK Rural Women's Health) will only allow access to participants who have been invited to join as a "Friend" and have accepted the request to view information posted on the study site. Any interaction on the closed study Facebook site will also not appear in your "Newsfeed", preventing any other friends or family members from seeing that they are engaged in the study. Other participants in the study may see the information you post in the group, however.

In both study groups, potential risks may also be associated with being asked questions in the interview that you do not feel comfortable asking. It is possible, that you may experience anxiety, emotional distress, or other negative reactions due to the content of the interview questions, HIV/HCV testing procedures, and/or intervention participation. You do not have to answer any questions that you do not want to answer, and you can stop answering questions or quit at any time. The study staff are making every effort so that the information you provide is not available to anyone except specific study personnel. Also, you may experience physical or psychological/emotional problems such as anxiety and depression should you learn that you have HIV or HCV. A member of the research staff will provide post-test counseling and will be able to refer you to community services. There are also minor risks associated with the finger-prick blood draw that may include soreness, bruising, pain, bleeding, fainting and infection.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There is no guarantee that you will get any benefit from taking part in this study. However, some people have reduced drug use and risky sexual activity when participating in the prevention intervention in other studies.

WHAT WILL IT COST YOU TO PARTICIPATE?

There is no cost to you for participating in the study.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

We will make every effort to keep private all research records that identify you to the extent allowed by law. Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered on everyone in the study. You will not be personally identified in these papers or reports. We may publish the results of this study; however, we will keep your name and other identifying information private. You will be asked to

provide your social security number for payment purposes only. You can however, participate in the study if you chose to withhold their social security number.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. All research data will be kept in locked file cabinets in the office of the Principal Investigator at the University Of Kentucky Department of Behavioral Science. Your records with us will not include your name – we assign only a number to your file. All research data will be identified by this number only. Computer files will be retained and all electronic data will be password protected, stored on secure UK-maintained servers, and accessible only to the researchers on this study.

You should know that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused, if you pose a danger to yourself or someone else.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

In addition, if your screening test for HIV is positive, you will have the option of having these results reported to the Kentucky Department for Public Health in Frankfort. This reporting is confidential, meaning once the state receives the report, they will not share it with anyone, including the health department in your county. Thus, none of this information will be made known to anyone but select research staff.

Officials from the National Institutes of Health (National Institute on Drug Abuse, which funds this study) and the University of Kentucky may look at or copy pertinent portions of records that identify you. However, it is the policy of these agencies and these investigators that every attempt will be made to resist demands to release information that identifies you. When results of this study are published, your name will not be used.

If you are selected for the private Facebook group, other members of the group can see any information you post on the group “wall,” comments, likes, and/or reactions to posts. If you have any questions that you do not want to post to the group, you are welcome to reach out to the UK research team confidentially. Activity on the Facebook group and with the UK research team will be monitored, but we will not record your name, username, or other identifying information along with those data. Also, there are always privacy risks with information online. We will give you an information sheet of how to change your privacy settings, but we cannot control any data collected by Facebook itself.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. If you are selected for the Facebook group, you can remove yourself from the group at any time. You will not be treated differently if you decide to stop taking part in the study. The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give

you, if they find that your being in the study is of more risk than benefit to you, or if the agency funding the study decides to stop the study early for a variety of reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study. It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Michele Staton, Ph.D. at 859-312-8245 immediately. It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Therefore, these costs will be your responsibility. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will receive $25 for taking part in the research interviews for study at baseline and at follow-up (3-months post release). If you complete the follow-up interview, you will also receive a completion bonus of $25. You will have the opportunity to earn up to $75 over the next 3 months. If you earn $600 or above by participating in research in one year, it is potentially reportable for tax purposes.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

You will be informed if the investigators learn new information that could change your mind about staying in the study. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Michele Staton, Principal Investigator for this study, or a designee will contact you with information about research results or incidental findings that are determined to be important to you/your family's health. (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 60 women to do so. The National Institute on Drug Abuse is providing financial support and/or material for this study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you are under the supervision of the Kentucky Department of Corrections (DOC), (including prisoners, parolees, awaiting sentencing for felony convictions), then note that: The DOC requires researchers to provide the DOC with the name of participants and the title of the research study. By agreeing to be in the study, you are allowing the researcher to provide your name and the study title to the DOC. The information will be sent to the DOC's Director of the Office of Research and Legislative Services in Frankfort. The researcher will not share any of your research data or confidential information with the DOC. The DOC may ask you to sign a separate consent form that verifies that you are volunteering for a study that is not a part of the DOC. If you do not want to sign the DOC consent form, you should not choose to participate in this study, and if you chose not to sign the DOC consent we would have to withdraw you from this study.

FUTURE USE OF YOUR PROTECTED HEALTH INFORMATION OR SPECIMEN(S):

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

INFORMED CONSENT SIGNATURE PAGE

You are a participant or are authorized to act on behalf of the participant. This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____ _____
Signature of research subject **Date**

_____
Printed name of research subject *and, if applicable,*

_____ _____
Printed name of [authorized] person obtaining informed consent/HIPAA authorization Date

IF INFORMED CONSENT WAS PROVIDED BY PHONE, VIDO CONFERECE, OR BEHIND THE VISITATION GLASS: I confirm that this consent form was reviewed in full with the research participant and she provided verbal consent to proceed with the interview.

YES NO Signature of research staff: _____