Illinois Criminal Justice Information Authority

IRB

AMENDMENT APPLICATION: for Research Involving Human Subjects

Any change to an approved research protocol, including the research plan, consent process and form, co-investigators, other research personnel, and/or methods of subject recruitment requires the submission of an Amendment. Please clarify the change(s) to be made and the rationale for the change(s). A cover letter or additional information may also be attached.

Amendments to approved IRB applications must be submitted to the chair or co-chairs of the IRB and receive signed approval. Maintain for your records initial approvals and signatures.

Amendments to protocols may not be initiated until IRB approval has been obtained.

PROPOSAL INFORMATION

Co-Principal investigator(s): Jessica Reichert, Senior Research Analyst
Justin Escamilla, Research Analyst

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Project staff and affiliation: Christopher Mayer, Research Intern; Alysson Gatens, Research Analyst
Dr. Maureen Hillhouse, Senior Research Scholar; and Michelle Straubel, Assistant Project Director

Start date of project: December 7, 2017
(Initial IRB approval date)

End date of project: December 7, 2018

Title of proposal: Evaluation of PERC (Pathway to Enterprise for Returning Citizens)

Initial approval type: **Full IRB:** X **Expedited:** **Exempt:**

AMENDMENT INFORMATION

Amendment initiated by: PIs: Jessica Reichert and Justin Escamilla

What elements of the approved project are you proposing to change?

- X Investigators or research staff (I)
- X Project advisors or consultants (II)
- X Protocol (e.g., instruments, data collection, recruitment procedures, compensation) (III)
- X Consent procedures (IV)
- _____ Consent documents (V)
- _____ Project sites or study participants (VI)
- _____ Changes in confidentiality, privacy, or security (e.g., data dissemination, storage, security, personnel, access) (VII)
- _____ Funding/sponsorship (VIII)
- _____ Start or end date change or modification (IX)
- _____ Other (please specify) (X):
- _____ Risk/benefits assessment (XI)

I. INVESTIGATOR CHANGE ☐ Changes ☒ No changes

☐ Adding or ☐ changing co-principal investigator

Name: _____

Title: _____

Reason for change _____

IRB certified ☐ Yes ☐ No

Certification course: _____ Date certified: _____

Certification number (if applicable) _____

II. RESEARCH STAFF CHANGE ☒ Changes ☐ No changes

☒ Adding or ☐ Changing research staff

Name: Tyler Marcheschi and Lauren Weisner

Title: Research Interns

Reason for change New Summer 2018 interns starting

IRB certified [X] Yes [ ] No

Certification course: NIH Date certified: Start date of internship in May 2018

Certification number (if applicable) TBD

III. PROJECT ADVISORS OR CONSULTANTS [X] Changes [ ] No changes

[X] Adding or [ ] changing project advisor or consultant

Name: Waverly Deutsch, PhD

Title: Clinical Professor and Academic Director of University-Wide Entrepreneurship Content, University of Chicago, Booth School of Business

Reason for change Entrepreneurship expertise

IRB certified [X] Yes [ ] No

III. PROTOCOL CHANGE [X] Changes [ ] No changes

1.) Please explain in detail what changes you plan to make to the study design or protocol (such as changes to instruments used, data collection, recruitment procedures, or compensation)

Researchers are conducting an evaluation of the PERC program. PERC offers entrepreneur training and coaching to formerly incarcerated/returning citizens and the opportunity to receive a business loan to start their own business. The initial IRB application was approved for researchers to administer an informed consent form to participate in the study. Only those who consented to participation in the research study will be in the program.

Two new components of the study will be added at this time to further understand and evaluate the program. They are detailed below and related forms are attached to this application.

Component 1: Client interviews (n=20)

a.) *Time involvement of subjects*: 60 minutes

b.) *Location(s) the study will be conducted with subjects, including a description, if applicable*: The interviews will be completed at a private office or conference room at each of the four training agency location. All agencies in the PERC program are non-profit, community agencies in Chicago. Alternatively, interviews can be done at a mutually agreed upon location (public location with a private meeting room) or by phone.

Recruitment will be completed three ways:

1. Research staff will try to attend one or more classroom sessions to conduct interviews of clients who consent (schedule permitting) before or after class time.
2. The trainers and/or the PERC program manager will also offer clients a flyer in case they want to schedule an interview outside of classroom time either in person or by phone.
3. Researchers will directly contact those who were selected for the program (treatment group) but did not start or complete the program by phone or letter.

Note: Flyer and letter attached.

c.) *Amount of payment to subject, if any (consent form must note plan for payment if they withdraw voluntarily*): $20 gift card to Walgreens

d.) *What subjects will experience or do*: Subjects who consent will be asked questions about themselves—demographics and their life experiences, as well as all aspects of PERC including the application and intake process, classroom training, and mentors. The interviews will be semi-structured with a brief questionnaire given at the end (on trauma/PTSD). The interviews will be audio-recorded.

Note: There are no names collected on the forms, only an ID number will be used. The interviews will be audio recorded and then transcribed. Audio recordings will be deleted off audio devices after being downloaded to ICJIA computers. The data will be maintained on a password protected folder on a secure server accessible only to research staff on this project.

Component 2: Stakeholder focus group (n=10)

a.) *Time involvement of subjects*: 30 minutes

b.) *Location(s) the study will be conducted with subjects, including a description, if applicable:* In a conference room at ICJIA before or after the monthly PERC Leadership Meeting.

c.) *Amount of payment to subject, if any (consent form must note plan for payment if they withdraw voluntarily):* none

d.) *What subjects will experience or do*: Subjects who consent will be asked questions the

development of PERC and PERC operations. The interviews will be semi-structured and audio-recorded. Subjects who are stakeholders will include the PERC program manager, IDOC representatives, micro-lending group representatives, and ICJIA program coordinator.

Note: The interviews will be audio recorded and then transcribed. Audio recordings will be deleted off audio devices after being downloaded to ICJIA computers. The data will be maintained on a password protected folder on a secure server accessible only to research staff on this project.

2.) Please explain in detail the rationale for the above change(s). What prompted the investigators to propose the amendment? Is the amendment the result of an adverse/negative event?

This amendment is proposed to add study components of the evaluation to further understand and evaluate the PERC program. There have been no adverse or negative events with the research study to date. The rationale for the interviews (and brief survey) is to better understand program clients, their background and reentry challenges, as well as more in-depth information on their views of the many aspects of PERC. The data can inform on the program may indicate potential areas for staff training and other areas for program improvement. The rationale for the focus group component is to better understand the PERC stakeholders and how the program was developed and how it operates.

3.) Does this amendment alter, in any way, the assessment of potential risks described in your approved protocol?

_____ Yes _X_ No

4.) If you answered yes to question 3, please explain in detail how this alters the assessment of potential risk and whether the benefits of the study outweigh the risks.

IV. CONSENT PROCEDURES [X] Changes [ ] No changes

5.) If you are changing your consent procedures, please explain these alterations in detail.

Both the focus group and interview will have a consent forms; they are described below. In addition, interviews conducted over the phone will seek verbal consent rather than signed consent.

Component 1: Client interviews

a.) *Who will obtain consent?* ICJIA researchers will provide consent forms to all clients.

b.) *How will consent be obtained?* Research staff provide the clients with the consent form. Each

of the subjects will have already signed a consent form to be in the overall study when they completed an application and met eligibility requirements. This will be an additional consent form for the in-depth interview. If the interview is done by phone, subjects will be asked for verbal consent.

c.) *How often will consent be obtained (e.g., longitudinal or long-term field studies)?*
Once

d.) *How will you verify the subject fully understands the consent?* The consent form is written in a 9th grade or lower reading level. The consent form will provide contact information for the principal investigator, the Authority's attorney/IRB secretary to request further information about the study, their rights as a research participant, and PERC. When seeking verbal consent over the phone, participants will be required to say "yes" when asked if they understand the study, their rights as a participant, and want to participate in the interview.

e.) *How will your investigators be trained to use the informed consent process?*
Trained research staff will be in charge of informed consent process.

Component 2: Focus groups

a.) *Who will obtain consent?* ICJIA researchers will provide consent forms to all focus group participants.

b.) *How will consent be obtained?* Research staff provide the consent form.

c.) *How often will consent be obtained (e.g., longitudinal or long-term field studies)?*
once

d.) *How will you verify the subject fully understands the consent?* The consent form is written in a 9th grade or lower reading level. The consent form will provide contact information for the principal investigator, the Authority's attorney/IRB secretary to request further information about the study and their rights as a research participant.

e.) *How will your investigators be trained to use the informed consent process?*
Trained research staff will be in charge of informed consent process.

6.) Please explain in detail the rationale for the above change(s). What prompted the investigators to propose the change? Is this change the result of an adverse/negative event?

The rationale is to have all components of the study involve human subject consent. This is not due to an adverse/negative event.

V. CONSENT DOCUMENTS [ ] Changes [X] No changes

Note: researchers are adding forms not changing exiting forms.

7.) What types of changes are being made to the consent documents/forms?

_____ Adding or removing information from the consent form so that it is consistent with an already approved IRB statement (e.g., the cost section, or phone number change)

_____ Revising the consent form to reflect what was already approved in the protocol

_____ Defining a phrase(s) more clearly in lay language

_____ Incorporating in the consent form updated IRB-mandated language

_____ Minor editorial changes to the consent form which do not alter the meaning or procedures (e.g., spelling changes, revising a statement)

_____ Removal of questionnaires or instruments that required consent forms

_____ Other (please specify):

8.) Please explain in detail how you will alter the consent documents.

9.) Please explain in detail the rationale for the above change(s). What prompted the investigators to propose the change? Is this change the result of an adverse/negative event?

10.) Please submit the original and altered consent documents and highlight the changes. If filing the amendment electronically, are these documents appended to this form or contained in a separate document?

_____ Appended _____ Attached form

VI. PROJECT SITES OR STUDY PARTICIPANTS [ ] Changes [X] No changes

11.) What types of changes are being made to the project sites or study participants?

_____ Changing who is included in the study sample

_____ Inclusion of new or additional special populations as subjects

_____ Changing sites or programs

_____ Changing the number of subjects

_____ Other (please specify):

12.) Please provide a detailed explanation of how you will change who will be included in your study sample, if applicable.

13.) Please provide the rationale for making these changes.

14.) Will your study now include new or additional special populations? If yes, please indicate which ones:

_____ Minors under age 18

_____ Adult prisoners or individuals in secure confinement

_____ Juveniles in correctional or detention facilities

_____ Probationers, parolees, or individuals under court or correctional supervision

_____ Developmentally disabled, intellectually disabled, or cognitively impaired

_____ Individuals held in residential treatment, locked facilities, or hospitalized

_____ Pregnant women, if focus of research

_____ Non-English speakers

_____ Wards of the state

_____ Other—please specify:

15.) Please provide an explanation of why you are changing the sites or program of study, if applicable.

16.) Please provide the rationale for making these changes.

17.) Are you changing the number of subjects that will be included in your sample?

_____ Adding subjects to sample _____ Reducing sample size

18.) How many subjects will be added to or subtracted from your initial sample size and what will your final sample size be?

_____ Initial sample size _____ Number added _____ Number reduced _____ Final sample size

19.) Pease provide the justification for making this increase/decrease.

20.) Please explain any other changes you are making to the project sites or study participants and provide the rationale or justification for these changes, if applicable.

VII. CONFIDENTIALITY, PRIVACY, OR SECURITY ☐ Changes ☒ No changes

Note: researchers will maintain confidentiality and privacy consistent with the initial IRB application.

21.) What changes are being made that may affect the confidentiality or privacy of the subjects, or security of the subjects or data?

22.) Please provide the rationale for making these changes.

23.) Please indicate what steps will be taken to ensure the privacy, confidentiality, and security of the study subjects or data.

VIII. FUNDING OR SPONSORSHIP [ ] Changes [X] No changes

24.) How has the funding or sponsorship of this study changed?

_____ Funding added _____ Funding decreased _____ New funding source _____ Funding restored

25.) How will the changes in funding and/or sponsorship affect the protection of the human subjects in the study?

IX. DATE CHANGE OR MODIFICATION [ ] Changes [X] No changes

26.) What date changes are you making to the study?

[ ] Start date [ ] End date

Initial start date _____ New start date _____

Initial end date _____ New end date _____

27.) Please explain the necessity for these changes.

X. OTHER CHANGES ☐ Changes ☒ No changes

28.) Please provide a detailed explanation of other changes being made to the IRB that are not covered in previous sections.

29.) Please provide the rationale for the changes and provide a statement as to how they may affect the protection of human subjects in your study?

XI. RISK/BENEFIT ASSESSMENT

30.) Discuss how these proposed changes may affect the risks posed to human subjects.

There is minimal risk.

Names will not be collected on the client interview form, but there will be some demographics information collected.

The interviews and focus groups will be audio recorded, but confidentiality will be maintained.

Clients and focus group participants can choose to consent to participate and audio recording or opt-out of the research.

They can also skip questions or stop at any time. An incentive ($20 gift card to Walgreens) will be given to all who consent to the interview with clients before the interview or mailed to them if they participate in a phone interview. We do not believe the amount to be overly coercive.

The interview will feature a brief questionnaire on trauma/PTSD. We will offer a referral sheet to all human subjects that shares services for housing, entrepreneurship, trauma, domestic violence/sexual assault, and substance use disorders.

31.) Discuss how these proposed changes may affect the potential benefits of the project to subjects and or society.

These changes will enhance the potential benefits to subjects and society. These additions make the evaluation more rigorous and informative. They will allow researchers to answer additional research questions to understand how the program operated and how it can be enhanced. The knowledge gained can help better serve clients of this and similar programs in the future.

Attachments:

Attachment A Research interview flyer
Attachment B: Client interview letter
Attachment C: Client interview consent
Attachment D: Client interview schedule
Attachment E: Client trauma survey
Attachment F: Client interview resource list
Attachment G: Stakeholder focus group consent
Attachment H: Stakeholder focus group questions

Illinois Criminal Justice Information Authority

IRB

Amendment Application

SIGNATURE PAGE

Evaluation of PERC (Pathway to Enterprise for Returning Citizens)
Last Presented to IRB on: March 29, 2018

This page is to be signed by the principal investigator.

Signature of Principal Investigator — Date: 4-27-18

IRB ACTION:

Request Approved _____ **Request Denied** _____

IRB Requests Modifications (see explanation below) _____

_____ _____

Signature of IRB Chair — Date

Modifications Requested by IRB:

IRB Expiration:

The IRB approval granted for this project expires on _____

Date