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

1. **Principal investigator(s):**
2. **Principal investigator(s) email(s):**
3. **Office Address:**
4. **Office Phone:**
5. **Project staff:**
6. **Start date of project:**
7. **End date of project:**
8. **Title of proposal:**
9. **Date of initial approval**
10. **Initial approval type**

☐ **Full IRB** ☐ **Expedited** ☐ **Exempt**

Amendment Information

Amendment initiated by:

What elements of the approved project are you proposing to change?
(Please fill out the relevant sections)

☐ Investigators or research staff **(I)**

☐ Project advisors or consultants **(II)**

☐ Protocol (e.g., instruments, data collection, recruitment procedures, compensation) **(III)**

☐ Consent procedures **(IV)**

☐ Consent documents **(V)**

☐ Project sites or study participants **(VI)**

☐ Changes in confidentiality, privacy, or security (e.g., data, storage, 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

Adding ☐ **or changing co-PI** ☐

Name:

Title:

Reason for change:

IRB certified:

☐ Yes ☐ No

Certification course: Date certified:

Certification number:

Adding ☐ **or changing research staff** ☐

Name:

Title:

Reason for change:

IRB certified:

☐ Yes ☐ No

Certification course: Date certified:

Certification number:

Have updated privacy certificates been filed?

☐ Yes ☐ No (explain why):

II. Project Advisors or Consultants

Adding ☐ **or changing research staff** ☐

Name:

Title:

Reason for change:

IRB certified:

☐ Yes ☐ No

III. Protocol Change

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).**

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?**

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

   ☐ Yes ☐ 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

1. **If you are changing your consent procedures, please explain these alterations in detail.**

2. **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?**

V. Consent Documents

1. **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):

2. **Please explain in detail how you will alter the consent documents.**

3. **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?**

4. **Please submit the original and altered consent documents and highlight the changes.**

VI. Project Sites or Study Participants

1. **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 populations as subjects

☐ Changing sites or programs

☐ Changing the number of subjects

☐ Other (please specify):

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

3. **Please provide the rationale for making these changes.**

4. **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:

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

6. **Please provide the rationale for making these changes.**

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

☐ Adding subjects to sample ☐ Reducing sample size

8. **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

9. **Please provide the justification for making this increase/decrease.**

10. **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

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

2. **Please provide the rationale for making these changes.**

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

VIII. Funding or Sponsorship

1. **How has the funding or sponsorship of this study changed?**

☐ Funding added ☐ Funding decreased ☐ New funding source ☐ Funding restored

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

IX. Date Change or Modification

1. **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: ☐

2. **Please explain the necessity for these changes.**

X. Other Changes

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

2. **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

1. **Discuss how these proposed changes may affect the risks posed to human subjects.**

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

Signature Page

ICJIA IRB: Amendment Application

TO BE COMPLETED BY PRINCIPAL INVESTIGATOR:

Project Name:

_____ _____

Signature of Principal Investigator Date

TO BE COMPLETED BY IRB CHAIR:

☐ Request approved ☐ Request denied ☐ IRB requests modifications

Modifications, if requested:

_____ _____

Signature of IRB Chair or Designee Date