Illinois Criminal Justice Information Authority

Institutional Review Board Initial Application for Research Involving Human Subjects

IRB Application Checklist

Date:

Title of Proposal:

Principal Investigator:

☐ **Application**

Title(s):

☐ **Interview protocol**

Title(s):

☐ **Recruitment flyer**

Title(s):

☐ **Focus group protocol**

Title(s):

☐ **Recruitment script**

Title(s):

☐ **Survey**

Title(s):

☐ **Contact script**

Title(s):

☐ **Observation protocol**

Title(s):

☐ **Verbal or written consent**

Title(s):

☐ **Follow-up script**

Title(s):

☐ **Intake form/screen**

Title(s):

☐ **Payment protocol**

Title(s):

☐ Other

Title(s):

For which review process are you submitting this application?

☐ Full ☐ Expedited (select category below) ☐ Limited (select exemption below)

Select category | Select exemption

☐ Exempt

If submitting for exempt review, please include the corresponding application.

To determine if your project qualifies for expedited review, please review the OHRP Expedited Review Categories.

I. 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. **Is this IRB linked to other IRB approval?**

☐ Yes ☐ No

a. **If <u>yes</u>, please explain**:

10. **Will the data be primary or secondary?**

☐ Primary ☐ Secondary

a. **If <u>secondary</u>, please briefly indicate the source of the data**.

II. VULNERABLE SUBJECTS

11. Will any of the following groups potentially be included in your sample? (Hold ctrl to select multiple)

Adult prisoners or individuals in secure confinement
Developmentally disabled, intellectually disabled, or cognitively impaired
Individuals held in residential treatment, locked facilities, or hospitalized
Juveniles in correctional or detention facilities
Minors under age 18
Non-English speakers
Pregnant women, if focus of research
Probationers, parolees, or individuals under court or correctional supervision
Wards of the state
Other (please specify below)

12. For each project staff member, please list Human Subjects Research Certification date and expiration date. If more spaces for staff is needed, please attach a seperate sheet at the end of the application

Name	Certification date	Expiration date

III. PROJECT DESCRIPTION

A. PROJECT SUMMARY

13. Please provide a brief summary (3 – 5 sentences), in lay terms, of the purpose of the study and the procedures subjects will undergo.

B. PROCEDURES

14. Describe the procedures involving human subjects and list the steps you will take.

a. Time involvement of subjects:

b. Location(s) where the study will be conducted, including a description, if applicable:

c. Amount of payment, if any (consent form must note plan for payment if they withdraw voluntarily):

d. What subjects will experience or do:

C. EQUITABLE SELECTION OF SUBJECTS

15. Please enter the following information about your proposed sample:

a. Anticipated total number of subjects in study:

b. Number of subjects under 18:

c. Number of subjects 18 and older:

d. Number of prisoners or individuals in secure confinement:

e. Number of probationers, parolees, or other individuals under court or correctional supervision:

f. Race of subjects (hold ctrl to select multiple). Please provide number of subjects after description, if known:

- African American
- American Indian
- Asian
- Hispanic
- White
- Other
- Bi-Racial
- Unknown

16. How will the subjects be recruited?

17. Identify the criteria for inclusion/exclusion of subjects and provide a clear rationale for them.

D. RISK/BENEFIT ASSESSMENT

18. Briefly describe the potential benefits of the project to subjects and/or society. Note: Social science research typically does not provide a direct benefit to the subjects.

19. Does the study involve any of the following? (hold ctrl to select multiple)

Use of deception by researchers
Use of drugs by subjects for study purposes
Covert and/or participant observation
Induction of mental and/or physical stress to subjects by researchers
Procedures which risk physical harm to the subject
Materials or behaviors commonly regarded as socially unacceptable
Procedures by researchers that might be regarded as an invasion of privacy or cause a degree of discomfort
Possible/probable disclosure of information by subjects to researchers that may be harmful to the subject (e.

a. **If you checked <u>any of the above procedures</u>, please explain in detail, as well as providing the methods being used to control or minimize the danger to the subjects.**

b. **Please indicate the theoretical and/or methodological necessity for employing each procedure checked above.**

20. **If the study involves deception, when and how will the subjects be debriefed? Generally, the nature of the deception and its necessity should be explained to the subjects.**

21. **Will other care or counseling be available, or referrals made for the subject should he or she become physically injured, stressed, uncomfortable, angry, or experience psychological difficulties as a result of participating in the research?**

☐ Yes ☐ No ☐ Not Applicable

If <u>yes</u>, please explain:

22. Indicate whether subjects will be exposed to minimal or greater than minimal physical, psychological, or other (e.g. social, economic) risk. Risk is considered minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Degree of *physical* risk to the subject

☐ Minimal ☐ Greater than minimal ☐ High

Please explain why you chose this designation:

b. Degree of *psychological* risk to the subject

☐ Minimal ☐ Greater than minimal ☐ High

Please explain why you chose this designation:

c. Degree of *other* (e.g. social, economic) risk to the subject

☐ Minimal ☐ Greater than minimal ☐ High

Please explain why you chose this designation:

E. COMPENSATION

23. Will the participants be compensated monetarily for entering the study?

☐ Yes ☐ No

a. If yes, what is the amount and source of the funds?

Amount:

Source of funds:

b. If yes, how will that money be distributed to subjects (e.g. gift cards, cash)? Please explain.

24. Are there other inducements planned to recruit subjects?

☐ Yes ☐ No

a. If yes, please explain:

F. CONFIDENTIALITY

25. Will any data be gathered through photographic, video, or audio recording devices?

☐ Yes ☐ No

a. If yes, how will the confidentiality of the materials produced by such devices be protected? Note: A separate line of the consent form for the subjects to agree to be video/audio taped or photographed must be included.

b. What will be done with the still photos, videos, or audio recordings after the study has been completed? Will this information be destroyed, kept xx number of years, used in publications, etc.? How does the investigator define "completion" of the study?

26. Will names or individual identifiers of subjects be recorded?

☐ Yes ☐ No

a. If yes, where will the names or other individual identifiers be recorded (e.g. on test protocols, on a separate list with code numbers, etc)?

b. If yes, describe project procedures for maintaining the security of these records at every point in the data collection process.

c. If yes, would it be possible to conduct the proposed project without recording names or other individual identifiers? Please explain why or why not.

d. If yes, will access to names be under your exclusive control?

☐ Yes ☐ No

i. If no, what will be done to protect the confidentiality of subjects? Who would have access to names or other individual identifiers? Describe the procedures for maintaining security of paper files, automated files, or other records.

ii. **Will the names of subjects be included in any publication based on this study? If yes, please explain.**

27. **Sometimes research findings are presented in a manner that permits knowledgeable readers to infer the identity of a person used as a subject, even if names are omitted. Do you expect to present finding that may possibly provide such clues?**

☐ Yes ☐ No

a. **If yes, please explain:**

28. **Will you obtain a Certificate of Confidentiality or a Privacy Certificate for this study? If yes, please ensure the consent form reflects this.**

☐ Yes ☐ No

G. INFORMED CONSENT

29. **Please indicate the type of consent you will collect (for more information on which option is applicable to your study, please see the "Consent Documentation" informational sheet).**

☐ Written (includes electronic signature) (answer question d)

☐ Waiver of documented consent (choose consent type below)

☐ Verbal (answer questions b-e)

☐ Waiver of consent (answer question a)

☐ Broad consent (answer question e)

a. **Why is your project eligible for a waiver of consent?**

b. **Why do you not intend to use written forms?**

c. **In what manner and to what extent would potential subject be given advance information about the procedure in which they are asked to participate? If using a contact letter, please include it.**

d. **In what matter would potential subjects be advised that their participation and continuation in the project would be entirely voluntary? Please provide a copy of the text to be used.**

e. **Please attach a copy of the script or the consent form you will use to the end of this document.**

30. **Please give a detailed description of the process that will be used to obtain consent and answer all applicable questions.**
    a. **Who will obtain consent?**

    b. **How will consent be obtained?**

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

d. **How will you verify the subject fully understands the consent?**

e. **How will project staff be trained to use the informed consent process?**

31. **Will the consent form be translated for non-English speaking participants?**

☐ Yes ☐ No

a. **If <u>no</u>, please explain why.**

b. **If <u>yes</u>, please provide an explanation of who will translate the forms and their qualifications.**

32. **Does the consent form you have attached fully comply with ICJIA instructions for consent forms and general requirements outlined in the *Code of Federal Regulations?***

☐ Yes ☐ No

a. **If <u>no,</u> please explain why.**

33. **Will all project staff be IRB certified and trained to follow the basic guidelines for the ethical care of subjects?**

☐ Yes ☐ No

a. **If <u>no,</u> please explain why.**

☐

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

TO BE COMPLETED BY IRB MANAGER:

Application reviewed through:

_____ Full board review _____ Expedited review _____ Limited review

Application needs to be renewed by: _____