Illinois Criminal Justice Information Authority

IRB Exempt Application for Research Involving Human Subjects

NOTE: IRB member objections to Office of General Counsel (OGC) Notice of Exempt Status must be received by OGC within 10 working days of the mailing date of the Notice.

Some research involving human subjects may be exempt from regulations. This form describes these exemptions. Please note that an exemption can be invoked only if **ALL** components of the research fit the category as described.

Once you determine your project is eligible for exempt review, ICJIA General Counsel will review your research to determine if an exemption can be granted. If granted by the IRB, your exemption request will be returned to you with an approval in Section Three along with the signature of ICJIA General Counsel, and you may begin your research. You must notify the IRB if your research changes in any way, because the exemption may no longer apply.

If an exemption cannot be granted, your exemption request will be returned to you with the reason listed in Section Three and your research will require review from the full IRB.

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:**

II. CATEGORIES ELIGIBLE FOR EXEMPTION

9. **Does this project constitute research involving human subjects?**

☐ **Yes** (continue to exemptions)

☐ **No**

If no, explain:

Which exemption category(ies) do you believe applies to your research?

NOTE: The exemptions are applicable to subpart B (research with pregnant woman, fetuses, and neonates) as long as the conditions of the exemptions are met. The exemptions do not apply to research subject to subpart C (research with prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners. The exemptions at 1, 4, 5, 6, 7, and 8 can apply to subpart D research (research with children) as long as the conditions of the exemptions ae met. The first two provisions of exemption 2 are applicable to subpart D research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being

observed. The third provision of exemption 2 may not be applied to research with children. Exemption 3 does not apply to research with children.

☐ **1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.**

☐ **2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:**

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **or**
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111 (a)(7).

NOTE: *The first two provisions of exemption 2 (i and ii), are applicable to subpart D research involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. The third provision of exemption 2 (iii) may not be applied to research with children.*

☐ **3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:**

- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; **or**
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; **or**
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

NOTE*: Exemption 3 does not apply to research with children.*

☐ **4. Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:**

- The identifiable private information or identifiable biospecimens are publically available; **or**
- Information, which may include information about biospecimens, is recorded by the investigator in

such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; **or**

- The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **or**
- The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2020, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 4 U.S.C. 552a, and if applicable, the information used in the research was collected subject to the Paperwork Reduction act of 1995, 44 U.S.C. 3501 et seq.

☐ **5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as section 1115 and 1115A of the Social Security Act, as amended.**

☐ **6. Taste and food quality evaluation and consumer acceptance studies, which meet any of the following conditions:**

- If wholesome foods without additives are consumed; **or**
- If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection of the US Department of Agriculture.

☐ **7. Storage or maintenance for secondary research for which broad consent is required: storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).**

☐ **8. Secondary research for which broad consent is required. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:**

- Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); **and**
- Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; **and**

- An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section: **and**
- The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

III. ADDITIONAL REQUIREMENTS

1) If you indicated that you will be asking for exemption categories 1, 3, 4, 5, or 6, please attach the completed IRB Research Application to this request and submit for the normal exempt review process.
2) If you indicated that you will be asking for exemption category 2 or exemption category 3, **AND** "The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7)", then you are required to submit this application for a limited IRB review. Please attach the completed IRB Research Application to this request, ensuring all information regarding the protections of identifiable information is present, and submit for limited review.
3) If you indicated that you will be asking for exemption category 7, you are required to submit this application for a limited IRB review. Please attach the completed IRB Research Application to this request, ensuring all information regarding the broad consent process is present, and submit for limited review.
4) If you indicated that you are requesting and exemption under category 8, you are required to submit this application for a limited IRB review. Please attach the completed IRB Research Application to this request, ensuring all information regarding the broad consent process is present, and submit for limited review.

TO BE COMPLETED BY PRINCIPAL INVESTIGATOR:

Project Name:

_____ _____

Signature of Principal Investigator Date

☐ Exemption Allowed (Category: Choose a category)

☐ Exemption Not Allowed (Please see comments.)

Comments/justification regarding determination of exemption status:

_____ _____

Signature of ICJIA General Counsel Date

☐ **No IRB Objections** to Exempt Status Determination (within 10 working days)

☐ IRB Objections to Exempt Status Determination (within 10 working days) / **IRB Review Required**

Comments/justification regarding determination of exemption status:

_____ _____

Signature of ICJIA General Counsel Date