Office of the Human Research Protection Program

Checklist: Additional Requirements for Research Supported by the Department of Justice (version date: March 14, 2014)

This checklist outlines researchers' additional requirements for **research conducted within the Bureau of Prisons**, AND/OR **funded by the National Institute of Justice** (NIJ). See also UCLA OHRPP Guidance: Special Populations: Prisoners.

Research Conducted Within the Bureau of Prisons (the Bureau)

Researchers are responsible for communicating with the Bureau of Prisons (the Bureau) to ensure that all Bureau requirements are met prior to starting an IRB approved study.

DEFINING HUMAN RESEARCH:

- ☐ Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
- ☐ See UCLA OHRPP Guidance: Determining Which Activities Require UCLA OHRPP/IRB Review for additional direction.

ETHICAL STANDARDS AND PRACTICES:

The UCLA HRPP, IRB, and Researchers and Research Staff must follow the requirements of 28 CFR 512, including:

- ☐ The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- ☐ The research design must be compatible with both the operation of prison facilities and protection of human participants. The Researcher must observe the rules of the institution or office in which the research is conducted.
- ☐ Any Researcher who is a non-employee of the Bureau must sign a statement in which the Researcher agrees to adhere to the requirements of 28 CFR 512.
- ☐ All research proposals will be reviewed by the Bureau Research Review Board.

SCIENTIFIC OR SCHOLARLY VALIDITY:

- ☐ The project must have an adequate research design and contribute to the advancement of knowledge about corrections.

EQUITABLE PARTICIPANT SELECTION:

- ☐ The selection of participants within any one organization must be equitable.
- ☐ Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.

- Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:
  - No longer in Bureau of Prisons custody.
  - Participating in authorized research being conducted by Bureau employees or contractors.

PROCEDURES TO MAINTAIN CONFIDENTIALITY:

- A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
- Except as noted in the consent statement to the participant, the Researcher must not provide research information that identifies a participant to any person without that participant's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
- Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system
- If the Researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the Researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

ELEMENTS OF CONSENT: Required elements of disclosure include:

- Identification of the Researchers.
- Anticipated uses of the results of the research.
- A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a Researcher may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
- A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

STUDY DESIGN

- Researcher must have academic preparation or experience in the area of study of the proposed research.

- When submitting a research protocol, the applicant shall provide the following information:
  - A summary statement, which includes:

- Names and current affiliations of the Researchers.
- Title of the study.
- Purpose of the study.
- Location of the study.
- Methods to be employed.
- Anticipated results.
- Duration of the study.
- Number of participants (staff or inmates) required and amount of time required from each.
- Indication of risk or discomfort involved as a result of participation.

☐ A comprehensive statement, which includes:
- Review of related literature.
- Detailed description of the research method.
- Significance of anticipated results and their contribution to the advancement of knowledge.
- Specific resources required from the Bureau of Prisons.
- Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
- Description of steps taken to minimize any risks.

☐ Description of physical or administrative procedures to be followed to:
- Ensure the security of any individually identifiable data that are being collected for the study.
- Destroy research records or remove individual identifiers from those records when the research has been completed.

☐ Description of any anticipated effects of the research study on organizational programs and operations.

☐ Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.

☐ A statement regarding assurances and certification required by 28 CFR 46, if applicable.

☐ **RESEARCH OVERSIGHT:** Researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Researcher.

REPORTING REQUIREMENTS:

☐ At least once a year, the Researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.

☐ At least 12 working days before any report of findings is to be released, the Researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The Researcher shall include an abstract in the report of findings.

☐ In any publication of results, the Researcher shall acknowledge the Bureau's participation in the research project.

- The Researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
- Prior to submitting for publication the results of a research project conducted under this subpart, the Researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

National Institute of Justice (NIJ) Funded Research

Researchers are responsible for communicating with their NIJ Program Officer to ensure that all NIJ requirements are met prior to starting an IRB approved study.

- **PRIVACY CERTIFICATE**: All projects are required to have a privacy certificate approved by the NIJ human subjects protection officer.
- **CHILD ABUSE REPORTING**: Under a privacy certificate, Researchers and Research Staff do not have to report child abuse unless the participant signs another consent document to allow child abuse reporting.
- **EMPLOYEE CONFIDENTIALITY STATEMENTS**: All Researchers and Research Staff are required to sign employee confidentiality statements, which are maintained by the responsible Researcher.
- **CONFIDENTIALITY STATEMENT IN CONSENT FORM**: The confidentiality statement on the consent document must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
- **DEIDENTIFIED DATA SENT TO ARCHIVE**: A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

Regulations and References

U.S. Bureau of Prisons, Department of Justice – Research: 28 CFR 512
U.S. Judicial Administration, Department of Justice – Research: 28 CFR 46
UCLA OHRPP Guidance: Special Populations: Prisoners

Questions

If you have questions regarding Department of Justice requirements, please contact the relevant IRB committee or Kip Kantelo, OHRPP Director, at (310) 825-5855 or kip.kantelo@research.ucla.edu.