HRPP Document: **GUI341**

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Subject: **Guidance on Additional Requirements for Protocols Conducted by UAB and Sponsored by the Department of Department of Justice (DOJ)/National Institute of Justice (NIJ) and Research Conducted with the Bureau of Prisons (BOP)**

Investigators who are recipients of funds from the National Institute of Justice (NIJ) are required to comply with the Department of Justice (DOJ) regulations at 28 CFR 46 (Protection of Human Subjects).

- Obtains a privacy certificate approved by the NIJ Human Subjects Protection Officer;
- Includes in the Confidentiality Section of the Informed Consent the statement "The confidentiality can only be broken if the subject reports immediate harm to subjects or others."
- Submits a copy of the IRB approval as well as supporting documentation of the IRB's institutional affiliation, assurance, etc. to the NIJ prior to initiation of any research activities that are not exempt from the requirements of 28 CFR 46;
- Submits supporting documentation of the IRB's approval of the research meeting the criteria for exemption under 28 CFR 46.101(b);
- Signs and maintains an Employee Confidentiality Statement for themselves and their research staff;
- Sends a copy of all data which must be de-identified, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials to the National Archive of Criminal Justice Data.

Investigators conducting human subjects' research with the Bureau of Prisons are required to comply with the regulations at 28 CFR 512.

- Obtains review of the research proposal by the Bureau of Research Review Board (BBRB);
- Signs an agreement to adhere to the provisions of the Bureau of Prisons under 28 CFR 512;
- Provides a research project design that contributes to the advancement of knowledge about corrections;
- Provides a research project design that is compatible with both the operation of the prison facilities and protection of human subjects;
- Observes the rules of the institution in which the research is conducted;
- Provides a research project design that does not involve medical experimentation, cosmetic research, or pharmaceutical testing;

- Provides documentation that:
    - Risks to participants is minimized and risks are reasonable in relation to the anticipated benefits;
    - Selection of participants within any one organization is equitable; and
    - Incentives may not be offered to help persuade inmates to participant, unless snacks or soft drinks are consumed at the test setting.
    - Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
        - No longer in the Bureau of Prisons custody, and
        - Participating in authorized research being conducted by Bureau employees or contractors.
- Provides documentation of experience in the area of study of the proposed research;
- Provides documentation of review of related literature;
- Provides documentation that research records will be destroyed or individual identifiers will be removed from the records after the research is completed;
- Assumes responsibility as the investigator for actions of any research staff engaged to participate in the project;
- Provides documentation for maintaining confidentiality of data preliminary to the research, during and after the conclusion of the research by assuring:
    - Records are not in an individually identifiable form; and,
    - Advance written assurance has been provided to the Bureau of Prisons that the records will be used solely for statistical research or reporting.
- Agrees not to provide research information that identifies a subject to any person (i.e. cannot be admitted as evidence or used for any purpose in any action, suite or other judicial, administrative, or legislative proceeding) without the subject's prior written consent to release the information;
- Agrees not to maintain records electronically that contain non-disclosable information directly traceable to a specific person at UAB (NOTE: Computerized data records may only be maintained at an official DOJ site);
- Negotiates arrangements, prior to the beginning of the data collection of the project, to provide non-identifiable computerized data on individual subjects along with documentation to the Office of Research and Evaluation (ORE) if requested;
- Includes in the Informed Consent the following elements of disclosure:
    - Identification of the investigators;
    - Anticipated uses of the results of the research;
    - A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (e.g. the inmate will be returned to regular assignment or activity by staff as soon as possible);
    - A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law (i.e. an investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm

himself/herself or someone else, or if the subject 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 subject's release date or parole eligibility.
- Submits planned changes in the research to the IRB for review and approval prior to initiation;
- Provides, at least yearly, a report on the progress of the research to the Chief, Office of Research and Evaluation;
- Acknowledges the Bureau of Prisons participation in any publication of the results;
- Includes a disclaimer in the results for publication that the approval or endorsement of the published material is an expression of the policies or view of the Bureau of Prisons;
- Provides, at least 12 working days before any report of findings to be released, one (1) copy of the report, which shall include an abstract of the findings, to each of the following:
    - Chairperson of the BRRB;
    - The Regional Bureau of Prisons Director; and
    - The Warden of each institution which provided data or assistance;
- Submits two (2) copies of the results of the research project for informational purposes only to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons **prior to** submission for publication.

REFERENCES

28 CFR 512 (Judicial Administration Research Regulations)
28 CFR 22 (Judicial Administration Confidentiality of Identifiable Research and Statistical Information)
28 CFR 46 (Judicial Administration Protections of Human Subjects)