1.15 Research Subject to Department of Justice Regulatory Requirements

1.0 Purpose

The purpose of this policy and procedure is to specify the Organizations requirements for the review, approval, conduct and oversight of human subject research funded by or involving the U.S. Department of Justice (DoJ) and the Federal Bureau of Prisons (BoP).

2.0 Policy

- **2.1.** It is the policy of the Organization that it will comply fully with all approval requirements of DoJ and/or BoP when its IRBs review, approve and provide oversight of human subjects research funded by or otherwise contractually subject to DoJ regulations (28 CFR 46) and BoP regulations (28 CFR 512).
- **2.2.** The Organization requires that the research specified in Section 2.1 above will comply with the following DoJ requirements as applicable:
  - **2.2.1.** The Belmont Report.
  - **2.2.2.** Title 28 Code of Federal Regulations Part 46 (28 CFR 46), Department of Justice Regulations, “Protection of Human Subjects” (DoJ adoption of the “Common Rule”).
  - **2.2.3.** Title 28 Code of Federal Regulations Part 512 (28 CFR 512), Bureau of Prisons Regulations, “Research”.
  - **2.2.4.** Title 28 Code of Federal Regulations Part 22 (28 CFR 22), Confidentiality of Identifiable Research and Statistical Information.
- **2.3.** Education and Training
  - **2.3.1.** All research personnel must complete training in accordance with HRPP policy #1.23 (HRPP Training Requirements and Opportunities for Research Personnel).
  - **2.3.2.** Any other specific training related to DOJ requirements will be provided as necessary by the ORA.
- **2.4.** Responsibilities
  - **2.4.1.** Research Funded by the Department of Justice [28 CFR 46]
    - **2.4.1.1.** It is the responsibility of the PI to ensure compliance with all additional DoJ requirements for human subject protection.
    - **2.4.1.2.** It is the responsibility of the IRB to ensure that all additional DoJ requirements for human subject protection have been met before IRB approval of the research project.
  - **2.4.2.** Research Conducted Within the Bureau of Prisons

    - **2.4.2.1.** Regulatory Compliance [28 CFR 512]
        - **2.4.2.1.1.** It is the responsibility of the PI to ensure compliance with all additional BoP requirements for human subject protection.
        - **2.4.2.1.2.** All research proposals must be reviewed and approved by the Bureau Research Review Board (BRRB).
        - **2.4.2.1.3.** It is the position of the Organization that the IRB of record should, whenever possible, be the IRB appointed by the warden of the facility where the research will be conducted in accordance with 28 CFR 512.14. When multiple facilities are involved, the UNMC IRB may accept IRB approvals from multiple facilities, as appropriate.
        - **2.4.2.1.4.** It is the responsibility of the IRB to ensure that all additional BoP requirements for human subject protection have been met before IRB approval of the research project.
    - **2.4.2.2.** Limitations on Research Projects [28 CFR 512.11(a)(3)]: Research involving human subjects conducted within the BoP must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
    - **2.4.2.3.** Academic Preparation or Experience [28 CFR 512.11(a)(6)]: The PI must have academic preparation or experience in the area of study of the proposed research.
    - **2.4.2.4.** Personnel [28 CFR 512.11(a)(7)]: For all research conducted within the BoP, the PI assumes responsibility for actions of any person engaged to participate in the research study as an associate, assistant (i.e., personnel listed in Section I of the IRB application) or subcontractor(s).
    - **2.4.2.5.** Limitations on Incentives for Inmate Subjects [28 CFR 512.11(a)(5)]
        - **2.4.2.5.1.** Incentives may not be offered to help persuade inmate subjects to participate in research. However, soft drinks and snacks to be consumed at the test setting may be offered.
        - **2.4.2.5.2.** Reasonable accommodations such as a nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both: 1) No longer in BoP custody and 2) participating in authorized research being conducted by BoP employees or contractors.
    - **2.4.2.6.** For research conducted within the Bureau of Prisons, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered research.

3.0 Definitions [28 CFR 46.102]

- **3.1.** ***Human subject*** is defined a living individual about whom an investigator (whether professional or student) conducting research obtains:
    - **3.1.1.** Data through intervention or interaction with the individual and/or
    - **3.1.2.** Identifiable private information.
- **3.2.** ***Intervention*** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulation of the subject or the subject’s environment that are performed for research purposes.
- **3.3.** ***Interaction*** includes communication or interpersonal contact between PI and contact.
- **3.4.** ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and

which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the PI or associated with the information) in order for obtaining the information to constitute research involving human subjects.

4.0 Procedures

- **4.1.** Research funded by the Department of Justice
  - **4.1.1.** The IRB will review the application and complete the Department of Justice Checklist and ensure compliance with all applicable DoJ requirements, BoP requirements, and HRPP policies.
  - **4.1.2.** Requirement for Privacy and Confidentiality [28 CFR 22]: All research funded by the DoJ must maintain the following documents:
    - **4.1.2.1.** A privacy certificate approved by the National Institute of Justice (NIJ) Human Subjects Protection Officer. A Privacy Certificate Template and Privacy Certificate Guidance are available on the National Institutes of Justice Website.
    - **4.1.2.2.** Signed employee confidentiality statements for the PI and research staff, which are maintained by the PI.

> Note: “Research staff” is defined as anyone listed in Section I of an approved IRB application.

  - **4.1.3.** Requirement for Informed Consent [28 CFR 46.116; 28 CFR 22]: Research involving human subjects funded by the DoJ must include the following information in the ICF:
    - **4.1.3.1.** The name(s) of the funding agency(ies)
    - **4.1.3.2.** A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by the NIJ, the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified. If the PI intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any risks that might results from this disclosure and must explicitly provide written consent prior to participating in the research.

    - **4.1.3.3.** Under a privacy certificate, PIs and research personnel do not have to report child abuse unless the subject signs another ICF to allow child abuse reporting.

> Note: It is the position of the University of Nebraska that child abuse must be reported in accordance with Nebraska State Law. Therefore, the ICF must disclose this obligation.

  - **4.1.4.** Requirement for Reporting: For research studies involving human subjects funded by the DoJ, a copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the ICF, data collection instruments, surveys, or other relevant research materials.
- **4.2.** Research conducted within the Bureau of Prisons
  - **4.2.1.** The IRB will review the application and complete the Department of Justice Checklist and ensure compliance with all applicable DoJ requirements, BoP requirements, and HRPP policies.
  - **4.2.2.** The research design must be compatible with both the operation of prison facilities and protection of human subjects. The PI must observe the rules of the institution or office in which the research is conducted.
  - **4.2.3.** The research must have an adequate research design and contribute to the advancement of knowledge about corrections.
  - **4.2.4.** The selection of subjects within in one organization must be equitable.
  - **4.2.5.** Any researcher who is a non-employee of the BoP must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
  - **4.2.6.** For research conducted within the Bureau of Prisons, the 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.
  - **4.2.7.** For all research conducted within the Bureau of Prison, the PI must provide the following information:
    - **4.2.7.1.** A summary statement, which includes:
      - **4.2.7.1.1.** Names and current affiliations of the Researchers
      - **4.2.7.1.2.** Title of the study
      - **4.2.7.1.3.** Purpose of the study
      - **4.2.7.1.4.** Location of the study
      - **4.2.7.1.5.** Methods to be employed
      - **4.2.7.1.6.** Anticipated results
      - **4.2.7.1.7.** Duration of the study
      - **4.2.7.1.8.** Number of participants (staff or inmates) required and amount of time required from each
      - **4.2.7.1.9.** Indication of risk or discomfort involved as a result of participation
    - **4.2.7.2.** A comprehensive statement, which includes:
      - **4.2.7.2.1.** Review of related literature.
      - **4.2.7.2.2.** Detailed description of the research method.

        - **4.2.7.2.3.** Significance of anticipated results and their contribution to the advancement of knowledge.
        - **4.2.7.2.4.** Specific resources required from the BoP.
        - **4.2.7.2.5.** Description of all possible risk, discomforts and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks or discomforts will actually occur.
        - **4.2.7.2.6.** Description of steps taken to minimize any risks.
        - **4.2.7.2.7.** Description of physical or administrative procedures to be followed to:
            - **4.2.7.2.7.1.** Ensure the security of any individually identifiable data that are being collected for the study.
            - **4.2.7.2.7.2.** Destroy research records or remove individual identifiers from those records when the research has been completed.
        - **4.2.7.2.8.** Description of any anticipated effect of the research study in organizational programs and operations.
        - **4.2.7.2.9.** Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
        - **4.2.7.2.10.** A statement regarding assurance and certification required by 28 CFR 46, if applicable.
    - **4.2.7.3.** The researcher must demonstrate academic preparation of experience in the area of study of the proposed research.
- **4.2.8.** Requirement for Confidentiality [28 CFR 512.11, 12, 13, 15]: For all research conducted with the BoP:
    - **4.2.8.1.** A non-employee of the BoP may receive records in a form not individually identifiable when an advance adequate written assurance that the record will be used solely as a statistical research or reporting record.
    - **4.2.8.2.** Except as noted in the consent statement to the subject, the PI must not provide research data that identifies the subject to any person without that subject’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 who the data pertains.
    - **4.2.8.3.** Except for computerized data records maintained at an official DoJ 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.
    - **4.2.8.4.** If the PI is conducting a study of special interest to the Office of Research and Evaluation (ORE), but the study is not a joint project involving the ORE, the PI may be asked to provide ORE with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the study.
- **4.2.9.** Requirement for Informed Consent [28 CFR 512.16]: Research involving human subjects conducted within the BoP, must include the following elements of disclosure in the ICF:
    - **4.2.9.1.** Identification of the PI and research personnel listed in Section I of the IRB application.
    - **4.2.9.2.** Anticipated uses of the results of the research.

- **4.2.9.3.** A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the study at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- **4.2.9.4.** 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 PI may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
- **4.2.9.5.** A statement that participation in the study will have no effect on the inmate subject's release date or parole eligibility.

- **4.2.10.** Documentation and Waiver of Signed Informed Consent [28 CFR 512.16(a)(12)]
  - **4.2.10.1.** A PI who is a non-employee of the BoP, in addition to presenting the statement of informed consent to the subject, shall also obtain the subject's signature on the statement of informed consent prior to initiating the research activity.
    The PI may not be required to obtain the signature if the PI can demonstrate that:
    - **4.2.10.1.1.** The only link to the subject's identity is the signed statement of informed consent, or
    - **4.2.10.1.2.** That there is significantly more risk to the subject if the statement is signed.
  - **4.2.10.2.** The signed statement shall be submitted to the chairperson of the IRB of record.
- **4.2.11.** Request for Change [28 CFR 512.11(a)(14)]: The PI must submit planned methodological changes in a research study to the IRB for approval, and may be required to revise study procedures in accordance with the new methodology.
- **4.2.12.** Requirement for Reporting [28 CFR 512.19]: For research studies involving human subjects conducted within the BoP, the PI is responsible for the submission of the following:
  - **4.2.12.1.** A progress report of the research at least once a year to the Chief and ORE.
  - **4.2.12.2.** A copy of any report of findings, including an abstract, must be provided at least 12 days working days before it is to be released to the chairperson of the BRRB, the regional director and the warden of each institution which provided data or assistance.
- **4.2.13.** Requirement for Publication of Results [28 CFR 512.20]
  - **4.2.13.1.** For all research conducted within the BoP, the publication of results of any research studies involving human subjects is permitted in book form and professional journals. In any publication, the PI is responsible for the following:
    - **4.2.13.1.1.** An acknowledgment of the BoP's participation in the research study.
    - **4.2.13.1.2.** Expressly disclaiming approval or endorsement of the published material as an expression of the policies or views of the Bureau.
  - **4.2.13.2.** Prior to submitting for publication, the PI will provide two copies of the material, for informational purposes only, to the Chief, ORE, Central Office, Bureau of Prisons.

- **4.3.** Additional Requirements
  - **4.3.1.** New research and substantive scientific amendments to approved research shall undergo scientific review (including review by outside experts as needed) and that the review is considered by the IRB in accordance with HRPP policy #1.10 (Scientific and Other Committee Review of Research).
  - **4.3.2.** Disclosure regarding the provisions for research-related injury follows the requirements of the DoJ component.

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