

Guidance on Additional Requirements for Federally Funded Research

When human research is conducted or funded by federal entities, there may be additional regulations and requirements that must be followed. Following is a summary of these additional requirements for select organizations.

Additional Requirements for Department of Justice (DOJ)

When human research is conducted or funded by the DOJ, UNM commits to apply 28 CFR part 22.

1. The project must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer.
2. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.
3. 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.
4. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the participant signs another consent document to allow child abuse reporting.
5. 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.

When the research is conducted with the federal Bureau of Prisons, UNM commits to comply with 28 CFR part 512.

1. Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.
2. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
3. The research design must be adequate and compatible with both the operation of prison facilities and protection of human participants and must contribute to the advancement of knowledge about corrections.
4. Investigators must observe the rules of the institution or office in which the research is conducted.
5. Any investigator who is a non-employee of the Bureau of Prisoners must sign a statement in which the investigator agrees to adhere to the requirements of 28 CFR §512.
6. The research must be reviewed and approved by the Bureau Research Review Board.
7. Incentives cannot 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.
8. 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.
9. Except as noted in the consent statement to the participant, you 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.
10. 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.
 11. If you are conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, you 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.
 12. Required elements of disclosure additionally include:
 - a) Identification of the investigators.
 - b) Anticipated uses of the results of the research.
 - c) 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).
 - d) A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator 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.
 - e) A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.
 13. You must have academic preparation or experience in the area of study of the proposed research.
 14. The IRB application must include a summary statement, which includes:
 - a) Names and current affiliations of the investigators.
 - b) Title of the study.
 - c) Purpose of the study.
 - d) Location of the study.
 - e) Methods to be employed.
 - f) Anticipated results.
 - g) Duration of the study.
 - h) Number of participants (staff or inmates) required and amount of time required from each.
 - i) Indication of risk or discomfort involved as a result of participation.
 15. The IRB application must include a comprehensive statement, which includes:
 - a) Review of related literature.
 - b) Detailed description of the research method.
 - c) Significance of anticipated results and their contribution to the advancement of knowledge.

- d) Specific resources required from the Bureau of Prisons.
 - e) 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.
 - f) Description of steps taken to minimize any risks.
 - g) 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.
 - h) Destroy research records or remove individual identifiers from those records when the research has been completed.
 - i) Description of any anticipated effects of the research study on organizational programs and operations.
 - j) Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
16. The IRB application must include a statement regarding assurances and certification required by federal regulations, if applicable.
 17. You must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor.
 18. At least once a year, you must provide the Chief of the ORE with a report on the progress of the research.
 19. At least 12 working days before any report of findings is to be released, you must 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.
 20. You must include an abstract in the report of findings.
 21. In any publication of results, you must acknowledge the Bureau's participation in the research project.
 22. You must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
 23. Prior to submitting for publication the results of a research project conducted under this subpart, You must provide two copies of the material, for informational purposes only, to the Chief, ORE, Central Office, Bureau of Prisons.

Additional Requirements for Department of Education (ED)

1. Each school at which the research is conducted must provide an assurance that they comply with the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).
2. Provide a copy of all surveys and instructional material used in the research. Upon request parents of children involved in the research must be able to inspect these materials.
3. The school in which the research is being conducted must have policies regarding the administration of physical examinations or screenings that the school may administer to students.