

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 and 46. DOJ is not a signatory to the Revised Common Rule.

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 the results of a research project conducted under this subpart for publication, 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). See the UNM IRB [Guidance on FERPA](#).
2. PPRA Requirements are as follows:
3. No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:
 - a. Political affiliations.
 - b. Mental and psychological problems potentially embarrassing to the student or his or her family.
 - c. Sex behavior and attitudes.
 - d. Illegal, anti-social, self-incriminating and demeaning behavior.
 - e. Critical appraisals of other individuals with whom the student has close family relationships.
 - f. Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
 - g. Religious practices, affiliations, or beliefs of the student or student's parent.
 - h. Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.



4. Prior consent means:
 - a. Prior consent of the student, if the student is an adult or emancipated minor; or
 - b. Prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.
5. For certain types of research not funded by the ED and conducted in a school that receives funding from the ED, the IRB must verify compliance with ED regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:
 - a. The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.
 - b. Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
 - c. Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items listed in #3a-h above).
6. The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
7. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
8. The administration of physical examinations or screenings that the school or agency may administer to a student.
9. The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.
10. The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.
11. Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

Additional Requirements for Department of Defense (DoD)

1. When reviewing DoD-supported research, the IRB will consider the scientific merit of the research.
2. The IRB may rely on outside experts to provide an evaluation of the scientific merit (see SOP 204 “IRB Use of outside Expertise-Consultants”).
3. The DoD component will conduct an appropriate administrative review of the research involving human participants, including any applicable laws, requirements and cultural sensitivities when research is conducted in a foreign country. This review will be conducted prior to the final approval of the research by the UNM IRB.
4. See SOP 514 “Research Supported by the Department of Defense” for additional requirements to conduct research supported by DoD.