OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #302.9 Revision 9	**TITLE: Exempt Review of Human Research**	Effective Date: 1/13/2025
Approved By: Exec. Director	Signature 	Date 1/13/2025
Approved By: IRB Chair	Signature 	Date 1/13/2025

PURPOSE

To define policies and procedures for review of human research that meets criteria for exemption.

REVISIONS FROM PREVIOUS VERSION

Remove references to federally funded

POLICY

Human research projects that meet the categories set forth by the federal regulations [45 CFR 46.104(d)] may qualify for exemption. An IRB member reviews and grants exemption for research conducted by UNM affiliates and external partners as permitted under regulation. The determination may not be made by any other party or office. Research activities are exempt from the human research protection regulations when the only involvement of participants falls within one or more of the following categories, the research is not regulated by the Food and Drug Administration (FDA) and does not include incarcerated individuals, unless the research is aimed at involving a broader participant population that only incidentally includes prisoners:

1. Research conducted in established or commonly accepted educational settings that specifically involves normal education practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular or special educational instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) uninfluenced by the researcher, if at least one of the following criteria are met:
    - (i) Information obtained is recorded in such a manner that study participants cannot be readily ascertained, directly or through identifiers linked to the participants; **or**
    - (ii) Any disclosure of the study participants' responses outside the research would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation; **or**
    - (iii) Information obtained is recorded in such a manner that the identity of the study participants can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a **limited IRB review** to make the determination that, when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data (45 CFR 46.111(a)(7)).

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria are met:
    (i) Information obtained is recorded in such a manner that study participants cannot be readily ascertained, directly or through identifiers linked to the participants; **or**
    (ii) Any disclosure of the study participants' responses outside the research would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participants financial standing, employability, or reputation; **or**
    (iii) Information obtained is recorded in such a manner that the identity of the study participants can readily be ascertained, directory or through identifiers linked to the participants, and the IRB conducts a **limited IRB review** to make the determination that, when appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data (45 CFR 46.111(a)(7)).

    Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the researcher has no reason to think the subjects will find the interventions offensive or embarrassing (e.g. play online games, solve puzzles under various noise conditions, decide how to allocate a nominal amount of received cash between themselves and others). If the research involves deceiving the participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
4. Secondary research uses of identifiable private information or identifiable biospecimens for which consent is not required, if at least one of the following criteria is met:
    (i) Identifiable private information or biospecimens are publicly available; **or**
    (ii) Information, which may include information about biospecimens, is recorded in such a manner that study participants cannot be readily ascertained, directly or through identifiers linked to the participants, the researcher does not contact the participants, and will not re-identify participants; **or**
    (iii) Research involves only information collection and analysis involving the research use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E (i.e. HIPAA), for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **or**
    (iv) Research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine

public benefit (e.g. financial or medical benefits as provided under the Social Security Act) or services programs (e.g. social, supportive, or nutrition services as provided under the Older Americans Act) including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures or in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies:
   (i) If wholesome foods without additives are consumed; **or**
   (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. Exemption categories at 45 CFR 46.104(d)(7) and (d)(8) will not be used for research under the oversight of the UNM IRB.

Research must also meet the following ethical criteria, even if it falls into one or more exemption categories:

1. Research presents no more than minimal risk to participants;
2. Risks to participants are minimized and reasonable in relation to anticipated benefits;
3. Selection of participants is equitable;
4. If research involves interaction with participants:
   a) Informed consent will be sought from participants and documented if appropriate;
   b) The circumstances of informed consent minimize coercion and undue influence;
   c) Participants will be informed that the activity involves research, a description of procedures, that participation is voluntary and whom to call with questions; and
   d) Provisions for protecting the privacy interests of participants are adequate.
5. If private identifiable data are recorded, provisions for maintaining confidentiality of data are adequate.

RESPONSIBILITIES

Execution of SOP: IRB Chairs, IRB Members, Researchers, OIRB Staff.

PROCEDURE

Submission and Screening

1. The PI submits a complete new project package as per the IRB Submission Checklist to the OIRB through the ERA system. Instructions for preparing the application are available on the OIRB website. The researcher may call the OIRB with questions.
2. Upon receipt of the submission, OIRB staff conduct intake and pre-review activities as described in the Staff Processing of Submissions SOP. OIRB staff make a preliminary determination regarding project funding, whether the project meets the criteria for exempt review, including minimal risk, and identifies the exempt category(ies). If the application does not meet the criteria for exempt or expedited review, OIRB staff schedule the project for full board review according to the Initial Full Review SOP.

Assigning Reviewers

1. Qualified IRB reviewers will conduct exempt reviews. All reviewers undergo initial training with OIRB prior to conducting exempt reviews. Members who have served on the IRB for at least three months may qualify as an exempt reviewer.
2. The reviewer notifies OIRB staff if unavailable to conduct a review during the assigned time period or has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP. OIRB staff document who served as reviewer on the applicable reviewer form.

IRB Exempt Review

1. Reviewers are provided all documents submitted by the researcher.
2. The reviewer documents specific findings (e.g. exemption category, requirement for informed consent) by completing the Reviewer Checklists.
3. The reviewer is responsible for reviewing the application in enough depth to determine that all of the research procedures fit one or more of the exemption categories specified in this policy. The reviewer ensures that the research meets ethical principles and standards for protecting research participants.
4. During review, the reviewer ensures that the research does not include any of the following:
    - Prisoners, unless the research is aimed at involving a broader participant population that only incidentally includes prisoners;
    - Survey or interview techniques which include children as project participants (except for educational tests as described in 45 CFR 46.104(d)(1));
    - The observation of children where the researcher participates in the activities being observed (exemption category 2(i) and (ii) only);
    - FDA-regulated research.
5. If the reviewer is unable to respond within 7 days, OIRB staff may forward the protocol to another reviewer.

Review Outcome(s)

1. The reviewer makes one of the following recommendations by completing the Reviewer Checklist and returning it to the OIRB as soon as the review is completed but, if possible, no later than 7 days from receipt:
    - Additional information needed to determine exempt status;
    - Required modifications needed to qualify project for exempt status (if the modifications are minor, modifications can be verified administratively by OIRB staff);
    - Recommendation that it qualifies for expedited review or requires review by the fully convened IRB (if the latter, reviewer must provide a rationale for this determination);
    - Exempt (general comments or suggestions may be included but not required for approval).
2. When conducting limited IRB review, the reviewer cannot disapprove the project; instead, the reviewer would defer the project for review by the fully convened IRB.
3. The reviewer can also recommend that the activities do not fall under IRB purview (i.e. not human research). In these cases, the reviewer indicates this on the Reviewer Checklist, the review is complete and OIRB staff send a determination letter that IRB approval is not required to the PI.
4. Continuing review is not required for any project that meets exemption criteria.
5. The PI is responsible for submitting any requested modifications to the OIRB who then forward them to the reviewer for review and approval if appropriate. The reviewer determines whether the modifications are sufficient for approval of exempt status, and, if so, OIRB staff send an exemption determination letter to the PI.

6. If the reviewer determines the modifications are inappropriate or insufficient, he/she may request that the PI make further modifications. This review and modification process continues until there is a resolution.
7. IRB records and letters for all exempt determinations include the citation of the specific category for the exemption.
8. The IRB does not require further review of exempt projects unless changes to the project are made that may affect exempt status, including changes related to privacy and confidentiality procedures.

REFERENCES

21 CFR 56.104(d)
45 CFR 46.104(b)
45 CFR 46.102(j)
45 CFR parts 160 and 164, subparts A and E