OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #205.1 Revision 1	**TITLE: Review Standards for Minimal Risk Research Not Covered by Federalwide Assurance**	Effective Date: 1/19/2018
Approved By: OIRB Director	Signature	Date 1/19/2018
Approved By: IRB Chair	Signature	Date 1/19/2018

PURPOSE

This policy describes how the UNM IRB reviews and documents determinations for minimal risk research not covered by UNM's Federalwide Assurance (FWA) to ensure the highest standards for protection of research participants while allowing for the greatest amount of flexibility. A goal of the policy and practice is to reduce administrative burden for researchers, IRB members, and staff. For information about review of research involving greater than minimal risk, refer to SOP 303 Initial Full Review.

REVISIONS FROM PREVIOUS VERSION

Extensive revisions to policy for reviewing non-federally funded minimal risk research.

POLICY

This policy applies to UNM researchers and partner institutions under the oversight of the UNM IRB. The scope of UNM's FWA is limited to federally funded research only. This does not create a two tiered application of ethical principles or protections; rather, it allows for an appropriate level of flexibility without compromising protections. This policy only applies to non-federally funded research considered by the UNM IRB to be of no greater than minimal risk as defined by 45 CFR 46.102(i). A designated member of the IRB may review research covered by this policy on behalf of the fully convened IRB.

Reviewers only approve research that meets the federal criteria for approval as specified in 45 CFR 46.111. Reviewers also ensure that the informed consent process and documentation meets the requirements as specified in 45 CFR 46.116 and 45 CFR 46.117 unless the IRB waives the requirements (see Informed Consent SOP).

Reviewers exercise all of the authority of the IRB except that the reviewers may not disapprove the research. The IRB only disapproves a research activity after discussion and vote by a fully convened IRB.

1. UNM IRB applies commensurate protections for research projects that fall out of the scope of the FWA. The criteria for approval articulated in the regulations at 45 CFR 46.111 must be met to receive IRB approval.
2. The UNM IRB, with guidance from the OIRB, determines eligibility of research projects reviewed under this policy.
3. This policy does not apply to projects that receive federal support from agencies such as NIH, NSF, CDC, FDA, or USDA, as those projects are subject to the UNM's FWA. Projects that anticipate receiving federal funds (grant proposal is pending or planned) must be reviewed using the relevant regulations.
4. This policy does not apply to projects that obtain a NIH-issued Certificate of Confidentiality.

5. This policy does not apply to research involving data in repositories intended to be used to support applications to DHHS or FDA.

RESPONSIBILITIES

Execution of SOP: OIRB Staff, IRB, Researchers

PROCEDURES

Submission and Screening

1. The PI submits a completed submission package to the OIRB through IRBNet. Instructions for preparing the application are available on the OIRB website. The researcher may contact 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 that the project is minimal risk and is neither federally funded nor will be submitted for federal funding. If the project does not meet the criteria for review under this policy, OIRB staff schedule the project for exempt, expedited or full board review, according to applicable SOPs.
3. If applicable, OIRB staff note during the pre-review process that the protocol involves areas of research requiring protocol specific findings. OIRB staff provide the appropriate Reviewer Checklists to alert the reviewer(s) of the areas requiring determinations.
4. OIRB staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and/or Family Educational Rights and Privacy Act (FERPA) concerns. If the PI includes a HIPAA form or otherwise indicates that Protected Health Information (PHI) is being collected or if there are any HIPAA or FERPA concerns, OIRB staff may consult with the OIRB Director to ensure all legal requirements are addressed.
5. After completing pre-review, OIRB staff assign the project to a reviewer(s).

Assigning Reviewers

1. OIRB staff make reviewer assignments based on meeting attendance, familiarity with IRB issues and expertise. OIRB staff keep the approved list of reviewers on file.
2. The reviewer notifies OIRB staff if they are not available to conduct a review during the assigned time 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 Review Process

1. IRB reviewers are provided all documents submitted by the researcher.
2. The reviewer documents specific findings (e.g. Subpart C, D, or waiver of informed consent or documentation), if applicable, by completing the Reviewer Checklists.
3. Reviewers review all submission documents in enough depth to determine whether the research is minimal risk, and to determine whether the research meets the regulatory criteria for approval.
4. Research involving prisoner data, but not involving interaction with prisoners (e.g. existing data, record review) may be reviewed under this policy if a determination is made that the research involves no greater than minimal risk for the prison population being studied. The IRB prisoner representative may be consulted as appropriate.

Categories of Minimal Risk Research

1. Research involving educational tests or conducted in established or commonly accepted educational settings that specifically involves normal educational 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 and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that includes survey procedures, interview procedures, focus groups or observation of public behavior; may include visual and/or auditory recording.
3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) that involves brief, harmless behavioral interventions (e.g. solving puzzles, environment manipulation, completing an online task, etc.).
4. Prospective collection of biological specimens for research purposes by noninvasive means or blood samples by finger stick, heel stick, ear stick, or venipuncture.
5. Collection of data through noninvasive procedures (not involving x-ray, anesthesia or sedation) routinely employed in clinical practice or that use FDA approved medical devices (e.g. MRI, MEG, EEG, ECG, VO_2max testing, body composition).
6. Secondary research uses of identifiable private information or identifiable biospecimens for which informed consent is not required.
7. Storage or maintenance (repository) of identifiable private information or identifiable biospecimens for potential secondary research use.

Vulnerable Populations

Children: Requirements for assent and parental permission are consistent with the standards at 45 CFR 46 Subpart D.

Prisoners: Research projects involving prisoners are subject to the same requirements for review as those at 45 CFR 46 Subpart C, with the exception of the requirement for review by the Secretary cited at 45 CFR 46.306. Non-federally funded research is not required to get approval from the Secretary at HHS. Individuals incarcerated during participation in research may continue participation in non-federally funded projects without an IRB re-review by the prisoner representative. The UNM IRB will not consider persons in transitional custody whose liberty is restricted such as halfway houses, electronic monitoring, probation, or house arrest, to meet the federal definition of prisoner. For those individuals, the criteria at 45 CFR 46.111 offer sufficient protection for their level of vulnerability.

Pregnant Women, Human Fetuses and Neonates: Non-federally funded minimal risk research projects that include but do not target pregnant women are not subject to the requirements at 45 CFR 46 Subpart B. For those individuals, the criteria at 45 CFR 46.111 offer sufficient protection for their level of vulnerability.

Review Outcomes

1. Reviewers make the final determination as to whether research activities meet criteria for review under this policy.

2. The reviewers can recommend that the activities do not fall under IRB purview. In these cases the IRB handles the review using procedures outlined in the Determination of Activities That Need IRB Review SOP.
3. The reviewers determine whether the research meets the federal criteria for approval as outlined in 45 CFR 46.111.
4. Reviewers ensure that the researcher will conduct the informed consent process and obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117, unless the IRB waives the requirements. (See Informed Consent SOP.)
5. The reviewers only raise those controverted issues or request changes that they have determined do not meet the criteria for approval or OIRB policies.
6. The reviewers document on the Reviewer Checklist their determinations regarding risk level and whether the research meets the criteria for approval.
7. The reviewer makes one of the following three determinations:
   - APPROVED: IRB approval indicates that the reviewer(s) has concluded that the research and informed consent process meet the criteria for approval. An IRB approval verifies that the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application. OIRB staff send the researcher an approval letter.
   - MODIFICATIONS and/or ADDITIONAL INFORMATION REQUIRED: The reviewer(s) withholds approval pending submission of revisions/additional information. OIRB staff send the researcher a letter describing the modifications requested by the reviewer(s). The PI responds to modifications requested by the IRB in writing and sends the response to the OIRB. If the reviewer was unable to determine that all approval criteria were met, OIRB staff forward the responses to the reviewer for further review. If the modifications were minor, modifications are verified by staff administratively.
   - FULL REVIEW REQUIRED: The reviewer(s) may determine that the project requires full review by the IRB at a convened meeting.
8. The OIRB procedures for notifying the PI of the review outcome, obtaining follow up correspondence, and issuing approval letters are outlined in the Initial Full Review SOP.

Continuing Review

The IRB reviewer(s) assigns the approval period at intervals appropriate to the degree of risk. In most cases, minimal risk research will not be subject to continuing review by the IRB. However, at its discretion, the IRB may require continuing review of projects that meet certain criteria, including, but not limited to: inclusion of vulnerable populations, research on criminal behavior, use of substance use or mental health data, or research conducted at external sites (e.g. secondary schools).

If continuing review is required, it will be conducted according to SOP 305 Continuing Review. The date the reviewer completes the review in IRBNet for final approval on the project is the date the approval period starts. If OIRB staff verify the modifications, the approval period starts from the date the IRB reviewer completed their review. If applicable, OIRB staff document the approval period dates in the approval letter to the PI.

Amendments to Approved Protocols

Researchers may not initiate any changes in research procedures, consent/assent form(s), or other research related documents without prior IRB review and approval, except where necessary to eliminate

apparent immediate hazards to the participant. *The addition or removal of project team members (excluding PI) does not* require submission to the IRB. Examples of amendments that do require IRB review include, but are not limited to, changes in:

- Advertising materials (flyers, radio spots, etc.);
- Research procedures;
- Participant populations (e.g. addition of vulnerable population or change in inclusion/exclusion criteria);
- Location where research will be conducted;
- Consent/assent forms;
- Recruitment procedures.

Amendments are reviewed according to SOP 306 with the exception of minor amendments. When an amendment is a minor in nature, OIRB staff review and acknowledge it administratively. Minor changes include, but are not limited to:

- Changes to contact information or formatting in approved documents;
- New or revised recruitment advertisements or scripts if similar to already approved recruitment materials;
- Changes to surveys or interview questions if no increase in risk;
- Changes to improve the clarity of statements or to correct typographical errors provided the requested change does not alter the content or intent of the statement;
- Submission of project or consent documents translated into a foreign language and the required translation certificate(s).

Post Approval Monitoring

Projects reviewed under this policy will be subject to post-approval monitoring (PAM) by the UNM Human Research Protections Program to ensure that conduct of projects are in accordance with the IRB approved protocol and to confirm that funding status has not changed (see SOP 409 Post Approval Monitoring Program).