Standard Operating Procedures

SOP #205.0  
Revision 0  
TITLE: Review Standards for Research Not Covered by Federalwide Assurance  
Effective Date: 5/1/2016

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PURPOSE
This policy describes how the UNM IRB reviews and documents determinations for research not covered by the Federalwide Assurance (FWA) 00004690. To ensure the highest standards for protection of research participants allowing for the greatest amount of flexibility for research involving no greater than minimal risk. A goal of the policy and practice is to reduce administrative burden for researchers, IRB members, and staff.

REVISIONS FROM PREVIOUS VERSION
None

POLICY
UNM has chosen to limit the scope of its FWA 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 applies to research considered by the UNM IRB to be of no greater than minimal risk.

1. 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, where a grant proposal is pending or planned, are not subject to this policy but are reviewed using the appropriate “Federally Funded Research” policy or agency specific policy.
2. Eligibility of research projects under this policy is determined by the UNM IRB.
3. 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.
4. This policy applies to all research projects that are not externally funded or instances where the sponsor does not require adherence to federal regulations.
5. This policy does not apply to projects involving an NIH-issued Certificate of Confidentiality.
6. This policy does not apply to research involving data in repositories intended to be used to support applications to the FDA.

RESPONSIBILITIES
Execution of SOP: OIRB Staff, IRB, Researchers
PROCEDURES
This policy applies to UNM researchers and partner institutions under the oversight of the UNM IRB. The following are only examples and do not constitute the entirety of the scope of the policy in each subsection.

1. Reporting Requirements:
   a. Research projects that fall out of the scope of the FWA are not subject to the same reporting requirements as federally funded projects for reporting of serious or continuing non-compliance, suspensions or terminations, or reporting of unanticipated problems involving risk to subjects or others.
   b. The IRB does not report those matters to the federal agencies but follows internal reporting requirements as directed by institutional policy.

2. Children:
   a. Research projects involving children are subject to the regulations and tiered review standards at 45 CFR 46 Subpart D.
   b. Requirements for assent and parental permission are consistent with the federally funded research standards, though the IRB may, at its discretion, determine that consent from one parent is sufficient.
   c. Research that would otherwise be subject to the requirements at 45 CFR 46.407 may be handled locally, not through the Secretary of HHS.

3. Prisoners:
   a. 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. Unfunded or non-federally funded research is not required to get approval from the secretary at HHS.
   b. Individuals incarcerated during participation in research may continue participation in non-federally funded projects without an IRB re-review by the prisoner representative.
   c. The UNM IRB will not consider persons in transitional custody whose liberty is restricted such as half-way 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.

4. Pregnant Women, Human Fetuses and Neonates:
   a. 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.
   b. Research projects involving Pregnant Women, Human Fetuses and Neonates that are more than minimal risk are subject to the requirements at 45 CFR 46 Subpart B with the exception of the requirement at 45 CFR 46.204(d) which requires the research develop “important biomedical knowledge”, which precludes most social and behavioral sciences research with pregnant women.
   c. Research projects that are unfunded or funded by sources other than federal agencies, that involve greater than minimal risk, involve physical intervention, and include pregnant women, human fetuses, or neonates will be subject to the requirements of Subpart B irrespective of the funding source.
5. Expansion of Exempt Review Categories:
   a. Participant protections and ethical standards expected of unfunded exempt research will apply to new exempt category 7 which includes research involving no more than minimal risk that does not conform to a specific exempt category under 45 CFR 46. Examples include:
      i. Collection of data from voice, video, digital, or image recordings made for research purposes;
      ii. Online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk;
      iii. Behavioral games;
      iv. Studies requiring performance of a task that incur no risk;
      v. Studies involving focus groups, oral histories, ethnographies or program evaluation.

6. Extended Approval Period:
   a. Unfunded studies conducted by UNM faculty, involving no more than minimal risk may qualify for continuing review no less than once every two years.

7. Monitoring:
   a. Studies reviewed under this policy will be audited randomly to ensure that studies are being conducted in accordance with the IRB approved protocol and to confirm that funding status has not changed.