OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #109.4 Revision 4	**TITLE: Staff Processing of Submissions**	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature	Date 3/1/2019
Approved By: IRB Chair	Signature	Date 3/1/2019

PURPOSE

To describe policies and procedures for how Office of the Institutional Review Board (OIRB) staff conduct intake and pre-review of new submissions to the UNM IRB.

REVISIONS FROM PREVIOUS VERSION

Updates related to procedures for flex review, update name of Expiration of IRB Approval SOP, and other administrative changes

POLICY

In the environment of research, openness and honesty are indicators of integrity and responsibility. The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed project, but that the documentation they receive is complete and clear enough to allow for an adequate assessment of research design, procedures, and conditions.

RESPONSIBILITIES

Execution of SOP: OIRB Staff

PROCEDURE

1. OIRB Staff assess daily new submissions through IRBNet. The submission will first go through an intake process where OIRB Staff assess the submission for basic elements (e.g. submission application, expiration date, accuracy of information in IRBNet, status of PI compliance, etc.). Should IRB approval be expired for a project, OIRB staff will follow procedures described in the Expiration of IRB Approval SOP.
2. After intake is complete, submissions are assigned to the analysts who conduct a pre-review before assigning submissions to a reviewer.
3. Submissions are processed by analysts on a first-come first-served basis. Submissions may be processed more quickly at the discretion of OIRB Staff (e.g. administrative reviews, projects approaching expiration, short funding time lines, etc.)
4. Pre-review consists of assessing the completeness of each submission, checking for all required documents and signatures, reviewing documents for consistency, as well as determining if sufficient information has been provided for IRB review of criteria at 45 CFR 46.111 and/or 21 CFR 56.111.
5. OIRB staff pre-review the IRB submission to determine the policies/regulations applicable to the submission and ensure coordination with other university committee reviews as outlined in the applicable standard operating procedures. Examples of screening include, but are not limited to, the items listed below:
    - Projects are assessed to ensure the appropriate type of review is conducted (equivalent protections, Common Rule, FDA).

- If the research involves special populations, the project is appropriately flagged and OIRB staff send the protocol to an appropriate member for review and/or a member with the appropriate expertise will be present at the convened meeting, if undergoing full committee review.
- OIRB staff determine whether the research is supported by other federal agencies which have specific requirements (e.g. U.S. Department of Defense, U.S. Department of Energy, etc.). If so, OIRB staff inform the IRB in the pre-review comments.
- If review by other university committees (e.g. Institutional Biosafety Committee) is necessary, OIRB staff check to ensure that the PI has submitted the materials and committee determinations.

6. In the instance that OIRB staff have questions about a submission, a "clarifications requested" message will be sent to the researcher(s) through IRBNet and the IRBNet package will be unlocked to allow for changes. When the researcher(s) provide clarifications, they will "mark revisions complete" which will relock the package and allow for continued processing of the submission.
7. If a submission requires clarifications, OIRB staff will not schedule the submission for review until clarifications are addressed. If no response is received within 30 days, OIRB staff with withdraw the submission without IRB review.
8. Once the pre-review process has been completed, OIRB staff will assign the submission for review. For new projects, the analyst makes a preliminary risk assessment and assigns the project for either minimal risk or full board review (the reviewer(s) will make the final risk determination). For Amendments and Continuing Reviews, the submission will be assigned for review based on the previously determined risk assessment, review type, and current status of the project. If appropriate, the submission will be sent for administrative review (e.g. administrative changes or closures). If research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review except in limited circumstances as described in expedited categories (8) and (9).
9. When the reviewer has completed the review, OIRB staff will assess the reviewer documents for completeness and consistency. Should the analyst have questions, the reviewer will be contacted. Once the review is verified as complete, the analyst will send a letter to researchers with the IRB determinations.