Staff Processing of Submissions

I. Purpose

To describe how Human Research Compliance staff process and pre-review submissions to the WCM IRB.

II. Revisions from Previous Version

None.

III. Definitions

None.

IV. 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.

V. Procedure

1. The IRB Staff assess daily new submissions through WRG-HS. The submission will first go through an assignment process where IRB staff assess the submission for basic elements (e.g., submission application, expiration date, accuracy of information, consistency, status of PI compliance, risk level, etc.).
2. Submissions are assigned to the analysts who conduct a pre-review before assigning submissions to a reviewer(s).
3. Submissions are processed by analysts on a first-come first-served basis. Submissions may be processed more quickly at the discretion of IRB staff (e.g., administrative reviews, projects approaching expiration, short funding timelines, etc.).
4. Pre-review consists of assessing the completeness of each submission, checking for all required documents and approvals, 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. The IRB staff pre-review the IRB submission to determine the policies/regulations applicable to the submission and ensure coordination with auxiliary reviews. Examples of pre-review considerations include, but are not limited to, the items listed below:
   - Studies are assessed to ensure the appropriate type of review is conducted (Common Rule, FDA, other applicable regulations).
   - IRB 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, IRB staff inform the IRB in the pre-review comments.
   - If the research involves special populations, the project is appropriately flagged and IRB 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.
   - If auxiliary review(s) (e.g., Institutional Biosafety Committee, COI Committee, Radiation Safety Committee, etc.) is necessary, IRB staff check to ensure that the PI has submitted the materials and committee determinations.
   - Completeness and consistency of documents are assessed (e.g., risks are consistent between the protocol and consent form).
   - IRB staff will check that the consent and assent documents contain the required and applicable elements of consent.
• Staff will note when protocol specific justifications are needed.

6. In the instance that the IRB staff have questions about a submission, a “pre-review modifications required” message will be sent to the researcher(s) through WRG-HS and the submission will allow for changes. The researcher(s) should respond to provide clarifications and necessary revisions for continued processing of the submission.

7. If a submission requires clarifications, IRB staff will not schedule the submission for review until clarifications are addressed. If no response is received within 90 calendar days, IRB staff will withdraw the submission without IRB review.

8. Once the pre-review process has been completed, the IRB staff will assign the submission for review. For new projects, staff make a preliminary risk assessment and assigns the project for either exempt, expedited, 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).

9. When the reviewer has completed the review, IRB 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 requests for additional revisions and/or the IRB determinations, as applicable.

VI. References

45 CFR 46.111
21 CFR 56.111
45 CFR 46.116 and 117
21 CFR 50.25 and 27