Ascension Wisconsin IRB Guidance

Ancillary Reviews for Human Subject Research

Ancillary Review of human research proposals allow Ascension Wisconsin departments the ability to document their review and oversight required to assure compliance with institutional or regulatory requirements. Ancillary Reviews are completed by individuals or committees that have oversight for specific areas of a submission, such as scientific merit, conflict of interest or safety issues. These reviewers do not issue approval for the study a whole; only for their areas of oversight.

Ancillary Reviews are often triggered and facilitated by Research Integrity and Protection (RI&P), and are many are performed in parallel with the IRB review. Not all studies require ancillary reviews. The IRB application will direct researchers to required ancillary reviews, depending on the research study. In some cases, the appropriate documentation must be submitted to RI&P with the IRB submission before IRB review can begin. RI&P staff will inform the PI during their review if/when Ancillary Review is required. Ancillary Review may be initiated at the time of an initial or continuing review, or modification request.

In most cases, if Ancillary Review is required, the IRB cannot issue final approval until all ancillary reviews are complete. A conditional approval letter may be issued by the IRB, when a specific type of required ancillary review is pending prior to the final approval of the research; however, a final approval letter cannot be issued until all applicable required ancillary reviews are complete.

The chart below identifies the required ancillary reviews that must occur before a research may begin.

Ancillary Review	Purpose	How to Obtain	When to Obtain
Department/Leader Administrative support	Certifies that the Researcher has applicable credentialing, appropriate training and adequate resources, time and staff to perform procedures outlined in this protocol.	Documented on the Signature page of the IRB application form. It is Investigator's responsibility to identify the appropriate person to provide this approval	Prior to submission to the IRB
Clinical Trials Office	Determines feasibility of study and availability of resources, specific to Clinical Trails staff and equipment, logistics of proposal, subjects, Investigators, investigation pharmacy, etc.	Contact the Clinical Trials Office: Jane Neu, 262-687-8757	Prior to submission to the IRB
Research Grants, Contract and Finance Administration	Determines feasibility of study and availability of resources, specific to budget, research billing, and contract/agreement.	Contact Research Grants, Contract and Finance Administration: Diana Lenhardt, 414-585-4865	Prior to submission to the IRB
Scientific or scholarly review	Required for all Investigator authored research conducted at Ascension Wisconsin. Evaluates the scientific or scholarly validity of the proposed research and confirm that research aligns with strategic goals, and employ sound research design.	Submit proposal to RI&P; RI&P staff can facilitate the review	Prior to or concurrent with IRB pre-review
Conflict of Interest (COI)	Federal regulations and institutional policy require the IRB to consider financial and non-financial conflicts of interest to ensure compliance, integrity of the research, and protection of subjects.	Researchers must complete training and disclosures of potential conflicts through the institutional system disclosures prior to IRB submission.	Concurrent with the IRB review
Radiation Safety Review	Radiation Safety review evaluates research when where subjects are exposed to ionizing radiation specifically for the research study. Additionally, Wisconsin Department of Health Services review is required before involving human subjects.	Submit proposal to RI&P, being sure to complete the section in the IRB application; RI&P staff can facilitate the review	Concurrent with the IRB review; WI review must occur after IRB approval, but before enrolling
Institutional Biosafety Committee (IBC)	The IBC is responsible for assessing the biosafety containment level for research involving recombinant DNA and synthetic nucleic acid molecules, as mandated by NIH Guidelines.	Submit proposal to RI&P, being sure to complete the section in the IRB application; RI&P staff can facilitate the review	Concurrent and after initial IRB approval- final IRB approval is issued after IBC approval
Marketing and Communications	In some cases, a research submission may require review to ensure institutional guidelines for marketing/ communications are met. For example, recruitment material that is part of a news story or video recording in a hospital as part of research.	Submit proposal to RI&P; RI&P staff can facilitate the review	Concurrent with the IRB review