SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	Ancillary Review Requirements	Effective: 10/23/2017
		Approved: 5/10/2017
SOP ID		Last Revised: 12/6/2017
IRB-SOP-304		Expiration: n/a

PURPOSE

The purpose of this document is to define the requirements and procedures for obtaining approval of various institutional committees, departments, groups or individuals and how the review relates to IRB review. Theses ancillary reviews provide the IRB and institution with information related to research feasibility, risk, regulatory requirements and to assure compliance with institutional or regulatory requirements.

SCOPE

This policy applies to all non-exempt human research studies conducted at Ascension Wisconsin or by Ascension Wisconsin staff.

DEFINITIONS

Human Subject Research is research that involves human subjects:

- Research is defined in 45 CFR 46.102(d) as a systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge. 21 CFR 50.3(c) defines research as an experiment that involves a test article and one or more human subjects.
- Human Subject is defined in 45 CFR 46.102(f) as an individual about whom an investigator conducting research obtains data through intervention or interaction with individual or identifiable private information. 21 CFR 50.3(g) defines human subject as an individual who is or becomes a participant in research, either as a recipient of a test article or as a control.

Investigator-Authored Research that is written by the investigator, not an external sponsor; may be funded or un-funded.

Non-Exempt Human subject research that does not qualify for exempt review as outlined in federal regulation or the IRB flex policy.

PROCESS

1. Ancillary reviews may be required based on the type of research and level of risk. Some proposals may require multiple ancillary reviews. The timing of the completion of reviews varies, depending on the requirement and results of review.

1.1. The PI is responsible for determining which ancillary committee approvals must be obtained to conduct the research activities and for ensuring any ancillary committee approvals required prior to IRB approval have been obtained. Investigators will indicate in the IRB application whether the research requires review by any of the institutional review committees, and, if applicable, will indicate which ancillary committee review(s) are necessary.

1.2. RI&P staff will review the ancillary reviews selected by the Investigator and will either concur with the selections or require changes based upon the research and the research procedures.

1.2.1. For reviews that are required to be completed prior to submission to the IRB, if the RI&P staff review the submission and determine that these reviews were required but not completed, the submission will be forwarded to the appropriate department, the PI notified and the IRB submission withdrawn.

1.2.2. For ancillary committee approvals that may occur concurrently with IRB review, RI&P staff will facilitate the review and document the determination.

1.2.3. For Ancillary committee reviews that may occur after IRB approval has been granted, the PI must ensure that all applicable ancillary committee approvals are in place prior to starting any research activities.

1.3. Ancillary reviewers may request modifications of the research; however, any such modification must also be approved by the IRB.

1.4. Ancillary review may be required for modifications to the protocol if the changes affect the review.

1.5. 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.

2. Institutional Ancillary Requirements

2.1. Department/Leader Administrative Support

2.1.1. Department/Leader Administrative support is required to ensure that department/ area leadership is aware of the conduct of the research and certifies that researchers has applicable credentialing, appropriate training and adequate department/area resources, such as time and staff, to perform procedures outlined in the protocol.

2.1.2. The Principal Investigator (PI) is responsible for obtaining support for the appropriate department or area leader prior to submission to the IRB and for providing documentation of the support to the IRB.

2.2. Research Grants, Contract and Finance Administration

2.2.1. Research Grants, Contract and Finance Administration reviews proposals, per their department policies and procedures, in to ensure that the proposed research meets institutional and regulatory requirements and aligns with the Ascension Research Institute strategic goals with specific focus on budgets, billing, contracts, awards or other agreements.

2.2.2. Any research that includes funding, billing for research procedures, or a contract, award or other agreement must receive a favorable feasibility assessment prior to being submitted to the IRB.

2.3. Clinical Research Office

2.3.1. The Clinical Research Office reviews proposals, per their department policies and procedures, to ensure that the proposed research meets institutional and regulatory requirements and aligns with the Ascension Research Institute strategic goals, with specific focus on study feasibility and the conduct of clinical trials, including investigational drug and device management.

2.3.2. Any research that is considered a clinical trial, involves any treatment or care, or receives any support from the Clinical Research Office must receive a favorable feasibility assessment prior to being submitted to the IRB.

3. Regulatory Ancillary Reviews

3.1. Conflict of Interest

3.1.1. It is the responsibility of an investigator to make required financial and non-financial disclosures of potential conflicts related to research per the RI&P Conflicts of Interest in Research policy and procedure and on the IRB application forms.

3.2. Institutional Biosafety Committee (IBC)

3.2.1. The IBC must review and approve human studies involving recombinant DNA, RNA inhibition (RNAi), microbiological agents (bacteria/viruses), gene transfer or animal to human transplantation. Ascension Wisconsin utilizes the WIRB IBC.

3.2.2. This review is coordinated through the Clinical Research Office

3.2.3. The IRB may grant conditional approval, but the IBC approval must be submitted to the IRB before the final IRB approval is released.

3.3. Radiation Safety Review

3.3.1. All research studies that involve the use of ionizing radiation as a research procedure require the radiation safety review and approval. Radiology procedures that involve ionizing radiation and are part of participants' routine care do not require review and approval by the committee.

3.3.2. Institutional radiation safety review must be completed for human research that meets the following criteria:

- Research activities involving exposure to ionizing radiation for research purposes (e.g., x-rays, fluoroscopy, CT); or
- Research to determine the safety and/or effectiveness of a radioactive drug.

3.3.3. RI&P staff will contact the Radiation Safety Official in the hospital or region where the main research site is located to initiate radiation safety review. RI&P staff will prepare summary and forward relevant documents such as the IRB application, protocol and consent form.

3.3.4. The Radiation Safety Official or his/her designee provides the IRB with radiation safety expertise, assesses the adequacy of the information in the informed consent form pertaining to radiation risks, and advises the IRB regarding whether radiation safety committee review is needed. If Radiation Safety committee review is recommended, the Radiation Safety Official will coordinate review per their department policies and procedures.

3.3.5. The Radiation Safety Official will report back to the RI&P staff approval decisions or any required or suggested modification that are required to obtain approval. RI&P staff works with the PI or research staff to address any concerns.

3.3.6. RI&P staff communicates the review findings the IRB and/or designated IRB reviewer.

3.3.7. IRB review and the Ascension Wisconsin Radiation Safety review may occur simultaneously; however, Radiation Safety, approval is required before final IRB approval will be granted.

3.3.8. Proposals that expose subjects to radiation outside of the normal standard of care must also be reviewed by the State of Wisconsin.

3.3.8.1. This review is coordinated through the Clinical Research Office.

3.3.8.2. The IRB may grant conditional approval, but the State approval must be submitted to the IRB before the final IRB approval is released.

REFERNCES

- WI DHS (Wis. Admin. Code D.H.S. §§ 157.03(155), 157.74(2)(f) (2014)

RELATED MATERIAL

- Ascension Wisconsin Policy: Financial Conflicts of Interest in Research

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon
02	12/6/2017	Change SOP number from 204 to 304	J. Blundon