SOP		
Department	**Title**	**Dates**
Research Integrity and Protections	IRB Reliance	Effective: 10/23/17
		Approved: 4/25/2017
SOP ID		Last Revised: 6/26/2019
IRB-SOP-810		Expiration: n/a

PURPOSE

In order to promote and accelerate collaborative research efforts among investigators at different institutions, Ascension Wisconsin will agree, under certain circumstances, to accept IRB oversight for another institution or defer oversight to another IRB.

This procedure describes the process for requesting for a single IRB review and execution of Authorization Agreements with other institutions.

SCOPE

These procedures apply to all non-exempt human subject research conducted at any Ascension Wisconsin facility or by Ascension Wisconsin staff or affiliates.

DEFINITIONS

Engagement in Research applies when an institution's employees or agents are interacting or intervening with human subjects or their private identifiable information for the purpose of conducting non-exempt human subject research. Ascension Wisconsin follows OHRP guidance on "Engagement of Institutions in Research" to apply this definition.

Federalwide Assurance (FWA) A formal binding agreement in which a research institution commits to DHHS that it will comply with the Federal Policy.

Investigator. For the purposes of this document, an investigator or collaborator is an individual whose involvement in the research meets the definition of engagement. Investigators include:

- Overall PI: The lead multi-site principal investigator with ultimate responsibility for the conduct and integrity of Research (generally, the initiating principal investigator or funding principal investigator, as applicable).
- Local PI: The investigator responsible for the oversight of the research at Ascension Wisconsin.
- External Investigator: Non-Ascension Wisconsin staff or affiliate whose institution has an IRB.
- Independent Investigator: Non-Ascension Wisconsin staff or affiliate whose institution does not have an IRB.

IRB Reliance Agreement This term may refer to any agreement about IRB review with other institutions or individuals, including the following:

- IRB Authorization Agreement (IAA): This is a formal agreement between two or more *institutions* that each have a FWA. The agreement specifies that one institution agrees to rely upon the IRB used by the other institution for some or all components of a study, and defines the responsibilities for the IRB and for each institution.
- Cooperative Agreements: Refers to formal written agreements between the UW and another institution that identify the IRB of record for classes or categories of research such that a study-specific authorization agreement between the institutions is not required.

- Master Reliance Agreement: This is a formal agreement between multiple IRBs to establish expectations and common requirements that will be followed for IRB reliance between those institutions.
- Individual Investigator Agreement: This is a formal binding agreement signed by individuals who are collaborating on research conducted by an institution, but who they are not acting as employees or agents of an institution. Individual Investigator Agreements can also be used by an institution that does not have a FWA and does not regularly conduct human subject's research. The agreement describes the expectations and responsibilities for the individual or institution.

Rely also known as "defer or cede". An institution agrees to transfer oversight of a study under its jurisdiction to another IRB. MCW requires a signed Agreement to be in place prior to final I RB approval of the project.

Relying Institution An Institution that cedes IRB review to a Reviewing IRB for an instance of Research under the Agreement.

Reviewing IRB The "IRB of record" that assumes IRB responsibilities, through an IRB Authorization Agreement, for a specific study or group of studies conducted by another institution.

PROCEDURES

Ascension Wisconsin will consider IRB reliance on another IRB or serve as the IRB of Record in various circumstances.

1. **Studies Eligible for Single IRB Review**
   - **1.1.** Study Requires Single IRB Review per the 2016 NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (effective date 1/25/2018), AW investigators and the RI&P will ensure Single IRB Review occurs for non-exempt human subject research studies funded by the National Institutes of Health (NIH) when those studies are carried out at more than one site in the United States.
   - **1.2.** Study requires single IRB review for non-exempt human subject research and exempt human subject research that requires a limited IRB review when the research is funded by one or more of the federal agencies that have codified the Federal Policy for the Protection of Human Subjects (i.e., Common Rule) (effective date 1/20/2020).
   - **1.3.** Other studies eligible for Reliance on an External IRB include the following:
     - Federally funded
     - No greater than minimal risk
     - Involves an Institutional Conflict of Interest
     - A phase III or IV drug study, or a device study where there is evidence of safety (i.e. not a pilot study) and Ascension Wisconsin is not the lead or coordinating site
   - **1.4.** Other studies eligible when Ascension Wisconsin may agree to serve as the Reviewing IRB include the following:
     - Research involves no more than minimal risk
     - A majority of the research activities will occur in an Ascension Wisconsin Hospital or Clinic, or with Ascension Wisconsin patients or identifiable data
     - The study is under direction of a local investigator
     - The other institution is partially owned by Ascension Wisconsin and they have a policy adopting the Ascension Wisconsin IRB policies and procedures and Standard Operating Procedures for Conducting Research. This process requires a formal written agreement signed by the Ascension Wisconsin IO and the partner institution

- A study initiated at Ascension Wisconsin that requires research-related procedures to be done at a site that does not have an FWA. In this case an Individual Investigator Agreement (IIA) must be in place.

1.5. The Director of Research Integrity and Protection and Institutional Official may agree to IRB reliance in other limited circumstances on a study-by-study basis.

2. Determination of IRB Reliance

2.1. The Local PI should contact Ascension Wisconsin Research Integrity and Protection if they are interested in requesting a reliance agreement. This should be done early in the process, before submission to any IRB. PIs should also note that any IRB may choose to not participate in IRB Reliance Agreements.

2.2. Research Integrity and Protection staff works with the IRB/Institution to confirm the institution's willingness to establish an IAA, negotiate the agreement, complete the execution of the agreement and ensure that a signed copy of the agreement is on file at each institution.

2.3. The Director of Research Integrity and Protection may make the decision whether to review for or rely on another IRB. The Institutional Official (IO) will be consulted as needed; the IO is vested with the signatory authority to enter into reliance agreements.

3. Request for the Ascension Wisconsin IRB to Rely on an External IRB

3.1. To request IRB reliance, the IRB Reliance Request Form should be submitted to Research Integrity and Protection for review, along with any documents or supporting materials requested on the form, such as the protocol and consent form. Similar forms from other institutions will also be accepted.

- If the study includes an informed consent or HIPAA authorization, the proposed documents must be provided for review. Research Integrity and Protection staff will work with the reviewing IRB to assure that the documents used at this site include language reflecting local standards and requirements.

3.2. Research Integrity and Protection staff will:

- Work with the Local Investigator and/or the reviewing IRB staff to gather any additional information needed.
- Review the proposal and considerations as described above , and will identify if the project falls under any established agreement or if a new IAA is required.
- Facilitate and document IO, OGC or other institutionally required reviews.

3.3. The local investigator will be notified as soon as possible regarding a reliance decision.

3.4. The local investigator must provide the Ascension Wisconsin the IRB approval letter for involvement of this site, once received from the reviewing IRB.

4. Request for the Ascension Wisconsin IRB to Provide Oversight for an External IRB/Institution

4.1. Ascension Wisconsin may choose to accept oversight for another IRB or institution on a study-by-study basis.

4.2. To request IRB reliance, the IRB Reliance Request Form should be submitted to Research Integrity and Protection for review, along with any supporting materials or documents requested on the form, such as the protocol and consent form. Similar forms from other institutions will also be accepted.

4.3. Research Integrity and Protection staff will:

- Work with the Local Investigator and/or the reviewing IRB staff to gather any additional information needed.
- Review the proposal and considerations as described above , and will identify if the project falls under any established agreement or if a new IAA is required.
- Facilitate and document IO, OGC or other institutionally required reviews.

4.4. The local investigator will be notified as soon as possible regarding a reliance decision.

4.5. When the Ascension Wisconsin IRB agrees to serve as the Reviewing IRB for another institution/IRB, the standard IRB submission process applies, with the following additional requirements:

- The Local Investigator must also provide adequate information regarding the conduct of the study at each location. This includes research activities, investigator qualifications, and information about relevant state law , cultural or other local context issues. This information may be documented in the IRB Reliance Request form, protocol or other supporting documents.
- The Ascension Wisconsin IRB consent form template, located in Mentor, should be used to develop a consent form for all sites. The local investigator should work with the collaborating investigators to develop a consent form that meets local standards and requirements. The local investigator must provide the consent form for each site for review. The IRB will approve the consent form that must be used at the non-Ascension Wisconsin site(s).

5. Investigator Responsibilities

5.1. All Local Investigators must comply with the Investigator responsibilities outlined in the IRB Policies and Procedures and all Institutional requirements, in addition to specific responsibilities for studies that are conducted under and IRB reliance agreement.

5.2. For studies where Ascension Wisconsin relies on an External Reviewing IRB, the local investigator has the following additional responsibilities:

- Obtain approval from the Reviewing IRB before starting any research activities.
- Ensure that all institutional policies and requirements are met before initiating human subject research activities at that site, including safety committee reviews, study budget and contract or other agreements are in place.
- Follow the SOPs of the Reviewing IRB and adhere to the Reviewing IRB determinations.
- Ensure that all study staff engaged in research at Ascension Wisconsin complete and maintain human subjects research training, per Ascension Wisconsin requirements.
- Notify the Ascension Wisconsin IRB through Mentor of the following:
  - The initial IRB approval from the other IRB
  - Study staff and PI updates
  - Updates to Ascension Wisconsin locations involved
  - Unanticipated Problems and Noncompliance at the Ascension site(s)
  - Study closure, once closed with the IRB of Record

5.3. For studies where Ascension Wisconsin IRB provides oversight for an external IRB/Institution, the local investigator has the following additional responsibilities:

- Obtain approval from the Ascension Wisconsin IRB before research activities begin at any site and make sure that investigators at the relying site receive a copy of the IRB approval letter, approved protocol, consent form, and any other applicable documents.
- Identify study staff from the relying site in Mentor.
- Notify investigators at relying sites of all Ascension Wisconsin IRB determinations and communications, including those for initial review, continuing review, amendments and reportable events.

REFERNCES

NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
Federal Policy for the Protection of Human Subjects (45 CFR Part 46)

RELATED MATERIAL

IRB FORM: IRB Reliance Request Form
IRB Submission Guide: IRB Submissions for Studies Delegated to Single IRB Review

IRB GUIDANCE: Requesting Single IRB Review for Multi-Site Studies
IRB GUIDANCE: IRB Reliance on the National Cancer Institute IRB

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	04/11/2017	New- Initial Integration Update	J. Blundon
02	10/23/2017	Addition of Related Material, References and Revision History sections.	J. Blundon
03	5/09/2018	Update SOP number, additional information about studies eligible for IRB reliance and single IRB requirements, other clarifications and editing updates	J.Blundon-Kirchen
04	06/23/2019	2.3. Clarification that Director can make reliance determinations, but IO must sign agreements.	