Ascension Wisconsin IRB Guidance

Requesting Single IRB Review for Multi-Site Studies

The Ascension Wisconsin (AW) Institutional Review Board (IRB) is responsible for the oversight of all research that involves human subjects (as defined by HHS and FDA regulations) conducted at an Ascension Wisconsin hospital or facility and/or by Ascension Wisconsin associate(s) or medical staff.

For research projects that are being conducted at multiple sites, Investigators may request for a single IRB to conduct the IRB review for both institutions. For a single IRB review to occur, the IRBs must establish an IRB Reliance Agreement (IRA) so that one IRB can defer oversight to the other IRB. Not all institutions will agree to rely on or accept oversight for other institutions. If both IRBs agree to establish an IRA, the Investigator will then submit the project to a single IRB (which is called the IRB of record). However, there may still be other reviews or approvals needed at each institution, so it is important to work with each institution and their requirements.

Additionally, Ascension Wisconsin participates in the National Cancer Institute (NCI) Independent Model of review for Cooperative Group adult clinical trials. *The information in this Guidance is not applicable for studies delegated to NCI CIRB; see the separate policies, Guidance and Instructions for NCI CIRB Review.*

When will Ascension Wisconsin IRB consider relying on a Central IRB or another institution's IRB?

Requests for the Ascension Wisconsin IRB to rely on the review of another IRB are evaluated on a case-by-case basis. This evaluation focuses on all aspects of a study including, but not limited to: study procedures, level of risk, researcher history and experience, conflicts of interest not otherwise precluding ceding and funding. Additionally, the proposed IRB of record must be able to document adequate standards for human subject protection and be willing to serve as the IRB of record.

Examples of when the Ascension Wisconsin IRB may agree to cede oversite to another IRB:

- A study protocol falls under and existing broad Reliance Agreement
- Ascension Wisconsin staff have limited involvement in research activities (e.g. data analysis, consultation or other administrative roles)
- Federal funding agency (i.e. NIH) require the use of a single IRB (and ceding is not prohibited)
- Only minimal risk activities are occurring at a Ascension Wisconsin

Examples of when the Ascension Wisconsin IRB will not cede oversite to another IRB:

- Ascension Wisconsin is not engaged in human subjects research
- The study is exempt (once declared exempt, ceding is not necessary unless the study changes)
- A majority of the research activities will occur in an Ascension Wisconsin facility
- The study is more than minimal risk and the role of Ascension Wisconsin personnel is substantial
- Substantive compliance concerns resulted in a finding of serious or continuing noncompliance, suspension or termination within the past year involving the researcher, other study personnel or (in some cases) the department. Other substantive compliance concerns outside of that window will be evaluated on a case-by-case basis in determining whether ceding is appropriate.
- The Ascension Wisconsin researcher is the regulatory sponsor for an investigator-initiated drug, device or biologic clinical trial
- The proposed IRB of record does not have sufficient knowledge or expertise to assume IRB oversight and/or is unwilling to apply required Ascension Wisconsin policies and/or unable to come to agreement on contract terms

When will the Ascension Wisconsin IRB consider accepting oversight for research conducted at another institution?

Requests for the Ascension Wisconsin IRB to serves as the IRB of record on a study-by-study basis. Typically, study activities occurring at the other institution will be minimal risk.

Examples of when the Ascension Wisconsin may agree to accept oversight for another institution:

- The majority of the study is being done at Ascension Wisconsin or with Ascension Wisconsin patient records
- A study initiated at Ascension Wisconsin requires research-related procedures to be done at a site that does not have an IRB
- The institution is partially owned by Ascension Wisconsin and has a policy adopting the Ascension Wisconsin policies and standard operating procedures for the oversight and conducting of research.

Is having an IRA the same as IRB approval?

No. The IRA is the formal, written agreement between the IRBs that allows only one IRB to complete the review. The researcher must submit the project to the IRB of record and obtain IRB approval before beginning any research activities. The IRB of record will send you a notice when the study is approved.

How do I request to defer IRB approval?

Preliminary discussions

- Contact both IRBs to see if they will consider an IRA, usually starting with the site that you think should be the single reviewing IRB. As a reminder, institutions do not have to agree to defer IRB oversight. Also, some sites may have existing IRAs that the project already qualifies for. It's a good idea to contact them before spending time preparing multiple IRB submissions or requests.

- Be ready to provide the following:
    - Protocol or overview of the study
    - Where the research activities will be occurring
    - Where subjects are recruited or data/biospecimens are collected
    - Who is involved in conducting research activities (i.e. recruiting, obtaining consent, data collection and data analysis)

- If the IRBs agree to conduct a single IRB review, you still need to receive notification from both IRBs before beginning any study activities.

Submit request to the Ascension Wisconsin IRB

- If both sites are willing to establish an IRA, complete the IRB Reliance Request Form and submit it to the Ascension Wisconsin IRB per the instructions on the form.

- Deferral determinations are typically completed within 10 days. However, we encourage investigators to seek guidance as early as possible to determine the feasibility of an agreement. If a reliance arrangement is possible, the process of actually executing an appropriate agreement can take significant time and many of the factors influencing timing are outside of the control of the local investigator and Research Integrity and Protection.