

Investigator Responsibilities When UW-Madison Serves as the Reviewing IRB

When the UW-Madison agrees to serve as the reviewing IRB for external sites or personnel, the UW-Madison study team must comply with relevant UW-Madison requirements and be responsible for completing several steps in the IRB reliance process. Several of these requirements must be met before UW-Madison can agree to serve as the reviewing IRB. These responsibilities and requirements include:

- Contacting the Education and Social/Behavioral Science (ED/SBS) IRB Office (<https://irb.wisc.edu/irb-office/>) to:
 - Discuss whether UW-Madison can act as the single IRB for all or some institutions or personnel participating in this study or whether another external IRB would be appropriate.
 - Identify who will act in the role of the Lead Study Team (e.g., your own study team, another site's study team, or both). The Lead Study Team assumes additional responsibilities when single IRB review will be used.
 - Provide the Reliance Team with details about the study, including the study-wide protocol and template consent document(s), which will help facilitate the discussion of single IRB review options.
 - Identify all sites that will be engaged in human subjects research and thus need IRB coverage.
- If UW-Madison agrees to serve as the single IRB for the study, the UW-Madison study team must:
 - Include the relevant reliance request in the ARROW application for the study.
 - Work in collaboration with the ED/SBS IRB to determine and document specific roles and responsibilities for communicating and coordinating key information to Relying Institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
 - Promptly respond to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the ED/SBS IRB.
 - Participate in conference calls regarding a study as requested.
 - Provide the Site Investigators with UW-Madison HRPP and ED/SBS policies. This includes, but is not limited to, policies for reporting unanticipated problems, non-compliance, and subject complaints.
 - Provide Relying Site Study Teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
 - Prepare and submit IRB applications on behalf of all sites, including initial reviews, local changes, personnel updates, local reportable events, and study wide information for continuing review.
 - As part of preparing the IRB application, the UW-Madison study team must:
 - Have a mechanism in place to obtain and collate information from Relying Site Study Teams and/or Relying Site Points of Contact (POCs), depending on who is designated to provide that information at the Relying Institution, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification and processes.
 - Assist Relying Site Study Teams and/or POCs at the Relying Institution(s), depending on who is designated to provide that information, in ensuring consent documents follow the Reviewing IRB's template form and include applicable site-specific required language from each Relying Institution.

- Notify Site Investigators of all ED/SBS IRB determinations and communications, including those for initial review, continuing review, changes, and reportable events.
- When agreed upon in coordination with the ED/SBS IRB, promptly report to the Site Investigator (or designee) any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research (i.e., the specific study or studies ceded to the Reviewing IRB) at the Relying Institution.
- During the continuing review process, if applicable, the UW-Madison study team will notify any affected Relying Site Study Team of any lapse in approval for their site and any applicable corrective action plans, whatever the cause of the lapse in IRB approval.
- Promptly notify Relying Site Study Teams of any change in the continuing review requirement for the study (e.g., the study originally was excepted from ongoing continuing review but a change or other event means the study now does require continuing review).
- Provide access, upon request, to study records for audit by the Relying Institution, the ED/SBS IRB, and other regulatory or monitoring entities.
- Follow all requirements of the Relying Institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a Relying Institution.
- For any external individuals (rather than sites) for which UW-Madison is serving as the Reviewing IRB, the UW-Madison Study Team ensures that all such personnel have completed required human subjects research and, if applicable, Good Clinical Practice training prior to initiating any study activities. The UW-Madison Study Team is also responsible for keeping appropriate documentation of any relevant training certificates for these external individuals. For more information, see [Training Options for External Personnel](#).