

Brief Summary of Investigator Responsibilities When IRB Oversight is Ceded to a Non-UW-Madison IRB

When the ED/SBS IRB agrees to cede IRB oversight for a study to an external IRB, the UW-Madison study team must still comply with relevant UW-Madison requirements. Study teams also must be familiar with the requirements of the reviewing IRB, which may be different from what might be required by the ED/SBS IRB. Several of these requirements must be met before the ED/SBS IRB can agree to cede IRB oversight. These responsibilities and requirements include:

1. The UW-Madison PI for the study must fulfill the responsibilities described in the [Summary of Investigator Responsibilities](#) document.
2. Study teams must ensure that all their study team members complete and maintain current human subjects research training certification and, if applicable, Good Clinical Practice training certification. All UW-Madison study team members must have complete and current training certifications before IRB oversight can be ceded to an external IRB.
3. Study teams must adhere to the requirements of any UW-Madison ancillary committees (e.g., conflict of interest), as applicable. If ancillary committee review is required, this typically will need to be completed before IRB oversight can be ceded to an external IRB.
4. Study teams are responsible for ensuring that all budgetary and contractual issues relevant to the UW-Madison's conduct of the study are resolved before starting their research.
5. Study teams are responsible for ensuring language in consent forms does not conflict with clinical trial agreement or other funding agreement.
6. Study teams are responsible for ensuring required agreements for data or specimen transfer (e.g., data use agreements, etc.) are in place prior to the UW-Madison receiving or transferring data or specimens.
7. UW-Madison study teams are responsible for providing Research and Sponsored Programs (RSP) with documentation that a study has been ceded to and approved by an external IRB. For additional guidance, see [Research and Sponsored Programs \(RSP\) Release of Grant Funds When Studies Are Ceded to Another Institution's IRB for Review and Approval](#).
8. The UW-Madison study team cannot begin any research activities for a study ceded to an external IRB until the reviewing IRB has formally agreed to assume IRB oversight (e.g., the IRB of record has signed an IRB authorization agreement) and the reviewing IRB has approved the UW-Madison's involvement in the research. In addition, study activities cannot begin until all institutional requirements are met and approvals obtained, as applicable for each study.
9. Study teams must report to the reviewing IRB any changes (including funding changes and personnel changes), reportable events, and continuing review progress reports in accordance with the reviewing IRB's policies and procedures.
10. Changes in funding, changes to UW personnel or their conflicts of interest, and study closure must be reported to the ED/SBS IRB in addition to the reviewing IRB.
11. Potential unanticipated problems, serious adverse events, or noncompliance that occur at UW-Madison may need to be reported to the ED/SBS IRB in addition to the reviewing IRB. Study teams should contact the ED/SBS IRB for guidance when such an event occurs.