

Institutional Review Board

Request to Use an External IRB

IRB Survey

|  |
| --- |
| This form should be submitted with the IRB Reliance Request Form by the Ascension PI when requesting a single IRB review between the Ascension Wisconsin IRB and another institution or IRB, where the AW IRB will rely on an external IRB.The form should be completed by someone at the non-Ascension Wisconsin Institution or IRB.They should also be provided with the Form: Local Context Information about Ascension Wisconsin.If you have any questions, contact the IRB at IRB@ascension.org or 414-465-3134. |
|  |
| 1. **Study Information**
 |
| Study Title | Click here to enter text. |
| Main Contact/PI at Ascension Wisconsin | Click here to enter text. |
|  |
| 1. **Institution/ IRB Contact Information**
 |
| Institution | Click here to enter text. |
| Responsible Investigator at external site | Click here to enter text. |
| Institution or HRPP/IRB staff completing this form | Click here to enter text. |
| Email | Click here to enter text. | Phone | Click here to enter text. |
|  |  |
| 1. **IRB Information**
 |
| **FWA****IRB** | Click here to enter text. Click here to enter text.  |
| **Is the Institution’s HRPP/IRB accredited?** | [ ] No [ ]  Yes *If yes, by whom?* Click here to enter text. |
| **FDA Inspection** | Date of last FDA Inspection: Click here to enter text. Results (i.e. 483b findings- brief summary) Click here to enter text. |
| **HIPAA Authorization** | [ ]  No PHI will be used and/or disclosed- HIPAA not applicable[ ]  The IRB of record will be responsible for the HIPAA Privacy Board review and determinations (i.e. granting waivers, HIPAA authorization review) [ ]  The Ascension Wisconsin IRB will be responsible for the HIPAA Privacy Board review and determinations at their site (i.e. granting waivers, HIPAA authorization review) [ ]  Other/Comments: Click here to enter text. |
| **Conflict of Interest** | [ ]  Ascension Wisconsin research staff will follow the Ascension Wisconsin financial COI reporting policy, which requires reporting of financial interests from all individuals responsible for the design, conduct or reporting of the research and complies with Federal requirements. [ ]  Other/Comments: Click here to enter text. |
| **Training, Credentialing and Qualification Requirements** | [ ]  The Ascension Wisconsin IRB will be responsible for maintaining files documenting training and qualifications for key personnel where Ascension Wisconsin is engaged in human subject research, per our local Polies and Procedures.[ ]  The External IRB requires CITI training maintained at least every three years for all study staff. The completion for will be certified at the time of reliance. |
| **IRB AUTHORIZATION/ RELIANCE AGREEMENT** | Submit the IRB Reliance Agreement that the Ascension Wisconsin IRB will be asked to sign with this form.  |