

Institutional Review Board

IRB Reliance Request Form

Submit this form to the Ascension Wisconsin IRB to request for single IRB review.

You should check with both IRBs first to be sure they are willing to consider single review. This request should be sent to one IRB, the IRB staff will contact the other IRB to discuss the agreement.

*This form is not an IRB application.* Before you can submit your protocol for IRB review, both IRB’s must agree to a reliance agreement. After the IRB Reliance is confirmed, you can submit the appropriate application for IRB review. Research activity cannot begin at Ascension Wisconsin until you receive a final acknowledgement from the Ascension Wisconsin IRB, even if another IRB has granted approval.

*This form should not be used to request deferral to the NCI CIRB (see IRB Guidance on* [*Relying on NCI CIRB*](https://www.axiommentor.com/pages/dms/pop_p.cfm?osw=go&path=30,19880&inline=1&id=19881)*).*

**Submit this completed form to** [**IRB@Ascension.org**](mailto:IRB@Ascension.org)**.** You may submit a request using a similar form from the other IRB form instead of this one, if you have already completed it.

For questions, contact Jackie Kirchen at 414-465-3134 or [jackie.kirchen@ascenion.org.](mailto:%20jackie.kirchen@ascenion.org)

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| 1. **Reliance Requested** | |
| Select one of the following | ☐ Request IRB review by a non-Ascension Wisconsin IRB  ☐ Request Ascension Wisconsin IRB to provide IRB review for another IRB/Institution |
| Date of Request | Click here to enter a date. |

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| 1. **Contact Information** | | | | | | | | | | | | | | |
| **Study Contact Person** Identify the person who will serve as the study team point of contact for this request. This person is responsible for communicating questions and IRB decisions to study team members at all sites. (The study team Point of Contact could be the PI or an individual coordinating the study) | | | | | | | | | | | | | | |
| Contact Name | | | Click here to enter text. | | | | | | | | | | | |
| Institution | | | Click here to enter text. | | | | | | | | | | | |
| Email | | | Click here to enter text. | | | | | Phone | | | Click here to enter text. | | | |
| **Contact person/ Researcher at Ascension Wisconsin site** (if different form above) | | | | | | | | | | | | | | |
| Contact Name | | |  | | | | | | | | | | | |
| Email | | | Click here to enter text. | | | | | Phone | | | Click here to enter text. | | | |
| **IRB Contact Information Provide the contact information for each IRB Office with which a deferral agreement is requested.** | | | | | | | | | | | | | | |
| Institution /IRB Contact Name | | | Click here to enter text. | | | | | | | | | | | |
| Institution/IRB | | | Click here to enter text. | | | | | | | | | | | |
| Email | | | Click here to enter text. | | | | | Phone | | | Click here to enter text. | | | |
| Institution /IRB Contact Name | | | Click here to enter text. | | | | | | | | | | | |
| Institution/IRB | | | Click here to enter text. | | | | | | | | | | | |
| Email | | | Click here to enter text. | | | | | Phone | | | Click here to enter text. | | | |
| Institution /IRB Contact Name | | | Click here to enter text. | | | | | | | | | | | |
| Institution/IRB | | | Click here to enter text. | | | | | | | | | | | |
| Email | | | Click here to enter text. | | | | | Phone | | | Click here to enter text. | | | |
| 1. **Study Overview** | | | | | | | | | | | | | | |
| Study Title | | Click here to enter text. | | | | | | | | | | | | |
| Funding | | No funding  There is funding and the source is: Click here to enter text.  If funded:   * Is single IRB review a requirement of funding? No  Yes * If federally funded, who is the study coordinating site: Click here to enter text. * Has funding been awarded? No  Yes Awardee Institution: Click here to enter text. * Is there a subcontract/subaward? No  Yes List institution(s): Click here to enter text. | | | | | | | | | | | | |
| IRB Review | | No  Yes Has the study already been submitted to an IRB?  No  Yes Does this study already have IRB approval?  If yes to either:   * Which IRB: Click here to enter text. * What is the IRB assigned study number Click here to enter text.: | | | | | | | | | | | | |
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| 1. **Subject Populations** | | | | | | | | | | | | | | |
| Check subject populations that apply | | Inpatients  Outpatients  Outpatients  Children or infants  Pregnant women/fetuses  Non-English speaking subjects  Students or residents  Employees  Prisoners  Adults with impaired decision-making capacity (e.g., coma, dementia, confusion, etc.)  Other potentially vulnerable populations (describe): Click here to enter text. | | | | | | | | | | | | |
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| 1. **Study Sites, Personnel & Activities** | | | | | | | | | | | | | | |
| **Describe the activities involved in the research and the site(s) involved with each activity.** When appropriate, provide clarification of how Ascension facilities, staff, patients or patient data/ biospecimens will be involved in the activity. Include at which Ascension facility(ies) the activity will occur. | | | | | | | | | | | | | | |
| **Name of institution(s)** | | | | Ascension Wisconsin | | | Click here to enter text. | | Click here to enter text. | | | Click here to enter text. | | **Description of Ascension activities** |
| Handing out/ posting recruitment flyers or information | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Identifying subjects by reviewing the medical records/database | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Obtaining informed consent | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Collecting data/biospecimens  Describe origin of data/biospecimens to be reviewed | | | | describe | | | describe | | describe | | | describe | | Click here to enter text. |
| Use, storage, transportation or banking data/biospecimens | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Maintain key code to link data/specimens to identifiers | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Interacting with subjects (like interviews, surveys, etc.) | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Audio or video recording | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Intervention with subjects (i.e. blood draw, giving drug) | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Storage, management of investigational drug or device | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Use of potential biohazards (i.e. recombinant/synthetic nucleic acids) | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Use of radiation for research (x-ray imaging, radiopharmaceuticals, etc.) | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Other services ( like biostatistics, use of institutional equipment) | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Data/specimen analysis | | | |  | | |  | |  | | |  | | Click here to enter text. |
| Other (describe) | | | | describe | | | describe | | describe | | | describe | | Click here to enter text. |
| **Responsible Investigator and Key Personnel**  List the name(s) and role of key personnel at each institution, including a responsible investigator if there are multiple personnel at an institution or site. | | | | | | | | | | | | | | |
|  | **Home Institution** | | | | **Contact Name (w/credential)** | | | | **Role in study** (i.e. responsible investigator, study coordinator, etc.) | | | | **Describe if individual is a student or resident** | |
| **Lead Site** | Click here to enter text. | | | | Click here to enter text. | | | | **PI for study overall** | | | | Click here to enter text. | |
| **Participating sites** | Click here to enter text. | | | | Click here to enter text. | | | | Click here to enter text. | | | | Click here to enter text. | |
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| **Study Risks and Monitoring/Reporting Responsibilites** | | | | | | | | | | | | | | |
| **Risk Level** | | | | All study activies are no more than minimal risk  Study includes activities that pose greater than minimal risk to subjects | | | | | | | | | | |
| **For studies that are greater than minimal risk** | | | | List the institution where activites that are more than minimal risk will occur and the person at each institution who is responsible for evaluating and responding to subject complaints and reporting unanticipated events to the reviewing IRB. | | | | | | | | | | |
| **Institution** | | | | | | **Name of responsible person** | | | | |
| Click here to enter text. | | | | | | Click here to enter text. | | | | |
| Click here to enter text. | | | | | | Click here to enter text. | | | | |
| Click here to enter text. | | | | | | Click here to enter text. | | | | |
| Click here to enter text. | | | | | | Click here to enter text. | | | | |
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| 1. **Study Summary** | | | | | | | | | | | | | | |
| Briefly state the broad research goal and specific aims of the study in lay terms. | | | | Click here to enter text. | | | | | | | | | | |
| Describe:  (a) the procedures to be used to meet the specific aims of the study,  (b) at which site they will be done, and  (c) who will perform the procedures | | | | Click here to enter text. | | | | | | | | | | |
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| 1. **Conflict of Interest** | | | | | | | | | | | | | | |
| Reported Conflicts of Interest | | | | | | Do any key personnel engaged in the proposed research activity or their family members have a potential conflict of interest that requires disclosure as required by the individual’s institutional conflict of interest policy?  No  Yes  If yes:   * List the individual and institution: Click here to enter text. * Has this conflict of interest been reported to the individual’s institution? No  Yes | | | | | | | | |