

# INVESTIGATOR RELIANCE REQUEST FORM

## Introduction:

- IRB reliance only applies to human subject research. If you suspect your study may qualify as a QA/QI project or might not qualify as human subject research, please consult with your home institution's IRB Office before completing and submitting this reliance request.
- The purpose of this Request Form is to request a coordinated or single IRB review for a multi-site study. This Request Form can be used for initial submissions or when adding other institutions to an already IRB-approved project.
- A single IRB review means that you will need to submit an application to only one IRB, and you will need to follow their submission process and policies. The reviewing IRB will provide oversight for the life of your study.
- If you are using this Request Form, do not submit an IRB application until you receive a response from the IRB Administrator to whom you submitted the Form.
- This Request Form is NOT an IRB application.

## Instructions:

1. Complete this form with the requested information and submit only to one IRB Office. If the form is submitted to another office, your request may not be processed.
2. Complete the form fully to allow the IRBs to process your request quickly. If sections are incomplete, the form will be returned for completion.
3. Once received by an IRB Administrator, the Request Form will be reviewed, shared, and discussed among IRB Administrators from all involved institutions.
5. After deliberation among the IRBs, you will be notified by the IRB Administrator who received your Request Form if a single IRB review is acceptable and which IRB will provide review and oversight.
4. Do not submit an IRB application until you are notified which IRB(s) will provide review.
5. Once you are notified that a single IRB review is possible, an IRB application must be submitted to the reviewing IRB. The submission procedures and policies for the reviewing IRB must be followed.
5. Note that a coordinated or single IRB review is not guaranteed.
6. If you have questions about this process or the Request Form, contact one of the IRB Administrators listed below.

### **For studies involving the sites listed below, submit this form to only one IRB office listed:**

Children's Hospital of Wisconsin (CHW)

Marquette University

MCW, BloodCenter of Wisconsin (BCW), or Froedtert Health (i.e. Froedtert Hospital, Community Memorial Hospital or St. Joseph's Hospital)

Milwaukee School of Engineering (MSOE)

UW-Milwaukee

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## **Definitions of Terms Used in This Form:**

**Primary Principal Investigator:** The overall multi-site Principal Investigator who has the ultimate responsibility for the conduct of research to ensure subject safety and data integrity for research that will be carried out collaboratively among two or more institutions. The Primary Principal Investigator is responsible for assuring proper conduct of the protocol at each site, communication between sites, and assuring that IRB determinations are disseminated to each involved site. The Primary Principal Investigator may or may not be the Lead Investigator at their home institution.

**Responsible Investigator:** The individual at a study site who is responsible for assuring compliance with institutional policies and guidelines, communicating on a regular basis with the Primary Principal Investigator, and assuring adherence to the protocol as approved by the reviewing IRB. When there are multiple investigators at a site, a Lead Investigator must be identified in this Request Form for each institution involved in the research. The Lead Investigator cannot be a student.

**Key personnel:** Individuals (including the Lead Investigator) at a study site who contribute substantively to the scientific development or execution of a study.

**Coordinating Site:** The site that is responsible for coordinating study activities, monitoring data, and assuring communication among all study sites. This site may also be the location of data storage and/or data analysis.

**Interacting:** Any communication or interpersonal contact between investigator and subject, for example, collecting specimens from individuals, conducting questionnaires or surveys, conducting focus groups, or drug administration.

**Rely/defer/cede:** An institution agrees to transfer oversight of a study under its jurisdiction to another IRB.

**Record review:** Review of any type of record including confidential records such as medical, educational, or financial, whether paper or electronic.

**Recruiting:** Providing information about a research study to potential subjects, for example, putting up flyers at a college campus or hospital clinic, putting an ad in a local newspaper or on a website, sending an email to potential subjects, discussing a study with a patient during an office visit.

**Retrospective:** Data or biospecimens to be analyzed for this study already exist at the time of submission to the IRB.

**Prospective:** Data or biospecimens will be collected as part of this research studies.

**Risk:** The possibility that harm may occur. In research ethics, risk is defined as the magnitude of potential harm or discomfort and the probability of the harm or discomfort occurring.\* There are many different types of possible harms, for example psychological distress, embarrassment, physical injury, or legal, social or economic harm. Although a record review may appear to present no risk, there is a risk of loss of confidentiality whenever confidential records are accessed or used.

**Minimal risk:** means that the probability and magnitude of harm or discomfort anticipated in the research are not in and of themselves greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**NOTE:** This form must be completed in sufficient detail in order for institutions to make a determination on engagement and IRB oversight. Please answer all questions completely and in sufficient detail.

1. Basic Study Information	
Study Title:	
Is the investigator a student doing work on a dissertation or thesis? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, specify with which institution the student is affiliated:	
If yes, Provide name & contact information for faculty advisor:	
Funding: <input type="checkbox"/> No funding <input type="checkbox"/> There is funding and the source is:	Awardee Institution: Has the funding been awarded? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is there a subcontract or subaward? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, specify with which institution:	

2. Study Status	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does this study already have IRB approval?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Has the study already been submitted to an IRB?
	If yes to either of these questions, specify which IRB:
	If yes to either of these questions, specify IRB assigned project/study number:

3. Subject Populations (check all that apply)	
<input type="checkbox"/> healthy subjects	<input type="checkbox"/> inpatients <input type="checkbox"/> outpatients <input type="checkbox"/> decisionally impaired <input type="checkbox"/> Non-English proficient
<input type="checkbox"/> pregnant women	<input type="checkbox"/> residents/students/employees <input type="checkbox"/> minors (anticipated % minors:      ) <input type="checkbox"/> prisoners <input type="checkbox"/>
other:	

4. Study Sites, Personnel, Activities (indicate which institution/site will be involved in the study for each activity)				
Name of institution or site where research activities will be conducted				
Handing out flyers about the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reviewing medical records/databases before informed consent to determine eligibility	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Obtaining informed consent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Interacting with subjects, including interviews, surveys, focus groups	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Testing, designing, or developing equipment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intervening with subjects, e.g. collecting blood or saliva for research purposes, administering drugs or other investigative articles, manipulating the subject or subject's environment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of ancillary services (e.g. biostatistics, pharmacy, nursing, etc.) or institutional equipment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use of scanning equipment, e.g. x-ray, CT, US, DEXA, MRI, etc. Specify which equipment (e.g. 1.5T MRI, 7T MRI, DEXA, etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Use, storage or banking data/biospecimens	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Origin of data/biospecimens to be reviewed				
Data/specimen analysis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Conducting research in a lab	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**5. Responsible investigator and key personnel**

Name(s) of key personnel at each institution, including a responsible investigator if there are multiple personnel at an institution or site	Home institution for each individual listed	Role in study, e.g. responsible investigator, study coordinator

**6. Study Summary (explain the purpose of the study, activities checked in section 4 in more detail, and who at each site will conduct those activities).**

Briefly state the broad research goal and specific aims of the study in lay terms:

Describe (a) the procedures to be used to meet the specific aims of the study, (b) at which site they will be conducted, and (c) who will be performing those procedures:

If the study is federally funded, identify the coordinating site for the study:

For more than minimal risk studies, list the individuals at each site who will be responsible for evaluating and responding to subject complaints and reporting unanticipated events to the reviewing IRB:

Name of individual	Institution

**7. Conflict of Interest Disclosure**

Do any key personnel who will be 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?

Yes    No

If yes, list the individual and institution:

If yes, has this conflict of interest been reported to the individual’s institution?  Yes    No

**8. Study Team Point of Contact Information**

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 Principal Investigator or an individual coordinating the study)

Name:

Email:

Phone:

When requesting that MCW rely upon another IRB complete the following additional section. Then submit this entire form along with the protocol\* and consent form, if applicable, to [MCWIRBReliance@mcw.edu](mailto:MCWIRBReliance@mcw.edu).

**NOTE: If the proposed reviewing IRB is CHW, Marquette University, MSOE, or UW-Milwaukee, the protocol and consent form are not required.**

<b>9. Proposed reviewing IRB information</b>
Name of proposed reviewing IRB: IRB FWA#:
Name of IRB contact: Email: Phone:
<b>Funding information</b>
Funds will come to MCW/FH/BCW through: <input type="checkbox"/> direct award/contract <input type="checkbox"/> subcontract <input type="checkbox"/> service agreement <input type="checkbox"/> Not funded
<b>Local information</b>
Recruitment procedures to be used locally at MCW, FH, or BCW, if applicable: Will you review medical records prior to consent to determine eligibility? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, specify source of records (e.g. FH, BCW, CHW):
Consent process will be conducted at MCW, FH or BCW as outlined in the protocol: Yes <input type="checkbox"/> No <input type="checkbox"/> If not included in the protocol or if different than in the protocol, explain the process for this site:
<b>Activities at local site</b>
Briefly describe all study activities to be conducted at MCW, FH and/or BCW:

- \* Protocol summaries, narratives or grant applications should include (at a minimum) the following sections: Purpose, Aims, Research Design, and Procedures to be conducted at each site.