**COORDINATED IRB REVIEW REQUEST FORM**

Introduction:

* The following institutions have established a working relationship and process for considering a coordinated or single IRB review:

Blood Center of Wisconsin Children’s Hospital of Wisconsin

Froedtert Hospital Medical College of Wisconsin

Marquette University Milwaukee School of Engineering

UW-Milwaukee

* The purpose of this Request Form is to request a coordinated or single IRB review when a study involves two or more of these institutions. This Request Form can be used for intial 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 of the IRB Administrators listed below. If the form is submitted to someone else, your request may not be processed.
2. Provide as much information as possible to allow the IRBs to process your request quickly.
3. Once received by an IRB Administrator, the Request Form will be reviewed, shared, and discussed among the 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.

**Submit this form to only one of the following IRB Administrators:**

BloodCenter of Wisconsin Marcia Iverson (Marcia.iverson@bcw.edu)

Children’s Hospital of Wisconsin (CHW) Justin Nebel (jnebel@chw.org )

Marquette University Benjamin Kennedy (Benjamin.kennedy@marquette.edu)

MCW/Froedtert Hospital Connie Byrne (cbyrne@mcw.edu)

Milwaukee School of Engineering (MSOE) Loretta Krenitsky (krenitsk@msoe.edu)

UW-Milwaukee Melissa Spadanuda (spadanud@uwm.edu)

**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.

Lead 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.

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. \*\*

# Principal Investigator, Study Title and Funding

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| --- | --- |
| Primary Principal Investigator’s Name:       | Primary Principal Investigator’s institution:       |
| Study Title:       |
| Is the investigator a student doing work on a dissertation or thesis? [ ]  Yes [ ]  No If yes, specify with which institution the student is affiliated:       If yes, a faculty advisor is required and must be listed on this Request Form. |
| Funding:[ ]  No funding[ ]  There is funding and the source is:        | Has the funding been awarded? [ ]  Yes [ ]  NoAwardee Institution:       |
| Is there a subcontract or subaward? [ ]  Yes [ ]  No If yes, specify with which institution:        |

# Study Status

|  |  |
| --- | --- |
| [ ]  Yes [ ]  No | Does this study already have IRB approval?  |
| [ ]  Yes [ ]  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:       |

# Subject Population(s)

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| Indicate whether of any of the following subject populations will be/are enrolled in this study:[ ]  Minors or newborns (subjects 17 years old and younger)[ ]  Adults [ ]  Adult patients at CHW[ ]  Non-English/Limited English Proficiency[ ]  Limited literacy[ ]  Students from school(s)/institution(s):      [ ]  Employees from institution(s):      [ ]  Patients from institution(s):      [ ]  Blood donors[ ]  Prisoners[ ]  Pregnant women/fetuses[ ]  Adults who have impaired decision-making capacity (e.g., coma, dementia, confusion, or mental disorders)[ ]  Other potentially vulnerable populations, e.g., institutionalized people. (describe)        |

# 4. Study Sites, Personnel, and Activities

Indicate which institution or site will be involved in the study and check which activity will occur at each site.

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| --- | --- | --- | --- | --- |
| Name of institution or site |       |       |       |       |
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| Recruiting | [ ]  | [ ]  | [ ]  | [ ]  |
| Interacting with subjects, including interviews, surveys, focus groups | [ ]  | [ ]  | [ ]  | [ ]  |
| Audio or video recording | [ ]  | [ ]  | [ ]  | [ ]  |
| Testing, designing, or developing equipment | [ ]  | [ ]  | [ ]  | [ ]  |
| Conducting informed consent | [ ]  | [ ]  | [ ]  | [ ]  |
| Use of ancillary services (e.g. biostatistics, pharmacy, nursing, etc.) | [ ]  | [ ]  | [ ]  | [ ]  |
| Data/biospecimen storage  | [ ]  | [ ]  | [ ]  | [ ]  |
| Data/biospecimen banking | [ ]  | [ ]  | [ ]  | [ ]  |
| Retrospective record review | [ ]  | [ ]  | [ ]  | [ ]  |
| Prospective record review | [ ]  | [ ]  | [ ]  | [ ]  |
| Origin of data/biospecimens to be reviewed |       |       |       |       |
| Use of institutional equipment | [ ]  | [ ]  | [ ]  | [ ]  |
| Data/specimen analysis | [ ]  | [ ]  | [ ]  | [ ]  |
| Involves investigational drug(s) | [ ]  | [ ]  | [ ]  | [ ]  |
| Involves investigational device(s) | [ ]  | [ ]  | [ ]  | [ ]  |
| Level of risk (e.g. minimal, greater than minimal risk, high) |       |       |       |       |

List all key personnel and their home institution or site. When any part of a project will be conducted at a CTSI institution, a at least one investigator at the institution must also be listed.

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| Name(s) of key personnel at each institution, including a Lead Investigator if there are multiple personnel at an institution or site | Home institution for each key personnel  | Role in study, e.g. lead investigator, study coordinator | Contact information for at least one individual from each institution |
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**5. Study Summary**

In this section, explain the activities checked in section 4 in more detail. For example, if “interacting with subjects” is checked, what type of interaction will be conducted with subjects at what site, and by whom. A protocol or protocol summary may be attached, but specifics about what activities will be done at which site must be included in the protocol or else described in this section of the Request Form.

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| 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:       |

**6. Conflict of Interest Disclosure**

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| Do any key personnel to 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 [ ]  NoIf yes, list the individual and institution:      If yes, has this conflict of interest been reported to the individual’s institution? [ ]  Yes [ ]  No  |

# 7. Contact Information

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| Identify the person who will serve as the point of contact for this request. This person is responsible for communicating questions and IRB decisions to study team members at all sites. (such as the Principal Investigator or an individual coordinating the administrative details of the study)Name:      Email:      Phone:      Date of this Request:       |

\*From *Institutional Review Board: Management and Function,* E.A. Bankert, E.J. Amdur, p. 134.

\*\* From Code of Federal Regulations: Title 45, Part 46.102(i)