**INVESTIGATOR RELIANCE REQUESTING SINGLE/CENTRAL IRB SERVICE FROM MCW IRB**

Introduction:

* The purpose of this Request Form is to request that the MCW IRB serve as the single/central IRB for a multi-site project. This Request Form can be used for initial submissions or when adding other institutions to an already IRB-approved project.
* This Request Form is NOT an IRB application. Information in this form will be used to make a decision by the MCW IRB as well as the relying IRBs. Be sure to complete all sections thoroughly.

Instructions:

1. Complete this form with the requested information and submit this form + a protocol only to the MCW IRB Office via the email address provided below. If the form is submitted to another office or email address, your request will 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. If you have questions about the single/central IRB process or the Request Form, contact the MCW IRB Reliance Team at [MCWIRBReliance@mcw.edu](mailto:MCWIRBReliance@mcw.edu).

Important note: A fee structure may apply when the MCW IRB serves as a single/central IRB. This form will be reviewed and a budget estimate will be provided.

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| **1. Basic Project Information** |
| Project Title: |
| PI of entire project:  Coordinating Center for the project:  MCW investigator: |
| Funding:  No funding  Funding is being sought at this time and the funding source is:  Awardee Institution or primary awardee on grant application:  There is existing funding and the funding source is:  Awardee Institution or primary awardee on grant application:  Has the funding been awarded?  Yes  No |
| Is there a subcontract or subaward?  Yes  No  If yes, specify with which institutions: |
| Why are you requesting single IRB review for this study?  Funding requirement per NIH  Other Sponsor requirement  Other reason: |

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| **2. Local site investigator and key personnel** |
| **Local Context:** Once MCW IRB Reliance has indicated that the Central IRB service will move forward, the study team at the relying site will complete the study team section of the delegation log of the Site Local Context Form and forward to the Relying IRB/HRPP Office, where the relying HRPP/IRB Point of Contact will complete page 2, and the whole document will be sent to [MCWIRBReliance@mcw.edu](mailto:MCWIRBReliance@mcw.edu).  NOTE:  1) For AARPP accredited sites or members of a CTSA, Relying Site human subject research protections training will be accepted. Study teams not meeting these requirements must complete CITI training per MCW IRB policy.  2) CV for lead PI and narrative of resources available at Relying Institution must be provided with the IRB application (upload to section 52 in eBridge). |

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| **3. Project Status** | |
| Yes  No | Has the study already been submitted to the MCW/FH IRB? |
|  | If yes, specify IRB assigned project/study number: |

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| **4. Subject Populations (check all that apply)** |
| healthy subjects  inpatients  outpatients  decisionally impaired  Non-English proficient  pregnant women  residents/students/employees  minors (estimated % minors:       )  prisoners  other: |

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| **5. Project Summary (explain the purpose of the project, procedures to be used, and site specific information).** |
| 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(s) they will be conducted. Be specific and include all locations and their activities, including specifics for MCW, FH, BCW, and/or CHW: |

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| **6. Project Sites, Personnel, and Activities** |
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| List each site potentially relying on MCW IRB.  Please include sites involved in the following ways:   * The Institution will receive funding for this project * Personnel from the site will consent subjects * Personnel from the site will interact or intervene with subjects * Personnel from the site will obtain or analyze private information about subjects * Personnel from the sites are key decision-makers for the administration of the study * Research lab at the location will be involved in the project  |  |  |  |  | | --- | --- | --- | --- | | **Site Name** | **Site PI and email address** | **Site IRB/HRPP contact name and email address** | **Activities that will occur at this site** | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |  |  |  |  | |
| **Please select option a or b:** |
| **a.**  The protocol will be conducted exactly the same at each of the above sites, including recruitment and study activities.  **b.**  The protocol will NOT be conducted exactly the same at some or all sites. Be sure section 5 above describes what will be done differently at each site, e.g. not enrolling minors, not collecting specimens, different recruitment method. Alternatively, you may include an attachment, listing the sites and what will be done differently at each site. |
| Are there sites involved in the study but that will not rely on the MCW IRB?  Yes  No  If yes, please list: |

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| **7. Study Team Point of Contact** |
| 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: |

**Submit this entire form along with the protocol\* to** [MCWIRBReliance@mcw.edu](mailto:MCWIRBReliance@mcw.edu)**.**

* 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.