**Instructions:** This form gathers information about a participating site (p-Site), specifically local context and institutional requirements to support the sIRB review. This form must be submitted at the time of p-Site submission (see sIRB Manual (HRP-803) for more information). P-Site principal investigators must collaborate with their institution’s IRB when completing this form.

**Section 1. p-Site General Information**

**Instructions:** Consult your institution’s IRB office for information about the IRB.

1. **Protocol Title:**

|  |
| --- |
| Click or tap here to enter text. |

1. **p-Site Legal Name:**

|  |
| --- |
| Click or tap here to enter text. |

1. **Other names by which the institution is known:**

Include all alternate names, abbreviations, and acronyms by which the institution may be known to avoid confusion and/or potential delays in approvals or correspondence.

|  |
| --- |
| Click or tap here to enter text. |

1. **Federal Wide Insurance (FWA) #’s:**

Include all relevant FWA #’s. If the p-Site is within a network or system and has a separate FWA, provide it here.

|  |
| --- |
| Click or tap here to enter text. |

1. **p-Site Principal Investigator Name:**

|  |
| --- |
| Click or tap here to enter text. |

1. **p-Site PI Contact Information (Name, Email, Phone Number):**

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| --- |
| Click or tap here to enter text. |

1. **p-Site PI Study Team Point of Contact (Name, Study Role, Email, Phone Number):**

|  |
| --- |
| Click or tap here to enter text. |

1. **p-Site IRB Point of Contact (Name, Email, Phone Number):**

|  |
| --- |
| Click or tap here to enter text. |

1. **p-Site Institutional/Organizational Official (Name, Email, Phone Number):**

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| --- |
| Click or tap here to enter text. |

**Section 2. Participating Site Specific Legal or Institutional Requirements**

Instructions: Complete the questions that are relevant to this specific protocol. For example, if the research involves children, answer the question related to local assent requirements. However, if the research does not involve children, insert “not applicable for this protocol.” Do not describe general practices as those are guidance and are not policy driven.

|  |  |
| --- | --- |
|  | Provide a link (URL) or summary of the policy/law for each of the following. |
| Age of Assent | Click or tap here to enter text. |
| Emancipated Minors | Click or tap here to enter text. |
| Age of Majority | Click or tap here to enter text. |
| Legally Authorized Representatives | Click or tap here to enter text. |
| Human Research Training | Click or tap here to enter text. |
| Conflict (s) of Interest | Click or tap here to enter text. |

**Section 3. Participating Site Local Context Related to the Overall Study Protocol**

Instructions: The following questions are meant to gather local context information that is relevant to the overall study protocol to help the sIRB conduct an IRB review of the p-Site.

1. **Does the p-Site PI or p-Site as an institution, have a financial interest or business interest in a business entity related to this research in the following ways?**

* The business entity is sponsoring the project
* The business entity's products are used in this research
* Your licensed intellectual property is being developed or evaluated as part of this project
* Part of the work on this project will be subcontracted to the business entity
* Other relationship not listed above

Yes  No

If yes, provide a summary of the conflict. A conflict of interest management plan must be submitted to the sIRB in addition to this form. See sIRB Manual (HRP-803) for more information.

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| --- |
| Click or tap here to enter text. |

1. **Do local requirements or state laws stipulate requirements for enrolling vulnerable populations at your site that differ from University of Minnesota’s requirements for research involving vulnerable populations (see sIRB Manual (HRP-803) for UMN requirements that must be followed)?**

Yes  No

If yes, describe the differences:

|  |
| --- |
| Click or tap here to enter text. |

1. **Do local requirements or state laws stipulate requirements for how data will be accessed and/or stored at your site that differ from those described in the overall study protocol (for example, use of a different platform other than Box)?**

Yes  No

If yes, describe the differences:

|  |
| --- |
| Click or tap here to enter text. |

1. **Do local requirements or state laws stipulate requirements for your site’s initial contact, recruitment plan, and/or informed consent procedures that differ from those described in the overall study protocol?**

Yes  No

If yes, describe the differences.

|  |
| --- |
| Click or tap here to enter text. |

1. **Do local requirements or state laws stipulate any other requirements for the implementation and/or conduct of the protocol at your site that differ from those described in the overall study protocol?**

Yes  No

If yes, describe the other local or state law requirements:

|  |
| --- |
| Click or tap here to enter text. |

1. **Given the nature of this particular research study, is there any additional local context (i.e., any additional factors particular to this study site or the community, such as community attitudes, ethnic diversity, language, etc.) that should be considered by the single IRB?**

Yes  No

If yes, describe the additional local context:

|  |
| --- |
| Click or tap here to enter text. |

**Section 3. Participating Site Principal Investigator Attestation**

I agree to conduct the study in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the overall study/lead UMN PI, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described research.

I agree to inform any patients, or any persons used as controls, what activities are research activities and/or standard of care procedures.

I will ensure that the requirements relating to obtaining informed consent approved by the UMN IRB are followed.

I agree to follow U of M IRB requirements to report promptly reportable events to the overall study/lead UMN PI that occur in the course of the research.

I have read and understand the research protocol, including the potential risks of the research.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study at the participating site are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with regulatory requirements and to make those records available for inspection by regulatory oversight agencies, including the University of Minnesota.

I agree to provide participating site information, including the progress report to the overall study/lead UMN PI in a timely manner to comply with continuing review requirements (if applicable) and any other requests related to IRB oversight of the multi-site research.

I also agree to promptly report to the overall study/lead UMN PI all changes in the research activity and all unanticipated problems involving risks to human research participants or others, which would be communicated to the UMN IRB.

I will not make any changes in the research without prospective U of M IRB approval, except where necessary to eliminate apparent immediate hazards to human research participants.

I agree to comply with all other requirements regarding the obligations of principal investigators as a participating site PI (see sIRB Manual HRP-803) and all other pertinent requirements that I must adhere to, including local state laws.

**p-Site Principal Investigator Signature:**

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**Section 4. Participating Institutional Review Board Attestation**

On behalf of the participating site Institutional Review Board, the information regarding local context requirements, including state law information is accurately reflected in this document.

**p-Site Institutional Review Board Signature:**

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