**Attestation of PI Responsibilities when UMN IRB Serves as sIRB (HRP-828)**

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When the UMN PI serves as the lead PI of a multi-site or collaborative human research study that requires a single IRB, it is important for the investigator to recognize that they have additional responsibilities. The following should be read carefully. Signing this attestation confirms that the UMN PI agrees to and understands these obligations.

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| **Principal Investigator and Study Information** |
| PI Name: Click or tap here to enter text. |
| PI E-Mail Address: Click or tap here to enter text. |
| Study Title: Click or tap here to enter text. |

**As the PI, I agree and understand I am responsible for adhering to the following requirements, as described in the sIRB Manual (HRP-803):**

1. Ensure that the overall/lead study team is adequately resourced and prepared to participate in the multi-site/collaborative study.
2. Assume responsibility for the overall conduct of the study, ensuring compliance with federal regulations including the Food and Drug Administration (FDA) if applicable and all applicable responsibilities outlined in the Investigator Manual (HRP-103) and current Human Research-related policies, SOPs, Worksheets, Checklists and templates found in the HRPP Toolkit Library.
3. Submit the overall study in ETHOS per the sIRB Manual (HRP-803).
4. Participate in conference calls regarding an sIRB study as requested.
5. Follow all requirements of the UMN IRB with regard to establishing reliance agreements, such as ensuring administrative requirements for documenting reliance agreements and local context reviews have been met before study activation occurs at a p-Site.

**I am also responsible for the following as it relates to participating sites:**

1. Ensure that participating site(s) are adequately resourced and prepared to participate in the multi-site/collaborative study and exclude from participation those sites that are not.
2. Confirmed that participating site(s) do not have a conflict of interest related to this study (institutional or individual). NOTE: In the event that there is a p-Site conflict or UMN institutional conflict, an external IRB must serve as sIRB for the study. This includes SBIR/STTR research.
3. Submit p-Site materials in ETHOS per the sIRB Manual (HRP-803).
4. Identify and document specific roles and responsibilities for communicating and coordinating key information to p-Sites; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).
5. Promptly respond to questions or requests for information from study teams and IRB/Human Research Protection Program personnel at institutions who are relying on the single IRB.
6. Provide the p-Site study teams with the IRB policies of the UMN IRB. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.
7. Provide p-Site study teams with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).
8. Prepare and submit IRB applications on behalf of all p-Sites, including initial reviews, local amendments, personnel updates, local reportable events, and study wide information for continuing review.
9. Provide adequate resources and support to p-Sites. Specifically to:
	1. Have a mechanism in place to obtain and collate information from p-Site study teams regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
	2. Assist p-Site study team in ensuring consent documents follow the UMN’s template form and include applicable site-specific required language from each p-Site.
10. Notify p-Site investigators of all UMN IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events.
11. When agreed upon in coordination with the UMN IRB, promptly report to the p-Site Investigator (or designee on the p-Site study team) any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research (i.e., the specific study or studies ceded to the UMN IRB) at the p-Site.
12. If a p-Site study team does not provide the UMN PI/study team (or designee) with the required information before the continuing review application is submitted to the UMN IRB, report the absence of this information as part of the continuing review and notifying affected p-Site study team of lapse in approval for their site and any applicable corrective action plans.
13. Provide access, upon request, to study records for audit by the p-Site, the UMN IRB, and other regulatory or monitoring entities.

**I also attest as the principal investigator that:**

1. I and/or co-investigator have no outstanding requirements related to an IRB determination of serious or continuing non-compliance for a study that where I and/or co-investigator is listed as study personnel.
2. I and/or co-investigator have not had a study suspended or terminated by the IRB within the past year.

**Signature of Principal Investigator:**

By signing below, you attest that you have reviewed the responsibilities and statements as outlined above and agree to comply with these responsibilities.

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

PI Signature Date