**Attestation of PI Responsibilities when Relying on an External IRB (HRP-829)**

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When relying on an External IRB, it is important for University of Minnesota investigators to recognize that they are responsible for adhering to University of Minnesota institutional requirements, unique UMN IRB requirements related to reliance, and the requirements of the external IRB. The following should be read carefully, as by signing this attestation, 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:**

1. Obtaining IRB approval from the external IRB.
2. Paying through a grant, sponsor, department or other means any IRB fees related to the use of an external IRB.
3. Communicating information about study progress to the external IRB via the mechanism established for such communications (e.g., either to the IRB directly, or to the lead study team or coordinating center).
4. Tracking study personnel updates, ensuring personnel are qualified and appropriately trained to perform their roles, and providing information about relevant personnel changes to the UMN IRB as well as the external IRB (including confirming personnel are qualified and appropriately trained) to the external IRB when required and via the mechanism established for such communications (e.g., either to the IRB directly, or to the lead study team or coordinating center).
5. Reporting unanticipated problems, noncompliance, and significant new information to the UMN IRB as well as the external IRB via the mechanism established for such communications.
6. Complying with the external IRB’s policies (e.g., reporting noncompliance, unanticipated problems, and subject complaints) which may differ from the UMN IRB.
7. Complying with the determinations of the external IRB.
8. Using the most current IRB-approved documents, including the protocol, consent forms, and recruitment documents.
9. Complying with applicable local context requirements of the UMN IRB (see WORKSHEET: Local Context Review for Relying on an External IRB (HRP-832).
10. Working with the lead investigator to make any local updates to the protocol or other approved documents
(e.g., consent form or recruitment materials), and ensuring the external IRB approves these changes before they are implemented.
11. Complying with all other relevant local institution committees and/or offices requirements that are not related to IRB review.
12. Complying with all other relevant local institution committees and/or offices requirements for post-IRB approval changes that may not require UMN IRB review but are subject to review prior to implementation (see WORKSHEET: Ancillary Review Matrix (HRP-309)).

**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