ATTESTATION OF LOCAL SITE PRINCIPAL INVESTIGATOR RESPONSIBILITES

When to use this form

Children's Wisconsin guidance *Multi-site Projects and Investigator Responsibilities* states that there must be a qualified CW local site PI to oversee all activities occurring at Children's. The qualifications are defined in CW Administrative Policy entitled *CRI – HRPP Conduct of Research on Human Subjects*.

The CW local site PI must be identified via this attestation signed by the individual designated to serve in this capacity, and this attestation must be included in Section 52 when a single submission is deemed appropriate for a study involving CW and MCW/FH/Versiti. This will be verified during CW Local Context review. The submission will not be able to move forward for IRB review until this has been completed.

Statement of responsibilities:

1. I have reviewed the proposal and affirm that I will conduct the project in full compliance with the CW Federalwide Assurance (FWA), policies of CW HRPP, corporate compliance, and other institutional policies and guidance related to the conduct of research at this institution, and all applicable federal, state, tribal, and local laws and regulations.
2. I will employ and assume the responsibility for the informed consent process in order to ensure that potential subjects understand the purpose of the project, the procedures they are being asked to undergo, the potential risks, benefits, and alternatives to participating in the project, their rights as a project subject, and have sufficient time to make a decision about participating. I will not enroll any subject in the project or conduct project procedures until such informed consent is obtained, unless waived by the IRB or record.
3. I will ensure that subjects are kept fully and promptly informed of any new information that may affect their willingness to continue to participate in the project.
4. I will maintain current and accurate records of data, outcomes and adverse events. I will ensure the privacy of subjects and maintain the confidentiality and security of research data in accordance with HIPAA, the CW HRPP SOP Manual and CW corporate compliance policies.
5. I will report, in a timely manner, all reportable events in accordance with the policies of the IRB of record and CW HRPP and make a reasonable effort to ensure that subjects who have suffered an adverse event associated with participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
6. I understand that it is my responsibility to submit the project in a timely manner for the Continuing Progress Review in order to obtain IRB renewal/approval, when required. I am aware that failure to do so will result in a lapse of project approval and all project activities must halt.
7. I agree to follow the protocol as approved by the IRB of record. All protocol deviations will be reported in accordance with procedures of the IRB or record and consistent with CW HRPP SOP Manual. Documentation of protocol deviations will be kept in the project regulatory files, and if applicable, in the subject's project files.
8. I will ensure that the project coordinators, co-investigators, and other research staff understand their association with and role in this project and will only delegate responsibilities to persons currently named on the IRB submission. I will provide access to a copy of the project protocol for the project coordinator(s), co-investigator(s) and other research staff. I will also ensure that all members of the research team have complied with CW Training Requirements outlined in the CW HRPP SOP Manual.
9. I have identified and disclosed all actual or perceived conflicts of interest in accordance with CW policies.

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By signing below, you acknowledge that you will assume the responsibility as CW Local Site Principal Investigator for this study.

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Signature of Local Site Principal Investigator accepting responsibilities for this study conduct at Children's Wisconsin