**AGREEMENT OF**

**INVESTIGATOR RESPONSIBILITES**

1. I have reviewed the proposal and will conduct the project in full compliance with the Federal Wide Assurances (FWA), institutional policies and applicable federal,state, tribal, and local 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 inthe 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.

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 the data in accordance with *IRB SOP: Privacy and Confidentiality*.

5. I will report to the IRB in a timely manner, all reportable events according to MCW IRB policy 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 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 MCW IRB. All protocol deviations will be reported to the IRB in accordance with MCW IRB procedures. 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. 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 *IRB SOP: Human Subject Research Protections Training Requirements*

9. I have identified and disclosed all actual or perceived conflicts of interest in accordance with MCW policies.

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Signature of Incoming Principal Investigator Date

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Print Name