***Wayne State University’s Institutional Review Boards (IRBs)***

PH1, MI, MP2 – Medical, B3 – Social, Behavioral, Education

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| **Instructions:** When WSU is the IRB of record, complete and submit this form to the WSU IRB as it pertains to the relying (non-WSU) institution. The completed form may be uploaded into eProtocol when submitting an amendment to add site info. | | | | |
| 1. | **Study Title:** | | | |
| 2. | **Study ID#:** | | | |
| 3. | **WSU PI:** | | | |
| 4. | **Relying Institution:** | | | |
| 5. | **Relying Institution PI:** | | | |
| **Project Specific Questions: Please complete this section for each study.** | | | | |
| 6. | **Are there any community or cultural differences for the local population of subjects that require consideration?**  No  Yes- Describe: | | | |
| 7. | **Are there any local or institutional policies or requirements that would affect the conduct or approval of the research, including any local ancillary reviews?**  No  Yes- Describe: | | | |
| 8. | **Provide any boilerplate language that must be added to the WSU IRB approved informed consent form(s) that is standard language required by the relying institution for this study, such as language pertaining to availability of treatment and compensation for injury, payment or reimbursement of research costs incurred by participants, confidentiality, contraception, or local contacts for participants’ questions:** | | | |
| 9. | **Acknowledge below that if this project involves protected health information as defined by HIPAA where the relying institution is the covered entity, the relying institution assumes responsibility for reviewing HIPAA authorization language or requests for waivers of HIPAA authorization:**  Acknowledged  Study Does Not involve PHI | | | |
| 10. | **Acknowledge that the relying institution will perform its own conflict of interest review under its relevant policies and will provide WSU with any resulting conflict of interest determinations, prohibitions, and management plans and any applicable updates.**  Acknowledged | | | |
| 11. | **Acknowledge below that the relying institution is responsible for reviewing the congruence of any contract proposal with that institution for this study with the consent form and providing to the WSU IRB congruent language, such as compensation for injury:**  Acknowledged  Not Applicable | | | |
| 12. | **Acknowledge that the relying site has confirmed that all key personnel at the site have completed appropriate training and that any new key personnel added later will be confirmed by the relying site. Also confirm that the resources are available locally to conduct the study at this site.**  Acknowledged | | | |
| ***Complete the following questions ONLY if the relying institution is outside the state of Michigan; otherwise, proceed to Question 14.*** | | | | |
| 13A. | **Are there any international and/or state laws and corresponding institutional policies regarding legally authorized representatives, if applicable to this study?**  Yes- Describe:  No  Not Applicable | | | |
| 13B. | **Is 18 the age of majority?**  Yes  No- Identify the age of the majority: | | | |
| 13C. | **Are there any international and/or state laws or requirements that the Reviewing IRB will need to consider when reviewing this study?**  Yes- Describe:  No | | | |
| **Complete the following question ONLY if WSU and the relying institution are using the SMART IRB agreement; otherwise, proceed to Question 15.** | | | | |
| 14. | **Does the relying institution agree to follow the SMART IRB SOPs with respect to the study referenced above?**  Yes-  No Describe (e.g. use of own policies and procedures): | | | |
| **Institutional Questions – Complete this section only if this Institution has not previously completed this section OR if the answers are different than previous projects.** | | | | |
| 15. | **Has the relying institution’s FWA been extended to non-federally funded research?**  Yes  No | | | |
| 16. | **Identify the office and person at the relying institution responsible for the oversight of the conduct of the research.** | | | |
| Office Name: | | | |
| Responsible Person: | | | |
| Phone number: | Email address: | | |
| Responsibilities include:   * 1. **Ensuring the initial and ongoing qualifications of investigators and research staff;**   2. **Overseeing the conduct of the research;**   3. **Monitoring protocol compliance;**   4. **Maintaining compliance with state, local, and institutional requirements related to the protection of human subjects; and**   5. **Providing a mechanism to receive and address concerns from local subjects and others about the conduct of the research.** | | | |
| **If the Institution is NOT Accredited by AAHRPP, please describe how this person ensures the safe and appropriate performance of the research at the relying institution, including all of the above (please feel free to attach policy/procedure):** | | | |
| 17. | **Identify the office and person at the relying institution responsible for identifying, managing, and reporting to the WSU IRB potential unanticipated problems and/or serious or continuing non- compliance, and audit findings that represent reportable information; if using SMART IRB, identify only if other than the SMART IRB POC.** | | | |
| **Office Name:** | | | |
| Responsible Person: | | | |
| Phone Number: | | Email Address: | |
| **If the Institution is NOT Accredited by AAHRPP, describe how potential unanticipated problems and/or serious or continuing noncompliance is identified and managed (please feel free to attach policy/procedure):** | | | |
| 18. | **Identify the office and person at the relying institution who should receive notifications of the following; if using SMART IRB, identify only if other than the SMART IRB POC.**   1. **Reviewing IRB review decision(s) (e.g., approval, disapproval, required modifications) regarding the identified study;** 2. **Reviewing IRB approved changes to the study;** 3. **Closure letters;** 4. **HRPP Site Visit Report;** 5. **Lapses in IRB approval for the study and any applicable corrective action plans;** 6. **Reviewing IRB review decisions, findings, and actions (including any suspension or termination of IRB approval) regarding unanticipated problems, subject injuries, and significant subject complaints in the study; and** 7. **Reviewing IRB findings and actions (including any suspension or termination of IRB approval) regarding serious or continuing or apparent serious or continuing noncompliance in the study and**   **any required remediation actions.** | | | |
| **Office name:** | | | |
| Responsible Person: | | | |
| Phone Number: | | | Email Address: |
| **Note that the WSU PI is responsible for providing copies of IRB-approved materials to the relying institution’s study team.** | | | |
| 19. | **If the Institution is NOT Accredited by AAHRPP, describe the relying institution’s process to receive and address concerns from subjects and others about the conduct of the research (please feel free to attach policy/procedure):** | | | |
| 20. | **If using the SMART IRB agreement, is the online reliance system being used, or a SMART IRB acknowledgement?** | | | |