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| **Instructions** | | | | |
| * Complete this template when requesting a change in Principal Investigator. * CLICK™ IRB   + Include the template with a Modification or a Modification and Continuing Review Submission.   + Select Modification scope “Other Parts of the Study” to change the Principal Investigator in the Basic Information SmartForm, Question 4.   + Upload this completed template to the “Supporting Documents” SmartForm page. * See HRPP Manual Section 4-9, Designation as Principal Investigator, and 4-6, Responsibilities of Investigators, for more information * If the project has enrolled subjects, the Compliance Office will typically perform a site visit of the project. This will typically occur prior to the modification approval to transfer oversight responsibility to the new PI. | | | | |
| **Complete this section if you are the PRINCIPAL INVESTIGATOR CURRENTLY LISTED ON THE STUDY** | | | | |
| **Enter the Study ID:** | | | | |
| As the Principal Investigator, my signature below indicates that I:   * Relinquish my role in this project as Principal Investigator. * Transfer oversight responsibility to the new Principal Investigator. * Have or will complete any change in PI notification, approval, or other requirements as needed with appropriate MSU offices (e.g. OSP/CGA, Business Connect) or with any other entities as otherwise required in conjunction with the NEW Principal Investigator. | | | | |
| Name: | | Signature: | Date: | |
| If the current Principal Investigator is no longer available (e.g. death, incapacity, left the university), please explain: | | | | |
| **Complete this section if you are the NEW PRINCIPAL INVESTIGATOR** | | | | |
| PIs have additional responsibilities for the oversight and conduct of human subject research studies, including hiring qualified staff, ensuring that the staff have current training on ethical human subject research and applicable rules, following the IRB approved research study, promptly reporting any non-compliance and unanticipated problems, maintaining IRB approval throughout the duration of the research, and being involved in or maintaining oversight of the recruitment, consent, and research procedures. *See HRPP Manual 4-9 “Principal Investigator” for who can be a PI on human research study.*  As the NEW Principal Investigator, my signature below indicates that I:   * Accept responsibility for conducting the proposed research in accordance with the protections of human subjects as specified by IRB, including the supervision of all co-investigators and research personnel. * Am ultimately responsible for the conduct of the study and that I am now responsible for all activities conducted under this project, including all previous activities that took place before accepting responsibility to be the PI. * Have or will complete any change in PI notification, approval, or other requirements as needed with appropriate MSU offices (e.g. OSP/CGA, Business Connect) or with any other entities as otherwise required in conjunction with the CURRENT Principal Investigator. * I agree to comply with all applicable MSU policies and procedures, and applicable federal, state and local laws.   Specific responsibilities of PIs include, but are not limited to:   1. Ensure that individuals conducting human subject research (e.g. research staff) receives appropriate training prior to contact with research subjects or their identifiable private information. See HRPP Manual 11-1-A “Education: Investigators and Research Staff.” 2. Maintain adequate and appropriate oversight over the conduct of the research study. Co-investigators and other members of the research team must adhere to appropriate policies and ethical standards related to the protection of human subjects. The PI is held responsible for the conduct of the research personnel (e.g. co-investigator, investigators, and research staff). 3. Use sound scientific study design in the research protocol and obtain peer review of the research study as appropriate, e.g., thesis committee review, sponsor peer review, academic unit review. See HRPP Manual 6-2-A “Minimization of Risks: Sound Research Design.” 4. Use research designs that protect human subjects’ privacy and confidentiality of their information appropriately. See HRPP Manual 6-6 “Privacy, Confidentiality, and Anonymity.” 5. Ensure that adequate resources are available to protect human subjects during the proposed research. See HRPP Manual 6-2-B “Minimization of Risks: Adequate Resources.” 6. Ensure informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, 45 CFR 46.116 and/or 21 CFR 50 Subpart B. 7. Obtain IRB approval or an exempt determination before involving human subjects in research.    1. Submit an application to the MSU IRB and obtain IRB approval of any planned activity that meets the definition of research involving a human subject (Common Rule 45 CFR 46), or the definition of clinical investigation involving a human subject (FDA regulations 21 CFR 50 and 56). See HRPP Manual 4-3 “Determination of Human Subject Research.”    2. Obtain IRB approval (or reliance) at each engaged non-MSU performance site. See HRPP Manual 6-9-F “Special Considerations: Multiple Research Sites,” 8-2 “Expedited Review Procedure,” and 8-5 “Initial Review.”    3. Submit an application to the MSU IRB for a determination of any human subject research that may be exempt. See HRPP Manual 8-1 “Exemptions.” 8. For studies where the exempt category requires limited IRB review under the Revised Common Rule (2018 Requirements):    1. Report any proposed changes in the research study that may impact the limited IRB review criteria.    2. For Exemption Category (2)(iii) and 3(iii), any proposed change to the provisions to protect the privacy of subjects and to maintain the confidentiality of data or that may impact those provisions must be submitted as a Modification for IRB review and approval before initiation of the changes.    3. Submit a study closure. 9. Report any of the following to the MSU IRB (see HRPP Manual 4-8 “Reporting Policy”):    1. Any unanticipated problems involving risks to subjects or others. See HRPP Manual 9-1 “Unanticipated Problems Involving Risks to Subjects or Others.”    2. Any potential or confirmed non-compliance with the regulations or the requirements or determinations of the IRB. See HRPP Manual 9-2 “Noncompliance.”    3. Emergency use of investigational drugs or devices. See HRPP Manual 7-3 “Emergency Use of Investigational Drugs and Devices.”    4. Premature completion of the study, completion of the study, or closure of the research. See HRPP Manual 8-9 “Closure.”    5. Any modifications, information, or unexpected or adverse events that would increase the risk or change the status of a study determined exempt by the IRB. See HRPP Manual 8-1 “Exemptions.”    6. Any subject complaints, including exempt studies. See HRPP Manual 9-4 “Subject Complaints.”    7. Any other circumstance that affects the rights and/or welfare of research subjects. 10. Obtain prior approval from the IRB for any modifications of the previously approved non-exempt research, including modifications to the informed consent process and document, except those necessary to eliminate apparent immediate hazards to subjects. See HRPP Manual 8-6 “Modifications to an Approved Research Study.” 11. When continuing review is required, submit an application for renewed approval to the IRB for non-exempt research (i.e., progress reports, data safety or monitoring reports, activities, events, and/or information) as requested and in sufficient time to allow for IRB review prior to the expiration date of current approval. See HRPP Manual 8-7 “Renewed Approval.” 12. Keep records relating to the research as required by MSU and applicable regulations after completion of the research study, for a minimum of three to six years depending on funding agency and type of record. This requirement also applies to research records for student research conducted under the supervision of the PI. See HRPP Manual 4-7 “Record Keeping” and MSU guidelines on “Research Data: Management, Control, and Access.” 13. If applicable, keep a log documenting oral consent process. See HRPP Manual 6-4-A “Informed Consent: Documentation of Informed Consent.” 14. Post the clinical trial consent form or assure such posting takes place, when required. See HRPP Manual 6-4-F “Posting of Clinical Trial Consent Forms.” | | | | |
| Name: | Signature: | | | Date: |