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| **Instructions** | | | | |
| * Single IRB Requirements:   + Revised Common Rule: For non-exempt studies funded or supported by a federal department or agency that had adopted the Revised Common Rule, a single IRB is required for any institution located in the United States that is engaged in cooperative research for that portion of the research that is conducted in the United States.   + National Institutes of Health: The Final NIH Policy on Use of a Single IRB for Multi-Site Research establishes the expectation that all domestic sites participating in multi-site studies involving non-exempt human subjects research funded by NIH will use a single Institutional Review Board (sIRB). * Complete this form when a federal department or agency grant proposal, including NIH, may involve a sIRB. * If you are unsure whether you need to submit this form or the HRP-513 - Template - External IRB Request, please contact [irbreliance@ora.msu.edu](mailto:irbreliance@ora.msu.edu). * See HRPP Manual 2-2-F-iii, Use of a Single IRB (U.S. Department of Health and Human Services, National Institutes of Health) for more information. * See HRPP Manual 2-2-G, Revised Common Rule Single IRB Requirement for more information. * Note: MSU does not typically enter into a reliance agreement for exempt research. Please submit an exempt application to the MSU IRB for a determination. For questions, please contact [irbreliance@ora.msu.edu](mailto:irbreliance@ora.msu.edu). * Click™ IRB   + Include the template with a New Study Submission. YOU DO NOT NEED TO COMPLETE ANY OTHER TEMPLATES AT THE TIME OF sIRB SUBMISSION.   + Upload this completed template to the Basic Information SmartForm page, Question 10. | | | | |
| **Complete Questions 1 – 13.** | | | | |
| 1 | Study title: | | | |
| 2A | Select the federal department(s) or agency(ies) to which a proposal will be submitted. *If the federal department or agency is not on the list below, please contact* [*IRBreliance@ora.msu.edu*](mailto:IRBreliance@ora.msu.edu) *to determine whether the Revised Common Rule Single IRB requirement applies to your study.* | | | |
| Agency for International Development  Agriculture  Central Intelligence Agency  Commerce (National Institute of Standards & Technology)  Defense  Education  Energy  Environmental Protection Agency  Health and Human Services (e.g. Agency for Healthcare Research and Quality, CDC, NIH, SAMHSA)  Homeland Security  Housing and Urban Development  Labor  National Aeronautics & Space Administration  National Science Foundation  Office of the Director of National Intelligence  Social Security Administration  Transportation  Veterans Affairs | | | |
| 2B | Identify the NIH institute or center to which a proposal will be submitted (if applicable): | | | |
| 2C | Submission deadline for proposal submission: | | | |
| 3 | Indicate the external sites (non-MSU) where this research will be conducted and collaborations with any of the following institutions or individuals from the following institutions for this research and the name(s) of the Principal Investigator at those sites: | | | |
|  | Genesys Health System | Name of Site PI: |  |
|  | Henry Ford Allegiance Health | Name of Site PI: |  |
|  | Hurley Medical Center | Name of Site PI: |  |
|  | McLaren Health Care | Name of Site PI: |  |
|  | Memorial Healthcare | Name of Site PI: |  |
|  | Mercy Health Saint Mary’s | Name of Site PI: |  |
|  | Michigan Department of Health and Human Services | Name of Site PI: |  |
|  | Michigan Public Health Institute | Name of Site PI: |  |
|  | MidMichigan Health | Name of Site PI: |  |
|  | Munson Medical Center | Name of Site PI: |  |
|  | Pine Rest Christian Mental Health Services | Name of Site PI: |  |
|  | Providence-Providence Park Hospital | Name of Site PI: |  |
|  | Sparrow Health Systems | Name of Site PI: |  |
|  | Spectrum Health System | Name of Site PI: |  |
|  | UP Health System Research - Marquette | Name of Site PI: |  |
|  | Van Andel Research Institute | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
|  | Other | List: | Name of Site PI: |  |
| 4 | Research may involve (select all that apply):  Children  Children who are wards of the state  Cognitively impaired adults  Neonates of uncertain viability  Nonsignificant risk device  Non-viable neonates  Pregnant women  Prisoners  Students / Employees  Waiver / alteration of the consent process  Waiver of consent documentation  Waiver of consent for emergency research  Waiver of HIPAA authorization  Waiver/alteration of the consent process | | | |
| 5 | Research involves (select one):  Minimal risk  Greater than minimal risk | | | |
| 6 | Research will be conducted in:  Within the United States  Michigan  Outside of Michigan, please describe:  Internationally (outside the United States), please describe: | | | |
| 7 | Estimated duration of the study (including analysis of private identifiable data). | | | |
| 8 | Select proposed sIRB type:  Requesting use of an External (non-MSU) IRB   * Answer question 6 of the Basic Information SmartForm as Yes. * Please note that an sIRB designation letter will be provided from MSU to confirm that MSU has agreed to use another IRB as IRB of record. * Please note that if the funding proposal receives a JIT notice, while MSU HRPP will work with the MSU research team and the external IRB to assist in meeting deadlines, the timeline for obtaining required IRB approval will be dependent upon the external IRB.   Requesting MSU serve as the IRB   * Answer question 6 of the Basic Information SmartForm as No. * Please note that documentation of the sIRB designation will be requested from the sites to confirm that they have agreed to use MSU as the IRB of record.   Unsure of which institution will serve as the sIRB | | | |
| 9 | Please explain the selection of the proposed sIRB: | | | |
| 10 | Costs. Acknowledge below the following MSU requirements regarding IRB costs:   * When MSU serves as the sIRB, researchers cannot include direct costs to support the administrative tasks of supporting a sIRB in the budget. * When another institution’s IRB serves as the sIRB, the federal department or agency’s requirements related to costs must be followed. Please consult with the federal department or agency.   Acknowledged | | | |
| 11 | Genomic Data Sharing. The NIH sIRB Policy does not apply to IRB review of the investigator’s proposal for data submission under the NIH Genomic Data Sharing Policy. Genomic Data Sharing certification must be provided for all sites contributing samples through a multi-center or single site certification. For a multi-center certification the primary site may submit one Institutional Certification indicating that they are providing certification on behalf of all collaborating sites. Alternatively, each site providing samples may provide their own single site Institutional Certification.  Does the study involve NIH Genomic Data Sharing certification?  Yes  No  Not Applicable, Not an NIH Proposal | | | |
| If you answered yes, complete 11A. | | | |
| 11A | What method of Genomic Data Sharing certification is planned?  Single Site Certification  Multi-Center Certification  Please explain your selection. | | | |
| 12 | Acknowledge below that after the sIRB review is complete, the PI will be asked to perform the “Withdraw” action in Click™ to allow submission of a complete IRB study or external IRB request upon notice of potential funding (e.g. just in time). The sIRB submission is to determine the sIRB only and does not permit researchers to conduct any human subject research.  Acknowledged | | | |
| 13 | Name of individual completing the form: | | | |