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| **Instructions** | | | | | | | |
| * For multi-site non-exempt research with engaged external sites, arrangements may be made for institutions to rely on one another for IRB review. MSU may enter into a written agreement (Institutional Authorization Agreement (IAA) or use the SMART IRB) to rely on another institution’s IRB review (i.e. an External IRB). Each IRB reliance is situation and context-dependent and the process may vary, depending upon the type of reliance agreement. The HRPP office coordinates the IRB reliance process to request use of an External IRB. * Complete this template for all requests to rely upon an External IRB. * *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 [ORA.irbreliance@msu.edu](mailto:ORA.irbreliance@msu.edu). * Click™ IRB   + Include the template with a New Study Submission.   + Upload the completed template to the Basic Information SmartForm page, Question 11. | | | | | | | |
| **Complete Questions 1 – 12 for All Requests to Use an External IRB.** | | | | | | | |
| 1 | Study title. | | | | | | |
| 2 | Please describe any funding that is or may be associated with this activity, including pending proposals. If there are subcontracts, please identify the primary sponsor and the subcontractor(s). | | | | | | |
| 3 | Indicate the external sites (non-MSU) where this research will be conducted and collaborations with any of the following organizations for this research and the name(s) of the Principal Investigator (PI) at those sites: | | | | | | |
|  | | Ascension Genesys Hospital | | | Name of Site PI: |  |
|  | | Henry Ford Health | | | Name of Site PI: |  |
|  | | Henry Ford Allegiance Health / Henry Ford Jackson Hospital | | | 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 / Trinity Health Grand Rapids Hospital | | | 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 / MyMichigan Health | | | Name of Site PI: |  |
|  | | Munson Medical Center / Munson Healthcare | | | Name of Site PI: |  |
|  | | Pine Rest Christian Mental Health Services | | | Name of Site PI: |  |
|  | | Sparrow Health Systems | | | Name of Site PI: |  |
|  | | Spectrum Health System / Corewell Health | | | Name of Site PI: |  |
|  | | UP Health System - 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: |  |
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|  | | Other | List: | | | Name of Site PI: |  |
|  | | Other | List: | | | Name of Site PI: |  |
| 4 | Please briefly describe what human research activities will occur at the sites. | | | | | | |
| 5 | Research will be conducted:  Within the United States  Michigan  Outside of Michigan, please describe:  Internationally (outside the United States), please identify the country(ies): | | | | | | |
| 6 | 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 | | | | | | |
| 7 | Research involves (select one):  Minimal risk  Greater than minimal risk | | | | | | |
| 8 | Estimated duration of the study (including analysis of private identifiable data). | | | | | | |
| 9 | Check the boxes to acknowledge or indicate that the requirement is not applicable to this study: | | | | | | |
|  |  | The MSU PI is responsible for assuring compliance with the determinations and requirements of the external IRB. The MSU PI must assure that they and their research team will cooperate as needed in the external IRB’s initial and continuing review (when required), review of modifications/amendments, recordkeeping, and reporting. All information requested by the MSU HRPP and by the external IRB will be provided in a timely manner.  Acknowledged | | | | | |
|  |  | The MSU PI is responsible for reporting promptly to the external IRB any proposed changes to the research, or for collaborating with the external site PI to promptly report to the external IRB any proposed changes. The MSU PI cannot implement changes to the research (including changes in the consent forms) without prior external IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.  Acknowledged | | | | | |
|  |  | Any data safety monitoring reports that the MSU PI or study team receives must be provided to the external IRB or to the external site PI in accordance with the external IRB’s requirements.  Acknowledged  Not Applicable | | | | | |
|  |  | When MSU researchers are responsible for enrolling research subjects and consent will be obtained, the MSU researchers must obtain, document, and maintain records of consent for each subject or each subject’s legally authorized representative in the manner required by the external IRB.  Acknowledged  Not Applicable | | | | | |
|  |  | MSU researchers are responsible for submitting reportable events to the external IRB or to the external site PI in accordance with the external IRB’s requirements and timelines.  Acknowledged | | | | | |
|  |  | In addition to reporting obligations with the external IRB, there is still an ongoing obligation for the MSU PI to report information to the MSU HRPP. See HRPP Manual 8-11, External IRB Submissions, for reportable events.  Acknowledged | | | | | |
|  |  | If a new consent form is added after an MSU reliance acknowledgement letter is issued, the new consent form must be submitted to the MSU HRPP as an External IRB Update in Click for review prior to its use.  Acknowledged | | | | | |
|  |  | If a consent form is modified after an MSU reliance acknowledgement letter is issued, the modified consent form must be submitted to the MSU HRPP as an External IRB Update in Click for review prior to its use if changes are made to MSU local context information such as:   * Confidentiality * Subject injury * Costs or compensation * Health Insurance Portability and Accountability Act (HIPAA) information   Acknowledged  Not Applicable | | | | | |
|  |  | Any research site(s) that will be engaged in research and/or clinical investigation with human subjects in addition to those initially approved with the external IRB must be submitted to the MSU HRPP to determine whether the addition will impact the reliance. This includes new or modified collaborating subcontractors. If engaged, those sites will need to enter into their own reliance with the external IRB.  Acknowledged | | | | | |
|  |  | The MSU study team will provide timely responses to requests for information from the MSU HRPP about the study’s current status. The MSU study team will notify the MSU HRPP when the study is closed or when MSU’s engagement in the study has ended.  Acknowledged | | | | | |
| 10 | Describe all the human research activities that MSU individuals (e.g. faculty, staff, students, agents) will conduct. | | | | | | |
| 11 | Describe how the MSU PI will maintain oversight of MSU’s engagement in this study. *Please see HRPP Manual 4-6, Responsibilities of Investigators, and HRPP Manual 8-11, External IRB Submissions, for more information.* | | | | | | |
| 12 | Select external IRB type:  Independent (Commercial) IRB – Complete Section A  Institutional IRB (e.g. University IRB, Hospital IRB) – Complete Section B  National Cancer Institute Central Institutional Review Board (NCI CIRB) – Complete Section C  *If you have questions about the external IRB type, please contact* [*ORA.irbreliance@msu.edu*](mailto:ORA.irbreliance@msu.edu) *for assistance.* | | | | | | |
| **Section A – Independent (Commercial) IRB**   * This request must be submitted and approved PRIOR TO submission of an application to an independent (commercial) IRB. * See HRPP Manual Section 1-4, Reliance on External Independent (Commercial) Institutional Review Boards, for more information. | | | | | | | |
| **Complete Questions A1 – A5 when requesting use of an Independent (Commercial IRB) as the External IRB.** | | | | | | | |
| A1 | Does the research involve any of the following? | | | | | | |
| No | | | Yes | Xenotransplantation | | |
| No | | | Yes | Embryonic stem cells | | |
| No | | | Yes | Phase I clinical trials | | |
| No | | | Yes | Review and approval by other committees – e.g. studies that involve recombinant DNA, radioisotopes, biorepositories | | |
| A2 | Is there a risk of injury to the subject(s)?  No  Yes | | | | | | |
| If yes, indicate which of the following statements in the consent form(s) will apply:  No costs will be paid standard language  Third party will pay standard language  Third party will pay clinical trial agreement dependent  *Contact* [*ORA.irbreliance@msu.edu*](mailto:ORA.irbreliance@msu.edu) *for standard language (dependent upon commercial IRB).* | | | | | | |
| A3 | Is this a study that is subject to the U.S. National Institutes of Health Single IRB policy or the Revised Common Rule single IRB requirement?  No  Yes | | | | | | |
| If yes, identify the institution that will submit the main study to the commercial IRB. *Please note all other institutions need to also submit as sites to the commercial IRB.* | | | | | | |
| A4 | Check the box to acknowledge that a finalized contract or clinical trial agreement is required before submitting to an independent (commercial) IRB.  Acknowledged | | | | | | |
| A5 | Please explain how the costs associated with review by a commercial IRB have been addressed by the sponsor. Costs include fees charged by the commercial IRB and an administrative fee charged by MSU ($500) to the sponsor. NOTE: It is important to note that the commercial IRB will charge your department if the sponsor does not pay the fees. | | | | | | |
| A6 | Upload the following documents in the SmartForm:   * Protocol (Basic Information SmartForm page, Question 11). * Draft informed consent document (Consent Forms and Recruitment Materials SmartForm page, Question 1). * Any full funding proposal, or draft or executed funding agreement. *Please note that the institution is responsible for reviewing the executed contract and the consent form(s) to assure that subject injury language is congruent. A finalized contract or clinical trial agreement is required before submitting to an independent (commercial) IRB.* (Supporting Documents SmartForm page). | | | | | | |
| **Section B - Institutional IRB (e.g. University IRB, Hospital IRB)**   * See HRPP Manual 1-3, Use of Institutional Authorization Agreements, or HRPP Manual 8-11, External IRB Submissions, for more information. * Note: If the reviewing institution’s IRB is not AAHRPP accredited (see <https://www.aahrpp.org/find-an-accredited-organization>), please contact [ORA.irbreliance@msu.edu](mailto:ORA.irbreliance@msu.edu) before submitting this template. | | | | | | | |
| **Complete Questions B1 – B4 when requesting use of an Institutional IRB as the External IRB.** | | | | | | | |
| B1 | Describe the current enrollment status of the study (e.g. planned recruitment to begin in X months, follow-up of subjects only, analysis of private identifiable data only, closed to accrual). *Please note that MSU engagement in human subject research activities cannot begin until the PI receives a reliance acknowledgement letter from the MSU HRPP regarding this study.* | | | | | | |
| B2 | Describe whether MSU individuals will enroll subjects in the study. Please indicate whether subjects will be enrolled at an MSU location. | | | | | | |
| B3 | Complete 3i – 3vi about the requested External IRB. | | | | | | |
| B3i | Activities taking place at the external site and roles (describe). | | | | | | |
| B3ii | External site FWA Number (if known). | | | | | | |
| B3iii | Name of external site PI and contact information. | | | | | | |
| B3iv | External IRB contact information. | | | | | | |
| B3v | External IRB tracking number / study ID / IRB#. | | | | | | |
| B3vi | External IRB approved level of review and category:  Expedited Review | Category  Full Board  *Please note that MSU does not enter into reliance agreements for exempt research (please do not submit this form for exempt studies).* | | | | | | |
| B4 | Requesting reliance under the SMART IRB agreement?  No  Yes  Unsure | | | | | | |
| B5 | Upload the following documents in the SmartForm:   * Protocol (Basic Information SmartForm page, Question 11). * External IRB approval letter (Supporting Documents SmartForm page). * External IRB approved consent forms (Consent Forms and Recruitment Materials SmartForm page, Question 1). * External IRB application (Supporting Documents SmartForm page). * Any full funding proposal, or draft or executed funding agreement. (Supporting Documents SmartForm page). * Any subcontract / subaward (Supporting Documents SmartForm page). | | | | | | |
| **Section C – NCI CIRB**   * See HRPP Manual 1-5, Use of the National Cancer Institute Central Institutional Review Board for more information. | | | | | | | |
| **Complete Questions C1 – C3 when requesting use of the NCI CIRB as the External IRB.** | | | | | | | |
| C1 | Cooperative Group: | | | | | | |
| C2 | Affiliate institution(s):  McLaren Greater Lansing  Sparrow Hospital  ANY sites in addition to those listed above must be submitted by the MSU HRPP to the NCI CIRB and approved by the NCI CIRB before subjects can be enrolled at those sites. | | | | | | |
| C3 | Involvement of affiliate institution (check all that apply and explain as appropriate):  Lab – Explain:  Pharmacy – Explain:  Nursing staff – Explain:  PHI – Explain:  Other – Explain: | | | | | | |
| C4 | Upload the following documents in the SmartForm:   * Protocol (Basic Information SmartForm page, Question 11) * NCI CIRB approved consent forms that include the NCI-approved MSU boilerplate text (Consent Forms and Recruitment Materials SmartForm page, Question 1). * Any full funding proposal, or draft or executed funding agreement. (Supporting Documents SmartForm page). * Any subcontract / subaward (Supporting Documents SmartForm page). | | | | | | |

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| **For MSU IRB Office Use Only – Not to be Completed by PI – Completed for Use of Independent (Commercial IRB)** | | | | | |
| StudyID: |  | Principal Investigator: | |  | |
| Michigan State University Human Research Protection Program Director or Designee | | | | | |
| My signature below indicates that this study meets the criteria to be submitted to the Commercial Institutional Review Board. | | | | | |
| Name: | | | Signature: | | Date: |