**ONLY use this template for multi-center studies where the sponsor has created the protocol and each site is following the same protocol
 (e.g. industry sponsored clinical trial).**

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| * Use this template for multi-center studies where the sponsor has created the protocol and each site is following the same protocol (e.g. industry sponsored clinical trial). If you are unsure which template to complete, please contact the IRB.
* Unless otherwise specified, provide only site specific information below.
* Not all questions or sections are applicable to every study. If the question or section is not applicable, check the “Not Applicable” box. All other questions are required.
* CLICK™ IRB:
	+ Include this template with a New Study Submission when applicable.
	+ Upload the completed template to the Basic Information SmartForm page, Question 10.
	+ Upload the entire sponsor’s protocol to the Basic Information SmartForm page, Question 10.
	+ When uploading documents to Click (e.g. consent documents, instrument), provide distinct file names.
* See the Click Quick Guides and the HRPP Manual for more information, available at hrpp.msu.edu
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| **Study Title:** |       |
| **Click Study ID (if known):** |       |
| **Sponsor (if applicable):** |       |
| **Sponsor ID (if applicable):** |       |

**1. Subject Population**

Study purposefully includes the following subject population(s)(check all that apply):

[ ]  Cognitively impaired adults

[ ]  Minors (children) (view information about the definition of a child)

[ ]  Minors who are wards of the state

[ ]  Pregnant women, fetuses, or neonates

[ ]  Prisoners

[ ]  Students

**2. Estimated Study Duration**

Provide the time estimated to complete all human subject research, including analysis of the subjects’ identifiable private information at this investigator’s sites.

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**3. Expedited Categories.**

**3A.** Please select the Expedited category(ies) and sub-categories as applicable to the study if the only involvement of human subjects in this study will be in one or more of the categories. If the study involves more than minimal risk or none apply, select “The study involves more than minimal risk or none of the expedited categories apply.”

***[ ]  The study involves more than minimal risk OR none of the expedited categories apply. IF THIS OPTION IS SELECTED, DO NOT SELECT ANY OF THE EXPEDITED CATEGORY(IES).***

[ ]  ***Expedited 1.*** Clinical studies of drugs and medical devices only when condition (a) or (b) is met. ***IF YOU SELECTED THIS CATEGORY, SELECT THE APPROPRIATE OPTION(S) BELOW.***

[ ]  (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

[ ]  (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

[ ]  ***Expedited 2.*** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture. ***IF YOU SELECTED THIS CATEGORY, SELECT THE APPROPRIATE OPTION(S) BELOW.***

[ ]  (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

[ ]  (b) from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week

[ ]  ***Expedited 3.*** Prospective collection of biological specimens for research purposes by noninvasive means.

[ ]  ***Expedited 4***. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

[ ]  ***Expedited 5.*** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

[ ]  ***Expedited 6.*** Collection of data from voice, video, digital, or image recordings made for research purposes.

[ ]  ***Expedited 7***. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**3B.** **For Studies Regulated by the U.S. Food and Drug Administration or the U.S. Department of Justice**. If you selected an expedited category, explain why the study presents minimal risk to subjects.

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**4. Risk**

**4A.** Describe the risks, considering physical, psychological, social, legal and economic risks.

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**4B.** Describe the procedures for protecting against or minimizing potential risks and provide an assessment of their likely effectiveness.

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**5. Sample Size**

**5A.** Total number of subjects who will be approached (including screen failures, controls and subject withdrawals) to reach enrollment numbers for the lifetime of the study at this investigator’s sites.

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**5B.** Total number of subjects who will be enrolled in the study at this investigator’s site.

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**5C.** Describe the rationale for the proposed sample size for the investigator’s sites.

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**6. Benefits**

Describe any potential direct benefit(s) to subjects in this study, if any and the importance of the knowledge that may reasonably be expected to result. Within the description, do not include payment to subjects as a benefit.

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**7. Screening, Recruitment, or Determining Eligibility**

**7A.** Describe how subjects will be identified and recruited, including who will perform the recruitment.

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| **7B.** The study team will obtain for the purpose of screening, recruiting, or determining the eligibility of prospective subjects (please select appropriate option(s)): | **[ ]  Not Applicable** |

[ ]  Information through oral or written communication with the prospective subject or legally authorized representative. Before the information is obtained for the purpose of screening, recruiting, or determining eligibility, consent:

[ ]  will be obtained.

[ ]  will not be obtained. *Please describe screening consent procedures in Question 8.*

[ ]  Identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. Before the information is obtained for the purpose of screening, recruiting, or determining eligibility, consent:

[ ]  will be obtained.

[ ]  will not be obtained. *Please describe screening consent procedures in Question 8.*

*Note: The revised Common Rule permits an exception from informed consent for screening, recruiting, or determining eligibility when certain criteria are met; this exception does not apply to studies subject to the Pre-2018 Common Rule Requirements and/or studies regulated by the U.S. Food and Drug Administration (FDA).*

**7B1.** Please explain your selection(s).

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**8. Consent Process**

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| **8A.** If the study involves adults, consent will be obtained from (select appropriate option(s)): | **[ ]  Not Applicable** |

[ ]  All subjects

[ ]  Some subjects

[ ]  No subjects (consent will not be obtained)

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| **8B.** If the study involves children, parental permission will be obtained from (select appropriate option(s)):  | **[ ]  Not Applicable** |

[ ]  Both parents or guardians (unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child)

[ ]  One parent or guardian

[ ]  Will not be obtained

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| **8C.** If the study involves children, child assent will be obtained from (select appropriate option): | **[ ]  Not Applicable** |

[ ]  All children

[ ]  Some children

[ ]  Will not be obtained

**8D.** Describe the consent process, including an explanation of your selection(s) above. If the study involves screening activities, please describe whether consent will be obtained and if consent will not be obtained, explain how the screening data will be used. If only some subjects will provide consent, explain who will or will not provide consent. If only some children will provide assent, explain which children will and will not provide assent.

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| **8E.** If consent will not be obtained, explain why. Describe why the research could not be practicably carried out if consent was required. If the research involves identifiable private information or identifiable biospecimens, describe why the research could not practicably be carried out without using such information or biospecimens in an identifiable format. | **[ ]  Not Applicable** |
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**8F.** If your study involves use of a consent form, complete i and ii. **[ ]  Not Applicable**

**8Fi.** Select the appropriate option(s) below for the documentation of consent.

[ ]  Will use a written consent document signed by subjects

[ ]  Will use a short form written consent document signed by subjects

[ ]  Will not obtain a signed consent document for some subjects

[ ]  Will not obtain a signed consent document for all subjects

**8Fii.** Describe when and how the subject will receive a copy of the consent form.

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**8G.** If subjects will not be signing the consent document, please explain why. If some subjects will not sign the consent document, explain who will and will not sign the consent.

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| **8H.** If the study involves cognitively impaired adults, explain the process to determine whether a subject is capable of consent, use of any legally authorized representative(s), and any assent process. | **[ ]  Not Applicable** |
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**9. Coercion or Undue Influence**

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| **9A.** If some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, describe additional safeguards that have been included in the study. | **[ ]  Not Applicable** |
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| **9B.** If you or your study team are associated with the subjects (e.g. your students, employees, colleagues, patients), explain the nature of any association and measures taken to protect subjects’ rights, including safeguards against any coercion or undue influence (e.g. pressure a subject might feel to participate based on the association). | [ ]  **Not Applicable** |
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**10. Privacy**

How will subjects’ privacy be protected? Consider the number of individuals interacting with the subject or subject’s records, location of consent process and study, presence of individuals not associated with the study, sensitivity of the research.

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**11. Withdrawal of Subjects** **[ ]  Not Applicable**

If there are any anticipated circumstances where the researcher will withdraw subjects from the study regardless of the subject’s wishes, describe the circumstances and the procedures when subjects are withdrawn from the study that will be followed locally, if different than the sponsor’s protocol, when subjects withdraw from the research.

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**12. Monitoring Plan to Assess Data to Ensure Safety of Subjects** **[ ]  Not Applicable**

Include a page reference to the monitoring plan to assess data to ensure safety of subjects in the Sponsor protocol. If there is not a monitoring plan, please explain.

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**13. Results and Data Sharing** **[ ]  Not Applicable**

**13A.** Could this research generate any results that could be clinically relevant, including individual research results, or general, or aggregate research findings?

[ ]  No

[ ]  Yes, clinically relevant individual research results

[ ]  Yes, clinically relevant general or aggregate research findings

**13A1.** If yes, explain what clinically relevant research results will be generated, whether they will be disclosed to subjects or others (e.g. subject’s primary care physician), and if so, under what conditions. Address individual research results and/or general or aggregate research findings, as appropriate. This also needs to be explained in the consent document.

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**13B.** Select all that apply:

[ ]  Overall study results will be shared directly with subjects

[ ]  Individual results or incidental findings of individual subjects will be shared with subjects or others

[ ]  Data will be submitted to a repository or database as part of data sharing agreement (e.g. genomic data sharing)

**13C.** Explain your selection(s), including how the data or results will be shared and with who (e.g. subject’s primary care physician, data repository).

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**14. Local Context and Multi-Site Study**

**14A.** Describe the locations of where the study team will obtain data through intervention or interaction with the subject or obtain the subjects’ private identifiable information.

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| **14B.** If the study will engage employees or agents of non-MSU organizations (e.g. performance sites), explain how the employees or agents will be engaged (e.g. will they perform research procedures, will they obtain informed consent from subjects). | **[ ]  Not Applicable** |
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| **14C.** If the study involves multiple performance sites, describe the methods for communicating with engaged sites related to the protection of human subjects (e.g. any potential unanticipated problems that may involve risks to subjects others). | [ ]  **Not Applicable** |
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| **14D.** If there are any cultural or local contexts or requirements that may impact the protection of human subjects or present additional risks to subjects that have not otherwise been described, please describe. If research is conducted outside the state of Michigan, this could include additional state or international requirements or laws. | [ ]  **Not Applicable** |
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| **14E.** If translations to a language other than English will be provided to subjects, describe the translation process. | [ ]  **Not Applicable** |
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**15. Resources and Financial Compensation and Costs**

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| **15A.** If someone will receive a payment for recruiting the subjects, explain the amount of payment, who pays it, who receives it, and why they are being paid. | [ ]  **Not Applicable** |
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| **15B.** If subjects will incur additional financial costs as a result of their participation in this study, explain the additional costs. | [ ]  **Not Applicable****[ ]  Unknown** |
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| **15C.** Describe any resources not otherwise described elsewhere in the submission (e.g. internal funding) for the protection of human subjects. | [ ]  **Not Applicable** |
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| **15D.** If subject’s biospecimens (even if identifiers are removed) may be used for commercial profit, describe whether the subject will or will not share in the commercial profit. *This also needs to be explained in the consent document.* | [ ]  **Not Applicable** |
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**16. Data and/or Sample(s) Management and Confidentiality**

**16A.** Select the appropriate option:

[ ]  Identifying or coded information will not be stored with the information and/or biospecimens(s)

[ ]  Identifying or coded information will be stored with the information and/or biospecimens(s)

**16B.** Please explain your selection. If you are storing identifying or coded information with the information and/or biospecimen(s), explain why identifiable or coded information and/or biospecimen(s) needs to be maintained and how long it will be necessary to maintain it.

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**16C.** Describe the procedures and safeguards you will use to secure the information and/or biospecimen(s), including during transport of information and/or biospecimen(s).

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**17. Drug and/or Device Storage, Handling, and Administration** **[ ]  Not Applicable**

Describe the procedure and plan for storage, handling, and administration of the drug and/or device so that they will be used only on enrolled subjects and be used only by authorized study personnel.

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**18. Future Research. [ ]  Not Applicable**

If the research involves the collection of identifiable private information or identifiable biospecimens, select the appropriate option:

[ ]  The subject’s information or biospecimens, even if identifiers are removed, could be used for future research studies or distributed to another investigator for future research studies

[ ]  The subject’s information or biospecimens, even if identifiers are removed, will NOT be used or distributed for future research studies

*Please be sure to carefully consider the appropriate option, as this needs to be explained in the informed consent and can limit what is done or used for future research.*

**19. MSU Additional Information**. **[ ]  Not Applicable**

Identify if your study involves any of the following: (check all that apply)

[ ]  Use of human stem cells

[ ]  Research with biospecimens will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). If so, this needs to be explained in the consent document.