**INSTRUCTIONS:**

* Use “MEDICAL TEMPLATE PROTOCOL (HRP-590)” to prepare a protocol for a biomedical study (see [InvestigatorManual(HRP-103)](https://drive.google.com/file/d/0B7644h9N2vLcOWtzU2FmSU5oS0U/edit)for a definition of biomedical research).
* Depending on the nature of what you are doing, some sections may not be applicable to your research. If so mark as “N/A”. For example, research involving a retrospective chart review may have many sections with N/A.
* Please do not delete sections if they do not apply to the study.
* We suggest that you use the word “participant” or “volunteer” rather than “subject” throughout your protocol. The reason is that “subject” has the sense of someone under the authority of the investigator while “participant” or “volunteer” has the sense of a person who understands and is an important contributor to the research.
* After you submit your protocol for review in ETHOS, your protocol will be saved there. You should use that saved version as your starting point for edits to the next version. You may choose to track protocol versions for yourself outside of ETHOS; however, you should ensure that any version you edit is the same as the most recently approved version in ETHOS.
* As you are writing the protocol, remove all instructions in red so that they are not contained in the final version of your protocol.
* To update page numbers in the Table of Contents, right click on the table and select “Update Field” and “page numbers only.”

**ANCILLARY REVIEWS**

**DO NOT DELETE. Submit the completed checklist below with your protocol.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Which ancillary reviews do I need and when do I need them?**  Refer to [HRP-309](https://drive.google.com/file/d/0B7644h9N2vLcMTl0ZE9yQkhLd3c/view) for more information about these ancillary reviews. | | | |
| **Select yes or no** | **Does your study…** | *If yes…* | ***Impact on IRB Review*** |
| **Yes**  **No** | Include Gillette resources, staff or locations? | *Gillette Scientific review and Gillette Research Administration approval is required. Contact:*  [*research@gillettechildrens.com*](mailto:research@gillettechildrens.com) | **Required prior to IRB submission** |
| **Yes**  **No** | Involve Epic, or Fairview patients, staff, locations, or resources? | *The Fairview ancillary review will be assigned to your study by IRB staff*  *Contact:* [*ancillaryreview@Fairview.org*](mailto:ancillaryreview@Fairview.org) | **Approval must be received prior to IRB committee/ designated review.**  **Consider seeking approval prior to IRB submission.** |
| **Yes**  **No** | Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection? | *The regulatory ancillary review will be assigned to your study by IRB staff*  *Contact:* [*medreg@umn.edu*](mailto:medreg@umn.edu)  *See:* [*https://policy.umn.edu/research/indide*](https://policy.umn.edu/research/indide) |
| **Yes**  **No** | Require Scientific Review? Not sure? See guidance in the [Investigator Manual (HRP-103)](https://drive.google.com/uc?export=download&id=0B7644h9N2vLcOWtzU2FmSU5oS0U). | *Documentation of scientific merit must be provided.*  *Contact:* [*hrpp@umn.edu*](mailto:hrpp@umn.edu) |
| **Yes**  **No** | Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco? | *Complete the* [*CPRC application process*](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee)*.*  *Contact:* [*ccprc@umn.edu*](mailto:ccprc@umn.edu) |
| **Yes**  **No** | Include the use of radiation?  (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy) | *Complete the* [*AURPC Human Use Application*](https://radsafety.umn.edu/human-use-application-and-resources) *and follow instructions on the form for submission to the AURPC committee.*  *Contact:* [*barmstro@umn.edu*](mailto:barmstro@umn.edu) | **Approval from these committees must be received prior to IRB approval;**  **These groups each have their own application process.** |
| **Yes**  **No** | Use the Center for Magnetic Resonance Research (CMRR) or MR at Masonic Institute for the Developing Brain (MIDB) as a study location? | *Complete the* [*CMRR pre-IRB ancillary review*](https://www.cmrr.umn.edu/preirb/user/user.php)  *Contact:* [*ande2445@umn.edu*](mailto:ande2445@umn.edu) |
| **Yes**  **No** | Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents? | *Complete the IBC application via* [*eprotocol.umn.edu*](https://eprotocol.umn.edu/userLogin.do) |
| **Yes**  **No** | Include the use of human fetal tissue, human embryos, or embryonic stem cells? | *Contact* [*OBAO*](https://research.umn.edu/units/obao/about-us/contact-us) *for submission instructions and guidance* |
| **Yes**  **No** | Include use of PHI (protected health information)?  OR  Include international collaborators that involves the collection, transmission, and storage of health data? | *If yes, HIPCO will conduct a review of this protocol.*  *Contact:* [*privacy@umn.edu*](mailto:privacy@umn.edu) |
| **Yes**  **No** | Include the use of a controlled substance? | *If yes, University Health and Safety Compliance for controlled substances will review the protocol.*  *Contact:* [*cshelp@umn.edu*](mailto:ancillaryreview@Fairview.org) | **Approval must be received prior to IRB approval.**  **These groups do not have a separate application process but additional information from the study team may be required.** |
| **Yes**  **No** | Plan to use CTSI Monitoring services, and/or have an IND, IDE, or designated NSR-IDE by the UMN IRB? | *The CTSI monitoring ancillary review will be assigned to your study by IRB staff.*  *Please note eligibility criteria* [*here*](https://ctsi.umn.edu/services/regulatory/clinical-trial-monitoring)*.*  *Contact:* [*fencl003@umn.edu*](mailto:fencl003@umn.edu) |
| **Yes**  **No** | Use data from CTSI Best Practices Integrated Informatics Core (BPIC)  Formerly the AHC Information Exchange (IE)? | *The Information Exchange ancillary review will be assigned to your study by IRB staff*  *Contact:* [*bpic@umn.edu*](mailto:bpic@umn.edu) |
| **Yes**  **No** | Use the Biorepository and Laboratory Services to collect tissue for research? | *The BLS ancillary review will be assigned to your study by IRB staff.*  *Contact:* [*bionet@umn.edu*](mailto:bionet@umn.edu) |
| **Yes**  **No** | Have a PI or study team member with a conflict of interest? | *The CoI ancillary review will be assigned to your study by IRB staff*  *Contact:* [*becca002@umn.edu*](mailto:becca002@umn.edu) |
| **Yes**  **No** | Need to be registered on clinicaltrials.gov? | *If you select “No” in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff*  *Contact:* [*fencl003@umn.edu*](mailto:fencl003@umn.edu) |
| **Yes**  **No** | Require registration in OnCore? | *If you select “No” or “I Don’t Know” in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff*  *Contact:* [*oncore@umn.edu*](mailto:oncore@umn.edu) | **Does not affect IRB approval.** |
| **Yes**  **No** | Does your research include collaborations with Tribal partners, Tribal communities, Tribal-serving institutions, or include focused recruitment of Indigenous Peoples? | *See* [*University of Minnesota Guidelines for Indigenous Research*](https://libguides.umn.edu/ResearchWithIndigenousPartners)*.* | **May not impact IRB review/approval.** |
| **Yes**  **No** | Do you propose to use eConsent via REDCap? | *REDCap Ancillary Review will be assigned to confirm IRB approval status prior to moving your eConsent to production in* [*REDCap*](https://ctsi.umn.edu/tools/redcap)*.* | **Does not affect IRB approval.** |
| **Yes**  **No** | Propose to use [Community- University Health Care Center](https://www.google.com/url?client=internal-element-cse&cx=002834015805923805805:c-0k--9bdkk&q=https://cuhcc.umn.edu/&sa=U&ved=2ahUKEwistMi00onuAhWVGFkFHUbnAncQFjABegQIAhAB&usg=AOvVaw2R6-oZwyd0n55FZTLJdCRi) (CUHCC) resources or include access to patients or their data? | *Contact* [*hlogren@uumn.edu*](mailto:hlogren@uumn.edu) |

**PROTOCOL COVER PAGE**

|  |  |
| --- | --- |
| **Protocol Title** | This should align with the ETHOS submission title. |
| **Principal Investigator/Faculty Advisor** | Name: |
| Affiliation:  UMN    Fairview    Gillette |
| UMN Home Department: |
| UMN Home Dept ID:  Note: New IRB applications from the Medical School must include documentation of resource review and approval.  Upload approval documentation in ETHOS.  Applications from the Medical school lacking this approval will be withdrawn by the IRB. |
| Telephone Number: |
| Email Address: |
| **Student Investigator** | Name: |
| Current Academic Status (Student, Fellow, Resident): |
| Department: |
| Telephone Number: |
| Institutional Email Address: |
| **Scientific Assessment** | Choose an item. |
| **IND/IDE # (if applicable)** | If not applicable, insert N/A. |
| **IND/IDE Holder** | If not applicable, insert N/A. |
| **Sponsor-Investigator: Please check box** | This study will comply with ICH GCP requirements for drugs, biologics, and devices.  If this is not a Sponsor-Investigator study, remove this statement. |
| **Investigational Drug Services # (if applicable)** | If not applicable, insert N/A. |
| **Version Number/Date:** | Include the current version number and date of this protocol. |

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

Table of Contents

[1.0 Objectives 8](#_Toc131576503)

[2.0 Background: 8](#_Toc131576504)

[3.0 Study Endpoints/Events/Outcomes 8](#_Toc131576505)

[4.0 Study Intervention(s)/Investigational Agent(s): 8](#_Toc131576506)

[5.0 Procedures Involved 10](#_Toc131576507)

[6.0 Data and Specimen Banking 11](#_Toc131576508)

[7.0 Sharing of Results with Participants 11](#_Toc131576509)

[8.0 Study Population 13](#_Toc131576510)

[9.0 Vulnerable Populations 14](#_Toc131576511)

[10.0 Local Number of Participants 16](#_Toc131576512)

[11.0 Local Recruitment Methods 16](#_Toc131576513)

[12.0 Withdrawal of Participants 18](#_Toc131576514)

[13.0 Risks to Participants 18](#_Toc131576515)

[14.0 Potential Benefits to Participants 18](#_Toc131576516)

[15.0 Statistical Considerations 19](#_Toc131576517)

[16.0 Health Information and Privacy Compliance 19](#_Toc131576518)

[17.0 Health Science Technology (HST) HIPAA Compliant Devices and Data Storage 21](#_Toc131576519)

[18.0 Confidentiality 23](#_Toc131576520)

[19.0 Provisions to Monitor the Data to Ensure the Safety of Participants 24](#_Toc131576521)

[20.0 Provisions to Protect the Privacy Interests of Participants 25](#_Toc131576522)

[21.0 Compensation for Research-Related Injury 25](#_Toc131576523)

[22.0 Consent Process 26](#_Toc131576524)

[23.0 Setting 30](#_Toc131576525)

[24.0 Multi-Site Research 30](#_Toc131576526)

[25.0 Coordinating Center Research 31](#_Toc131576527)

[26.0 Resources Available 32](#_Toc131576528)

[27.0 References 32](#_Toc131576529)

**ABBREVIATIONS/DEFINITIONS**

Include any abbreviations or definitions for key or technical terms you use in your protocol.

* [Abbreviation/Definition 1]
* [Abbreviation/Definition 2]
* [Abbreviation/Definition 3]

# **Objectives**

## **Purpose:**

Describe the purpose, specific aims, or objectives. If this protocol involves the treatment or prevention of cancer complete required notification and/or application processes for the [Cancer Protocol Review Committee](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee)*.*

# **Background:**

## **Significance of Research Question/Purpose:**

Describe the relevant prior research and gaps in current knowledge for your research question.

## **Preliminary Data:**

Describe any relevant preliminary data.

## **Existing Literature:**

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

# **Study Endpoints/Events/Outcomes**

## **Primary Endpoint/Event/Outcome:**

Describe the primary study endpoint, event, or outcome you will be evaluating or observing. Provide a) the testable hypothesis or b) a statement that this is either a hypothesis generating study or a descriptive study.

## **Secondary Endpoint(s)/Event(s)/Outcome(s):**

Describe any secondary study endpoints, events, or outcomes you will be evaluating or observing. Provide a) the testable hypotheses associated with each or b) a statement this is either a hypothesis generating study or a descriptive study.

# **Study Intervention(s)/Investigational Agent(s):**

## **Description:**

Describe the study intervention(s) and/or investigational agent(s) (e.g., drug, device) that is/are being evaluated. (Note that you will list information about other drugs or devices required for participation, but which are not necessarily being evaluated, later in the protocol.)

For studies involving IND exemption(s), a written statement in the protocol should be included, indicating that all the criteria for IND exemption have been met. For cases where the use of the drug is not identical to that described in the FDA approved labeling, provide a rational explaining how the research does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product.

For studies involving an investigational device, determination of IDE Exemption, Significant Risk(SR) or Non-Significant risk(NSR) should be described. For Non Significant Risk (NSR) devices, sponsors (or sponsor-investigators) are responsible for making the initial risk determination and presenting it to the IRB.

## **Drug/Device Handling:**

If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on participants and will be used by only authorized investigators.

* + - If the control of the drugs or devices used in this protocol will be accomplished by following an established, approved organizational SOP (e.g., please reference that SOP in this section, such as [Conducting Outpatient and Inpatient Clinical Research Using Legend or Investigational New Drugs](https://policy.umn.edu/research/investigationaldrugs-proc01) or [Fairview Health Services Investigational Drug Policy](http://www.fairview.org/fv/groups/internet/documents/web_content/s_033272.pdf). These policies require, among other items, applicable investigators to either contact Fairview Investigational Drug Services (Fairview IDS) for full services or enroll in a “Registered Only” status using the IDS Registration Only (RO) Form. Researchers who select the RO process bear full responsibility for ensuring the safe storage of their drugs.
    - Add the Investigational Drug Services number to the Study Summary Table (does not apply to research conducted at Gillette Children’s Specialty Healthcare). The IRB will not finalize approval of a protocol until after receipt of the Fairview Research Administration approval.

## **Biosafety:**

Identify whether the research involves recombinant or synthetic nucleic acid molecules (r/sNA; RNA, DNA), infectious agents, or biologically-derived toxins. This includes Human Gene Transfer, which is the deliberate transfer into human research participants of r/sNA via engineered cells/viruses/bacteria, or simply as DNA or RNA. See the NIH Guidelines for more specifics. If yes, also submit an application to the [Institutional Biosafety Committee](http://www.ibc.umn.edu/forms.html).

## **Stem Cells:**

Identify whether the research involves embryos or embryonic stem cells. Some Stem cell research requires review and approval from the Stem Cell Research Oversight Panel (SCRO). Covered research includes research with human embryos except for the use of embryos in non-experimental clinical care provided to patients undergoing reproductive treatments. See administrative policy [Conducting Research with Human Embryos or Embryonic Stem Cells](https://policy.umn.edu/research/embryonicstemcells).

## **Fetal Tissue:**

Identify whether the research involves human fetal tissue or cell lines derived from human fetal tissue. Oversight is led by the IRB or the Fetal Tissue Research Committee depending on if the intended use is for transplantation or non-transplantation purposes (respectively – see [administrative policies](https://policy.umn.edu/research/fetalresearch)). However, for all use, both groups are involved.

# **Procedures Involved**

## **Study Design:**

Describe and explain the study design.

## **Study Procedures:**

Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor participants for safety or to minimize risks. Consider including a schedule of events table for complex study procedures.

Describe:

* + - Procedures to be performed for research purposes and, if relevant, which procedures would be performed regardless of whether the research was conducted, e.g., procedures performed for diagnostic or treatment purposes.
    - All drugs and devices required for participation and specified for use in the research, the purpose of their use, and their regulatory approval status (e.g., if participants are taking amoxicillin as prescribed by their providers, but it is not required for participation and specified for use in the research, do not include amoxicillin here).
    - The data to be collected about participants and the source records that will be used to collect those data. (Attach all surveys, scripts, and participant-facing data collection forms in ETHOS in the Supporting Documents section.)

## **Study Duration:**

Describe the duration anticipated for an individual participant’s participation in the study.

* + - The duration anticipated to enroll all study participants.
    - The duration anticipated to complete all study procedures, including any long-term follow-up, and data analysis.

## **Use of radiation:**

Identify whether the research involves the use of radiation and describe its use as it pertains to the research. If this research will involve the use of x-rays or other imaging that involves exposure to radiation, the administration of radiopharmaceuticals, external beam, or brachytherapy complete the [Human Use Application](http://www.dehs.umn.edu/rad_forms.htm).

## **Use of Center for Magnetic Resonance Research:**

Identify whether the research will involve the Center for Magnetic Resonance Research facilities. If this research will involve the use of magnetic resonance imaging devices at the Center follow the [CMRR](https://www.cmrr.umn.edu/preirb/) processes.

# **Data and Specimen Banking**

If this study does not involve storing data or specimens for future use, type “N/A” and delete the sub-headings below. Otherwise, complete all items below. Ensure text below aligns with any plans outlined in a Data Management Plan or Data Management and Sharing Plan for NIH funded research.

## **Storage and Access:**

If data or specimens will be stored for future use, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens. Indicate whether the AHC IE will be used for data and/or if [BioNet](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement/tissue-procurement-facility) will be used for specimens, or if another data repository will be used.

## **Data:**

List all of the data elements to be collected and stored for future use. Specify which data will be associated with specimens.

## **Release/Sharing:**

Describe the procedures to release data or specimens, including whether data will be shared publicly or under restricted access. If the latter, describe the process to request a release, approvals required for release, who can obtain data or specimens, and the data elements to be provided. Include the parameters and process for which data may be shared for future use.

# **Sharing of Results with Participants**

## **Sharing Results:**

Describe whether results (study results or individual participant results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., participants’ primary care physicians) and, if so, describe how the results will be shared.

## **Sharing Genetic Results:**

### **Disclosure of Results:**

Describe whether the results of the genetic analyses will be returned to participants. If results will not be returned, provide rationale for not returning results. To the extent possible, participants and families should be anonymized in any publications, especially when research focuses on rare conditions which could allow participants to identify themselves in publicly available, published results.

### **Returning Results to Participants:**

Note: Any individual genetic testing results returned to participants must be confirmed in a lab certified under the Clinical Laboratory Improvement Amendments (CLIA). Please see the [Investigator Manual (HRP-103)](https://drive.google.com/file/d/0B7644h9N2vLcOWtzU2FmSU5oS0U/edit) for additional information about language that should be included in the consent form related to sharing of results.

* **Aggregate or individual results:**

Describe whether participants will receive aggregate or individual results. Aggregate results must be presented in a way that does not allow participants to infer their own genotype.

* **Laboratory results:**

Any individual testing results returned to the participant must be confirmed in a lab certified under the Clinical Laboratory Improvement Amendments (CLIA). Provide whether the laboratory is CLIA certified. If the lab is not CLIA certified, confirm that participants and/or health care providers will be informed of the nature of the finding and then given contact information for a CLIA laboratory that can provide confirmation of results. If participants will have to pay for this clinical information, this should be explicitly stated in the consent form.

* **Plan for return of results to participants:**

Describe when the results will be returned (including whether results will be given in person) and who will deliver the results to participants. \*Please note that the IRB’s preferred method for disclosure of results is an in-person disclosure of results by an appropriately credentialed genetics professional.

* **Types of results to be returned to participants:**

Describe the types of results to be returned to participants. The investigator has the discretion to choose the types of results that will be disclosed and subjects will be given the choice to “opt in” or “opt out” of receiving any types of results that the investigator is willing to disclose.

* + Include whether the primary target will be disclosed- The primary target of the analysis is the specific genetic change(s) that are believed to cause the disease/phenotype of the study.
  + Include whether secondary targets will be disclosed. Secondary targets are genetic variants that do not cause the primary phenotype under investigation, but have been clearly documented to have other medical significance. Such variants are likely to be encountered in large scale genetic studies (e.g. whole exome or whole genome sequencing).
  + Include whether variants of uncertain clinical significance will be disclosed. The following definition should be applied: genetic variations that cannot clearly be classified as “disease-causing” or “benign” (alternatively, variants with very modest effects on common disease phenotypes).
  + Include whether incidental findings will be disclosed. Incidental finds are unintended findings generated by the analysis of genetic data, such as evidence of non-paternity or incest. \*It is the strong preference of the IRB that such findings NOT be disclosed to subjects unless there is a compelling medical reason to do so. Participants should be aware that even though incidental findings are not formally reported, it is possible in some situations to infer this information from genetic testing.
  + Include whether the participant will be provided with complete datasets. If investigators wish to disclose a complete dataset to participants, the following should be considered:

1. Complete datasets must be reported through a CLIA certified laboratory.
2. Investigators should describe how the list of variants is curated for technical accuracy (e.g. it is not appropriate to release a raw dataset directly to subjects without curating the dataset for technical artifacts, etc.)
3. Investigators should describe what clinical interpretation (if any) will be provided with the dataset. If subjects will be directed to web-based resources, such resources should be provided to the IRB for review. If participants will be expected to pay for interpretive resources, this should be explicitly stated in the consent form.
4. Investigators should provide a detailed plan of how complete datasets will be disclosed, how participants understanding will be assessed, and how outcomes of disclosure (both positive and negative) will be assessed.

### **Future Analysis of genotypes:**

Describe whether there is a plan to conduct further analysis of the significance of genotypes in the future. Note that, if the understanding of a particular genotype changes in the future, the investigator may choose to disclose new information, but is not obligated to do so.

# **Study Population**

## **Inclusion Criteria:**

Describe the criteria that define who will be included in your final study sample.

Please reference Section: Vulnerable Populations. Please note that you may not include vulnerable populations as participants in your research unless you indicate this in your inclusion criteria.

## **Exclusion Criteria:**

Describe the criteria that define who will be excluded in your final study sample.

## **Screening:**

Describe how individuals will be screened or assessed for eligibility.

# **Vulnerable Populations**

University requirements for inclusion of vulnerable populations may be stricter than what may be acceptable for sponsors or for lead investigators at other institutions.

## **Vulnerable Populations:**

Identify which of the following populations will be allowed to participate in this study. You may not include members of the populations below as participants in your research unless you indicate this in your inclusion criteria above. Inclusion of an individual from one of these groups will require the investigator to develop additional safeguards (Section 9.2) proportional to the degree of vulnerability and proportional to the degree of risk and benefit.

|  |  |
| --- | --- |
| Population / Group | Identify whether any of the following populations will be focus of the research (targeted), included, but not necessarily the focus or excluded from participation in the study. |
| Children | Choose an item. |
| Pregnant women | Choose an item. |
| Fetuses | Choose an item. |
| Neonates | Choose an item. |
| Prisoners | Choose an item.. |
| Adults lacking capacity to consent and/or adults with diminished or fluctuating capacity to consent | Choose an item. |
| Non-English speakers | Choose an item. |
| Those unable to read (illiterate) | Choose an item. |
| Employees of the researcher | Choose an item. |
| Students of the researcher | Choose an item. |
| Undervalued or disenfranchised social group | Choose an item.. |
| Active members of the military (service members), DoD personnel (including civilian employees) | Choose an item.. |
| Individual or group that is approached for participation in research during a stressful situation such as emergency room setting, childbirth (labor), etc. | Choose an item. |
| Individual or group that is disadvantaged in the distribution of social goods and services such as income, housing, or healthcare. | Choose an item. |
| Individual or group with a serious health condition for which there are no satisfactory standard treatments. | Choose an item. |
| Individual or group with a fear of negative consequences for not participating in the research (e.g. institutionalization, deportation, disclosure of stigmatizing behavior). | Choose an item. |
| Any other circumstance/dynamic that could increase vulnerability to coercion or exploitation that might influence consent to research or decision to continue in research. | Choose an item.. |

## **Additional Safeguards, if any, to ensure inclusion is appropriate:**

If individuals or groups are identified as vulnerable, specific safeguards to protect the population should be implemented, such as consent monitoring or independent capacity to consent assessment, independent clinical monitoring, ensuring confidentiality, and ensuring that potential research participants are free to decline joining the study (Emanuel, Wendler, and Grady, 2008). If the research involves individuals Checked in Section 9.1 above, provide justification for their inclusion and describe additional safeguards included to protect their rights and welfare. Investigators should tailor protections to the nature and extent of vulnerability, the magnitude of risk, and the assessment of benefit.

* + - If the research involves pregnant women, review “[CHECKLIST: Pregnant Women (HRP-412)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves neonates of uncertain viability or non-viable neonates, review “[CHECKLIST: Non-Viable Neonates (HRP-413)](https://research.umn.edu/units/irb/toolkit-library/checklists)” or “[CHECKLIST: Neonates of Uncertain Viability (HRP-414)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves prisoners, review “[CHECKLIST: Prisoners (HRP-415)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves persons who have not attained the legal age for consent to treatments or procedures involves in the research, review “[CHECKLIST: Children (HRP-416)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - If the research involves cognitively impaired adults, or adults with fluctuating, diminished, or lacking capacity to consent, review “[CHECKLIST: Cognitively Impaired Adults (HRP-417)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information.
    - For research involving Tribal collaborators, Tribal communities, Tribal natural resources, and other Tribally-controlled or Tribal-serving institutions, Indigenous Peoples, places, and objects of cultural significance, provide additional information that addresses the considerations and guidelines established by the University of Minnesota (see [HRP-338 – WORKSHEET – Indigenous Research](https://research.umn.edu/units/irb/toolkit-library/worksheets)).
    - Provide justification for the inclusion of this population and describe the importance of the knowledge to be gained.
    - Explain how including this population represents the least degree of impairment compatible with the aims of this study.
    - Specify how risks are minimized and/or whether the risks or discomforts are greater for this population.

## **If research includes potential for direct benefit to participants, provide rational for any exclusions indicated in the table above:**

Explain why excluding certain populations from participation is appropriate (e.g., disease or condition under study does not occur in children). It is particularly important to explain why exclusion is appropriate If there is the possibility of direct benefit to the participant.

# **Local Number of Participants**

## **Local Number of Participants to be Consented:**

State the approximate number of participants you plan to enroll locally (e.g., the university, Fairview, or Gillette). Give the lowest number that will allow data analysis and the maximum that might agree to participate. If the research involves secondary analysis of existing data, give the estimated number of records that will be used.

# **Local Recruitment Methods**

## **Recruitment Process:**

Describe when, where, and how potential participants will be recruited. For example, will recruitment advertisements be sent to potential participants? Will advertisements be posted publicly?

## **Identification of Potential Participants:**

Describe the methods that will be used to identify potential participants. Describe whether participants will self-identify in response to posters, mailings, emails, etc., or whether they will be recruited based on information contained in private/protected records (e.g., medical records, student records; note that this also includes participants who will be recruited from the PI’s or Co-PI’s patient or student population.)

* + - For information contained in private/protected records, explain how the researcher has legitimate access to these records. For MHealth research (involving MHealth patients, resources, providers) a provider may contact patients with whom they have a direct treatment relationship to discuss study participation in IRB approved research. The treatment relationship may also be extended to patients under the care of providers in the principal investigator’s department. See [MHealth Research Recruitment Guide](https://www.fairview.org/~/media/Fairview/PDFs/Research/Research%20Recruitment%20Guide_FV_6.1.22.pdf).
    - Identify who will make initial contact with potential participants.
    - Identify whether the private/protected records will include **MEDICAL** records and the mechanism the PI will use to confirm that patients have agreed to release their PHI contained in their medical records for research purposes; for example, a particular patient has documented consent to research on their treatment, intake, or hospital admitting form. (MN Statute 144.334 Subd. 3; Access to Medical Records for Research), e.g., Academic Health Center Information Exchange (AHC-IE).

## **Recruitment Materials:**

Describe materials that will be used to recruit participants. (Attach copies of these materials in ETHOS in the Recruitment section. For advertisements, attach the final copy of printed advertisements. When advertisements are recorded for broadcast, attach the final audio/video recording in ETHOS. You may instead submit the wording or script for any recorded advertisements in ETHOS prior to recording them. This will preclude re-recording because of inappropriate wording, provided the IRB reviews the final audio/video recording after approving the initial wording or script. You would likely include any recording with a modification in ETHOS.)

## **Payment:**

Describe the amount, timing, and type of any payments to participants.

* + - Indicate whether gifts, payments, compensation, reimbursement, services without charge, or extra credit will be provided to the participants for participating in the research.
    - Describe the type of compensation and the maximum value participants may receive during the course of participation.
    - Describe when compensation will be provided, including a schedule, and whether payments will be prorated for multiple visits/sessions.
    - Describe who will receive payments, if not the participants themselves.
    - Describe whether Research Experience Points will be awarded*.*

Indicate whether the Greenphire ClinCard will be used for compensation. If used, include the template language in the consent document (see [Consent Template (HRP-592)](https://research.umn.edu/units/irb/toolkit-library/templates-forms)).

# **Withdrawal of Participants**

## **Withdrawal Circumstances:**

Describe anticipated circumstances under which participants will be withdrawn from the research (e.g. stopping rules met) without their consent.

## **Withdrawal Procedures:**

Describe procedures that will be followed when participants withdraw from procedures, including partial withdrawal, with continued data collection (e.g., participants withdraw, but you wish to continue collecting data from a private/protected record).

## **Termination Procedures:**

Describe any procedures for orderly termination and describe whether data will be used after termination.

# **Risks to Participants**

For each risk or set of risks below, include the procedures to be performed to lessen the probability, magnitude, duration, or reversibility of those risks.

## **Foreseeable Risks:**

* List the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to participants’ participation in the research.
* Include, as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks.
* Depending on the type of research, this description may or may not include statistical information. Categories such as common, rare, etc., may be acceptable.
* Consider physical, psychological, social, legal, and economic risks.

## **Reproduction Risks:**

If applicable, indicate which procedures may have risks to an embryo or fetus should the participants or participants’ partners be or become pregnant.

## **Risks to Others:**

If applicable, describe risks to others who are not participants.

# **Potential Benefits to Participants**

## **Potential Benefits:**

Describe the potential benefits that individual participants may experience from taking part in the research. Include, as may be useful for the IRB’s consideration, the probability, magnitude, and duration of the potential benefits.

Indicate if there is no direct benefit to individual participants. Do not include benefits to society or others.

# **Statistical Considerations**

Reference the [NIH/FDA Protocol Template section](http://osp.od.nih.gov/wp-content/uploads/Protocol-Template-Version-1.0-040717.docx) on statistics for further guidance.

## **Data Analysis Plan:**

Describe the data analysis plan, including any statistical procedures. The plan must include a description of how missing data will be handled (for example, imputation technique, if applicable). Provide justification for the method selected.

## **Power Analysis:**

Provide a power analysis, if applicable, justifying the sample size for this research study.

## **Statistical Analysis:**

Describe statistical analysis plans.

## **Data Integrity:**

Describe any procedures that will be used for quality control of collected data.

# **Health Information and Privacy Compliance**

[Protected Health Information (PHI):](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html) for guidance regarding the use, collection, storage and sharing outside of the covered entity of PHI please see: [UMN Privacy Office Policies](https://policy.umn.edu/operations/phi) and/or [Fairview Health Services Privacy Policies](https://www.fairview.org/Research/Forresearchers/Researchcompliance/Researchpolicies/index.htm), and [UMN HIPAA Agreement Templates](https://policy.umn.edu/contracts/categories/OT/240/253)*.* For research conducted at Gillette Children’s Specialty Healthcare refer to [Gillette Research Administration](https://www.gillettechildrens.org/for-medical-professionals/research/research-administration) for guidance.

Under the HIPAA Privacy Rule, research studies at the University are permitted to use and disclose PHI with the authorization of the research participants, or without individual authorization in limited circumstances. Please note that some of the following questions are related to questions in Section 11 of this protocol template.

## **Health Care Component:**

Are any research personnel working on this study part of the Health Care Component (HCC)?  All study personnel in colleges/departments covered under the HCC are automatically subject to HIPCO review to ensure HIPAA compliance. Note: Areas/personnel outside of the University's Health Care Components may also be subject to HIPAA if they act as a "Business Associate" of an organization that is subject to HIPAA and/or are accessing Protected Health Information (see definition of PHI in section below). Please view [this page (Section “What are the University's health care components under HIPAA?”)](https://healthprivacy.umn.edu/compliance/hipaa-compliance-university) for a list of areas within UMN that are deemed Health Care Components and Business Associates.

Yes

No

## **Select which of the following is applicable to your research:**

My research does not require access to individual health information and therefore assert HIPAA does not apply. Completion of this section is still required if you select this option per HIPCO ancillary review process.

I am requesting that all research participants sign a HIPCO approved HIPAA Disclosure Authorization to participate in the research (either the standalone form or the combined consent and HIPAA Authorization).

I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

**Appropriate Use for Research**: Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed.

An external IRB (e.g. Advarra) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of the U of M stand-alone HIPAA Authorization. Note: External IRB must be serving as the privacy board for this option.

## **Preparatory to Research. Please attest to one of the following statements:**

See HIPCO guidance for [Preparatory to Research Activities](https://healthprivacy.umn.edu/research/hipaa-related-research-issues).

I will only be accessing participant medical information/records for the purpose of Preparatory to Research Activities

I will be accessing participant medical information/records beyond the purposes of Preparatory to Research Activities

I am unsure and require HIPCO guidance to determine if the activities I am proposing are considered Preparatory to Research Activities

Not applicable to this study

## **Identify the source of Private Health Information you will be using for your research (check all that apply):**

I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me. Include a copy of the [BPIC](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic) Consultation form with the IRB Submission.  NOTE: HealthEast EPIC data is **not** included in the IE. Limited access to [EPIC](https://www.epic.com/) is allowable through the AHC-IE Security Gateway for validation/supplemental purposes only.

I will collect information directly from research participants.

I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database.

I will pull records directly from EPIC.

For EPIC records accessed outside of the Information Exchange.  Please provide the information requested below:

* Describe what you will access
* Indicate how many patients’ records you plan to access
* Describe how you will access the data
* Describe the authority you have to access the data
* Explain how you will exclude the records of those who have opted out of research

I will retrieve record directly from axiUm / MiPACS

I will receive data from the Center for Medicare/Medicaid Services

I will receive a limited data set from another institution.

If the limited data set used will contain information from somewhere other than the University of Minnesota or MHealth, then you must enter into a Data Use Agreement with the data source. You may use the University’s standard Data Use Agreement or another form approved by the health information Privacy & Compliance Office. (See [UMN De-Identification vs. Limited Data Set Chart](https://healthprivacy.umn.edu/research/hipaa-related-research-issues))

I will receive a de-identified data set from another institution. If there's a direct link between the study ID and PHI, it is not de-identified, but considered to be part of a Limited Data Set.  (See [UMN De-Identification vs. Limited Data Set Chart](https://healthprivacy.umn.edu/research/hipaa-related-research-issues).)

Other. Describe: Describe in detail the source of the information, including justification regarding the investigator’s authority to collect the information from the source or if approval (and from whom) was received to collect the information.

## **Explain how you will ensure that only records of patients who have agreed to have their information used for research will be reviewed:**

## **Approximate number of records required for review:**

If not applicable, enter N/A. UMN/Fairview researchers: If indicated you will retrieve records directly from EPIC and response is greater than or equal to 200, please explain below why you cannot use Informatics Consulting Service to retrieve data from the Information Exchange.

## **Please describe how you will communicate with research participants during the course of this research. Check all applicable boxes:**

This research involves record review only. There will be no communication with research participants.

Communication with research participants will take place in the course of treatment, through MyChart, or other similar forms of communication used with patients receiving treatment.

Communication with research participants will take place outside of treatment settings. If this box is selected, please describe the type of communication and how it will be received by participants.

For HIPAA applicable studies, email or text correspondence beyond simple scheduling reminders requires a signed [Unsecured Email Authorization](https://healthprivacy.umn.edu/hipco-forms) and/or [Unsecured Text Authorization](https://healthprivacy.umn.edu/hipco-forms). Please upload these documents to ETHOS to use as needed. Please read the[University’s Policy on E-Mail and PHI](http://policy.umn.edu/operations/phi-appa) which requires encryption of out-going emails containing PHI. More information can be found on the University’s encryption tool, [ProofPoint](http://it.umn.edu/technology/proofpoint-secure-email-center).

Communication may require the use of interpreter service(s) or translation service(s). Please refer to this [Appropriate Use of Interpretation and Translation Services in HIPAA Authorization Process](https://healthprivacy.umn.edu/research/hipaa-related-research-issues) document, which can be found on HIPCO’s website. Changes regarding the use of interpreter or translation services for a study subject to HIPAA rules requires review by HIPCO to ensure HIPAA compliance.

## **Explain how the research team has legitimate access to patients/potential participants:**

Information about provider contact with patients for MHealth research recruitment can be found in section 11.2. Explain why the research team is permitted to access medical records or any other sources of private information about the participants. (Note that you were asked a similar question above about access to information about potential participants. This item refers to information about participants who have consented to participate and about whom you are collecting research data.)

# **Health Science Technology (HST) HIPAA Compliant Devices and Data Storage**

This section must be completed if PHI will be digitally accessed, stored, analyzed, or transferred. HIPAA Compliant [HST](https://it.umn.edu/services-technologies/resources/health-sciences-technology-request) managed devices must be used to access PHI, including accessing BOX, REDCap, AHC-IE, HST Servers. Please refer to the [HIPCO Ancillary Review Aid: Computer Device Guide for Research](https://healthprivacy.umn.edu/research/hipaa-related-research-issues) for more information or reach out to [security@umn.edu](mailto:security@umn.edu) for support.

## **HST Device Number:**

Please list the HST device numbers of all PCs and other devices that will be used to handle PHI or any other non-HST devices that will be used to handle PHI.

**Other non-HST managed devices:**

Identify the device and data the device will handle.

UMP Computer(s)

Store  Analyze  Share

Fairview Computer(s)

Store  Analyze  Share

Other non-HST managed device(s):

Identify the type of device (computer, phone). Describe in detail the location and whether the data will be stored, analyzed, or shared, and in what ways. Include which data elements will be kept on the non-HST managed device.

## **Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply):**

In the data shelter of the [Information Exchange (IE)](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic)

Store  Analyze  Share

In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

Store  Analyze  Share

In REDCap (recap.ahc.umn.edu)

Store  Analyze  Share

In Qualtrics (qualtrics.umn.edu)

Store  Analyze  Share

In OnCore (oncore.umn.edu)

Store  Analyze  Share

In the University’s Box Secure Storage (box.umn.edu)

Store  Analyze  Share

Sponsor Electronic Data Capture Tool (i.e. Advarra or other)

Store  Analyze  Share

In UMP devices/servers

Store  Analyze  Share

In Fairview devices/servers

Store  Analyze  Share

In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact: The path should be in the form of “\\vp.ahc.umn.edu\vp\Research\Study0004” HIPCO requires this information to verify the data are in a properly encrypted server.

Store  Analyze  Share

Other. I will use a server not previously listed. Describe: Include the server type. Describe in detail the location and what data will be stored, analyzed, or shared, and in what ways.

## **Consultants. Vendors. Third Parties:**

Describe whether you will collect, store, analyze or share any information using a consultant, vendor, or third-party software application, system, device or technology (other than REDCap or OnCore). HIPCO will determine if a vendor review process is required– which will be completed through [security@umn.edu](mailto:security@umn.edu) – at which time Security will ensure that the third-party entity you wish to use is HIPAA compliant and/or if a Business Associate Agreement is required.

Note: If you will be sharing a dataset that contains elements of PHI outside the scope of a [Limited Data Set](https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/limited-data-set/index.html), then a [Business Associate Agreement](https://policy.umn.edu/media/419/download) (BAA), rather than a DUA,  is required. A BAA is used when PHI is being shared and/or when we are asking another group, individual, company, etc., to complete a function on our behalf. It is a contract agreement between the University of Minnesota and a Business Associate, commonly used with service providers, technology or application providers, cloud services, financial services, health services, research partners, higher-education institutions, and other vendors.

## **Data Ownership:**

It is important for HIPCO to understand who owns the data to determine if it is within our office’s purview to manage (versus Fairview, the Funding Agency, a combination, etc.) and/or to ensure the appropriate contractual agreements are in place with the owner of the data.

Indicate who owns the data in the research study - Check all that apply.

UMN

UMP

Fairview

Sponsor:

Third-party university:

Other (specify):

## **Links to identifiable data:**

Indicate how you will generate the links, how you will store these links, and how and when you will destroy these links.

## **Sharing of Data with Research Team Members:**

Indicate how you will share research data among research team members.

## **Storage of Documents:**

Describe how you will store any paper or electronic documents generated as a result of this research project.

## **Disposal of Documents:**

Describe if, when, and how you will dispose of research documents. Reminder: research regulations and policies require each investigator to retain research data not only while the research is being conducted but also after the research is completed. Retention requirements vary depending on whether federal funding was provided for the project, whether there is funding from industry with contractual provisions governing data retention, or whether the study was conducted under FDA regulations. It is recommended that researchers comply with the longest applicable standard.

# **Confidentiality**

## **Data Security:**

Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) for storage, use, and transmission of data. Include also whether a copy of the consent form or other research study information will be placed in the participants’ medical, employment, or educational records, and why that is appropriate (if so, this information must be included in the confidentiality section of the consent form).[Review the University’s Privacy Office guidance on securing and de-identification of data](https://www.healthprivacy.umn.edu/research).

## **Data Sharing:**

If storing data for future use, including sharing with other researchers or the public, describe the steps that will be taken to ensure confidential information is not disclosed (e.g., de-identification of data, selection of data or materials to share, work with external reviewers or curators).

# **Provisions to Monitor the Data to Ensure the Safety of Participants**

## **Safety Plan:**

* Minimal risk studies and greater than minimal risk studies must have a plan for monitoring the data collected to ensure the safety of participants. Refer to “[WORKSHEET: Data and Safety Monitoring Plan (HRP-335)](https://research.umn.edu/units/irb/toolkit-library/worksheets)”to see how the IRB will review your plan. The plan should be commensurate with the risks and complexities of the study.
* Studies that include questionnaires or interview questions about mental health, psychological functioning, or mood, or includes participants that are at elevated risk of suicide, must include a safety plan (see HRP-335 – WORKSHEET – Data and Safety Monitoring).
* All plans must include study team compliance with IRB reporting requirements ([Investigator Manual (HRP-103)](https://research.umn.edu/sites/research.umn.edu/files/hrp-103_-_investigator_manual_google_doc.pdf) “What should be promptly reported to the IRB?”).
* Plans for studies not greater than minimal risk (as determined by the IRB) could also include a) defined schedule/plan for PI review of aggregate data for participant safety; b) PI or a member of the study team delegated responsibility to review data in real time for participant safety.
* Plans for all greater than minimal risk research (as determined by the IRB) must have a plan for ongoing institutional or independent evaluation of the study. This institutional or independent review (defined as independent of the institution)) must include one or both of the following: a) clinical trial monitoring as described in International Conference on Harmonisation Good Clinical Practice (ICH GCP) guidelines, or b) Data and Safety Monitoring Board.

## **Data Integrity Monitoring:**

The plan to oversee the progress of the study and to ensure that it is conducted, recorded, and reported in accordance with the protocol, standard operating procedures, and applicable regulatory requirements.

* Describe the selection of and qualification of the monitor(s).
* Describe the extent and nature of monitoring based on the study characteristics, objective(s), purpose, design, complexity, blinding, size, and endpoint(s), event(s), or outcome(s).
* Describe the monitor’s responsibilities.
* Define monitoring procedures.
* List the expected elements of the monitoring reports, the distribution plan, and expected follow-up.

## **Data Safety Monitoring:**

* For studies that include a DSMB or DSMC, the DSMB or DSMC charter must be described in the protocol or a copy of the charter must be uploaded into Supporting Documents section of the SmartForm in ETHOS. Describe the following:
  + - The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.
    - What data are reviewed, including safety data, untoward events, and efficacy data.
    - How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
    - The frequency of data collection, including when safety data collection starts.
    - The stopping rules (i.e. study wide and individual participants, as appropriate).
    - Who will review the data.
    - The frequency or periodicity of review of cumulative data.
    - The statistical tests for analyzing the safety data to determine whether harm is occurring.
    - Any conditions that trigger an immediate suspension of the research.

# **Provisions to Protect the Privacy Interests of Participants**

## **Protecting Privacy:**

Describe the steps that will be taken to protect participants’ privacy interest. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal or sensitive information.

Describe any privacy concerns and what steps you will take to make the participants feel more comfortable with the research situation in terms of the questions being asked and the procedures being performed. “Comfortable” does not refer to physical discomfort only, but to the sense of intrusiveness a participant might experience in response to questions, procedures, or interactions with researchers or in certain settings.

## **Access to Participants:**

Explain why the research team is permitted to access medical records or any other sources of private information about the participants (information about provider contact with patients for MHealth research recruitment can be found in section 11.2). (Note that you were asked a similar question above about access to information about potential participants. This item refers to information about participants who have consented to participate and about whom you are collecting research data.)

# **Compensation for Research-Related Injury**

## **Compensation for Research-Related Injury:**

If the research involves greater than Minimal Risk to participants, describe the available compensation in the event of research-related injury.

## **Contract Language:**

Provide a copy of the contract language, if any, relevant to compensation for research-related injury.

# **Consent Process**

Note: The process and documentation plan must follow “[SOP: Informed Consent Process for Research (HRP-090)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)” and “[SOP: Written Documentation of Consent (HRP-091)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures).”

## **Consent Process (when consent will be obtained):**

Describe the consent process, including:

* Where the consent process will take place.
* Any waiting period available between informing the prospective participants and obtaining the consent.
* Who and how will it be determined that a potential participant understands the information.
* Any process to ensure ongoing consent.
* If you will document consent in writing, submit a consent document in ETHOS.
* Whether you will use the combined HIPAA Authorization / Consent document (HRP-588) or separate HIPAA Authorization and Consent document (HRP-592).

## **Waiver or Alteration of Consent Process (when consent will not be obtained):**

If you are not requesting a consent alteration or waiver, type “N/A” and delete the bullets below. Otherwise, provide rationale for the waiver or alteration:

* Review “[CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)](https://research.umn.edu/units/irb/toolkit-library/checklists) to ensure that you have provided sufficient information in this protocol for the IRB to make these determinations. Do not fill out the checklist. Describe how your protocol meets the requirements noted in HRP-410.
* If the research involves a waiver of the consent process for planned emergency research, please review “[CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information for the IRB to make these determinations.

## **Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained):**

If you are not requesting a waiver of documentation of consent, type “N/A” and delete the bullets below. Otherwise, provide rationale for the waiver.

* Review “[CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)](https://research.umn.edu/units/irb/toolkit-library/checklists)” and provide rationale as to why a waiver of written documentation of consent is appropriate for this research study.
* If you will obtain consent, but not document consent in writing, submit a consent script in ETHOS.

## **Non-English Speaking Participants:**

Indicate what language(s) other than English is/are understood by prospective participants or their representatives.

* + If participants who do not speak English will be enrolled, describe the process to ensure that the oral or written information provided to those participants will be in their own language. Indicate the language that will be used by those obtaining consent.
  + If you will be using an interpreter during recruitment, consent, data collection, or data analysis, specify how you will identify an appropriate interpreter and what the provisions will be for protecting the confidentiality of participants.
* If the protocol will allow for unexpected enrollment of non-English speakers, this should be included in this section. The IRB must approve the use of the Short Form process before it can be utilized in a study.
* Effective July 1, 2019, for studies that are greater than minimal risk and participation in the study is planned to last 30 days or more, investigators must translate the full study consent document. In addition, the investigator is responsible for ensuring that:
  + - The translation be certified and from a reputable translation service (See “What translation or certification services are acceptable or required?” in the Investigator Manual (HRP-103)) within 30 days of the initial consent obtained via the short-form method.
    - Once certified, the translated study consent document and the certification must be submitted to the IRB for review and approval, via a Modification in ETHOS.
    - Translated short forms are available on the UMN IRB website: <https://research.umn.edu/units/irb/toolkit-library/templates>.
  + Effective January 25, 2021, for minimal risk research or greater than minimal risk research where participation in the study is not planned to last more than 30 days, investigators do not have to translate the full-length study consent after use of the short form. However, if more than three potential participants of a specific language (e.g., French, Mandarin, Swahili) for a specific study need consent (forms) then a full-length consent form in the specific language must be developed and approved by the IRB. Refer to the Investigator Manual (HRP-103) for additional information.

## **Participants Who Are Not Yet Adults (infants, children, teenagers under 18 years of age):**

Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., in Minnesota, individuals under the age of 18 years.)

* For research conducted in Minnesota, review “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)” to be aware of which individuals in the state meet the definition of “children.”
* For research conducted outside of Minnesota, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “children” in “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures).”
* Describe whether parental permission will be obtained from:
  + Both parents, 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, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.
* Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.
* Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.
* When assent of children is obtained, describe whether and how it will be documented.
* Since informed consent is an ongoing process, provide a plan for minor participants who reach adult status during active participation in a research study. Include details regarding the re-consent process for any ongoing interactions, interventions, or access to data, as well as how data will be handled if the participant no longer wishes to be part of the research. An adult consent form should be uploaded to ETHOS.

## **Cognitively Impaired Adults, or adults with fluctuating or diminished capacity to consent:**

* Describe the process to determine whether an individual is capable of consent. Review “[POLICY: Capacity to Consent (HRP-110)](https://research.umn.edu/units/irb/toolkit-library/policies)” and “[POLICY: Research Involving Adults Under Court Jurisdiction (HRP-111)](https://research.umn.edu/units/irb/toolkit-library/policies)” for additional information. Reference “[CHECKLIST: Cognitively Impaired Adults (HRP-417)](https://research.umn.edu/units/irb/toolkit-library/checklists).”
* Indicate who will be responsible for assessing capacity to consent for this protocol. Review training requirements to ensure those responsible for assessing capacity to consent have completed the required training ([SOP: Education and Training (HRP-066)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)).
* Confirm use of one of the approved validated instruments to assess capacity to consent appropriate for the level of risk associated with the research (i.e., the MacArthur Competence Assessment Tool for Clinical Research for greater than Minimal Risk research or the UCSD Brief Assessment of Capacity to Consent for Minimal Risk research). If you will not be using one of these tools, describe the alternative validated tool(s) you propose to use instead. If available in electronic format, submit the alternative tool(s) for review by the IRB in ETHOS.
* Document plans, if any, to avoid seeking consent during periods of greater than normal impairment.

## **Adults Unable to Consent:**

### **Permission:**

List the individuals from whom permission will be obtained in order of priority (e.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)

* For research conducted in Minnesota, review “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures)” to be aware of which individuals in the state meet the definition of “legally authorized representative.” Additionally, be aware of special restrictions regarding recruiting or enrolling persons under a stay of commitment.
* For research conducted outside of Minnesota, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “legally authorized representative” in “[SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)](https://research.umn.edu/units/irb/toolkit-library/standard-operating-procedures).”

### **Assent:**

Describe the process for assent of the participants. Indicate whether:

* Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.
* If assent will not be obtained from some or all participants, an explanation of why not.
* Describe whether assent of the participants will be documented and the process to document assent.

### **Dissent:**

Describe the process of identifying the dissent of the participants. Reference the [Legally Authorized Representative Brochure](https://research.umn.edu/units/hrpp/education-training/order-print-participant-materials) and [Investigator Manual (HRP-103)](https://drive.google.com/open?id=0B7644h9N2vLcMGhpekhzTnZ3ODQ) for additional guidance.

# **Setting**

## **Research Sites:**

Describe the sites or locations where your research team will conduct the research.

* For international research sites, please include that information only in Section 23.2.
* Identify where your research team will identify and recruit potential participants.
* Identify where research procedures will be performed.
* Describe the composition and involvement of any community advisory board, school board, school principals or teachers, etc.
* For research conducted outside of your organization and its affiliates, describe:
* Site-specific regulations or customs affecting the research.
* Local scientific and ethical review structure.

## **International Research:**

General Data Protection Regulation (GDPR) applies to this study. Explain:

Indicate whether the [General Data Protection Regulation (GDPR)](https://privacy.umn.edu/general-data-protection-regulation-gdpr) applies to your research study. Research does not physically have to take place in the GDPR country for GDPR to apply. See the [Consent Template](https://drive.google.com/open?id=0B7644h9N2vLcVmwxR2dOZFRGSDg) for instructions on what must be included for GDPR compliance.

If you are using participant data received from countries that are subject to [**GDPR**](https://www.gdpradvisor.co.uk/gdpr-countries), please use the [EU and EEA International Consent (GDPR and GDPR-Related Countries)](https://healthprivacy.umn.edu/hipco-forms) when enrolling these participants. This GDPR consent form is required in addition to, **not as a replacement for**, the consent form(s) that will be used for the overall study, and should be uploaded to ETHOS.

This research will take place in one or more international locations. Explain:

* Review “[WORKSHEET: International Research (HRP-336)](https://research.umn.edu/units/irb/toolkit-library/worksheets)” when developing an international research protocol.
* Describe where the research will take place and how culturally appropriate access to the community will be obtained.
* Note if there are any aspects of the cultural, political, or economic climate that might increase risks for participants. Detail strategies to mitigate or minimize these risks.
* Describe relevant ways in which the cultural norms and/or laws differ between the host site and the United States.
* Indicate whether a local participant advocate will be available for participants.
* To minimize health and safety risks, University policy requires special permission from the University’s International Travel Risk Assessment and Advisory Committee (ITRAAC) prior to travel in specific circumstances, and applies as follows to both students participating in, and faculty/staff leading the education experience. For more information, visit the [ITRAAC website](http://global.umn.edu/travel/approval/index.html#who-tab).

This research will involve collaborators from outside the United States. Explain:

Describe how collaborators outside of the United States will be involved in this study. Study teams are responsible for knowing what agreements must be in place (see [HIPCO International Privacy Guidance](https://healthprivacy.umn.edu/hipco-forms)).

This research will involve data collection, sharing, access, or transmission between U.S. and international collaborators/institutions. Explain:

* If you are collecting data in the United States and sharing it with an international collaborator or institution, please provide details about what data will be shared internationally and what international locations data will be shared.
* If you are using participant data received from countries that are **not** subject to [**GDPR**](https://www.gdpradvisor.co.uk/gdpr-countries), please use the [General International Consent (Non-GDPR Countries)](https://healthprivacy.umn.edu/hipco-forms) when enrolling these participants. This international consent form is required in addition to, **not as a replacement for**, the consent form(s) that will be used for the overall study and should be uploaded to ETHOS.
* If you have further questions about handling and sharing domestic (PHI) and international (PII) participant data between UMN and international collaborators, please reach out to HIPCO at privacy@umn.edu.

# **Multi-Site Research**

If this is not a multi-site study where you are the lead investigator, type “N/A” and delete the sub-headings below. Otherwise, complete all items below. Note, if this is a federally funded research study, sIRB requirements may apply. Please review [information on sIRB](https://research.umn.edu/units/irb/how-submit/single-irb-sirb-external-irb-requests-process) prior to submitting to the IRB.

## **Study-Wide Number of Participants:**

Indicate the total number of participants to be accrued across all sites.

## **Study-Wide Recruitment Methods:**

If participants will be recruited by methods not under control of the local site (e.g., call centers, national advertisements), describe those methods. Local recruitment methods are described earlier in the protocol.

## **Study-Wide Recruitment Materials:**

Describe any template materials that will be used to recruit participants across all sites. (Attach copies of these materials in ETHOS if you will serve as the lead investigator and the University’s IRB will serve as the IRB of record for all sites.)

## **Communication Among Sites:**

If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:

* All sites have the most current version of the protocol, consent document(s), and, when applicable, HIPAA authorization.
* All required approvals (initial, continuing review, and modifications) have been obtained at each site (including by the site’s IRB of record).
* All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
* All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
* All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
* All non-compliance with the study protocol or applicable requirements will be reported in accordance with university or local policy.
* All other reportable events in accordance with university or local policy.

## **Communication to Sites:**

Describe the method for communicating to engaged participating sites:

* Problems (inclusive of reportable events).
* Interim results.
* The closure of the study.

# **Coordinating Center Research**

If the University of Minnesota is serving only as the Coordinating Center for this research study, describe the Coordinating Center functions and responsibilities. Include the center’s SOPs in your ETHOS submission.

## **Role:**

Describe the role of the Coordinating Center.

## **Responsibilities:**

Describe the responsibilities of the Coordinating Center. Indicate how you will assuring that all centers have the most current version of the protocol and that amendments to the protocol will be communicated to all centers.

## **Oversight:**

Provide each participating center FWA number with OHRP (if the research is federally funded). Provide a process for reporting and evaluating protocol events and deviations from participating centers (if applicable).

## **Collection and Management of Data:**

Provide your plan for collection and management of data from all centers.

# **Resources Available**

## **Resources Available:**

Describe other resources available to conduct the research. For example, as appropriate:

* If the study is being conducted by a student investigator, include a description of how the faculty advisor will support the student. Note that interventions or uses of investigational drugs or devices involving greater than Minimal Risk should include detailed information regarding faculty oversight and participation in the research.
* Justify the feasibility of recruiting the required number of suitable participants with the agreed upon recruitment period. For example, to how many potential participants do you have access? What percentage of those potential participants do you need to recruit?
* Describe the time that you will devote to conducting and completing the research.
* Describe your facilities.
* Describe the availability of medical or psychological resources that participants might need as a result of an anticipated or unanticipated consequences of the research.
* Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

# **References**

Include references to any scholarly articles or other materials used to discuss the background for the study or to justify any proposed procedures.