**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* | **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* | **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**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* |
| [ ]  **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* |
| [ ]  **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* | **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* |
| [ ]  **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)?ORInclude 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* |
| [ ]  **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* | **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* |
| [ ]  **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* |
| [ ]  **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* |
| [ ]  **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* |
| [ ]  **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* |
| [ ]  **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* | **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* |

**PROTOCOL COVER PAGE**

|  |  |
| --- | --- |
| **Protocol Title** |  |
| **Principal Investigator/Faculty Advisor** | Name: |
| Affiliation:  [ ] UMN   [ ]  Fairview   [ ]  Gillette |
| UMN Home Department: |
| UMN Home Dept ID: |
| 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)** |  |
| **IND/IDE Holder** |  |
| **Sponsor-Investigator: Please check box**  | [ ]  This study will comply with ICH GCP requirements for drugs, biologics, and devices.  |
| **Investigational Drug Services # (if applicable)** |  |
| **Version Number/Date:** |  |

**REVISION HISTORY**

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

# **Objectives**

## **Purpose:**

# **Background:**

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

## **Preliminary Data:**

## **Existing Literature:**

# **Study Endpoints/Events/Outcomes**

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

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

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

## **Description:**

## **Drug/Device Handling:**

## **Biosafety:**

## **Stem Cells:**

## **Fetal Tissue:**

# **Procedures Involved**

## **Study Design:**

## **Study Procedures:**

## **Study Duration:**

## **Use of radiation:**

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

# **Data and Specimen Banking**

## **Storage and Access:**

## **Data:**

## **Release/Sharing:**

# **Sharing of Results with Participants**

## **Sharing Results:**

## **Sharing Genetic Results:**

### **Disclosure of Results:**

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

* **Aggregate or individual results:**
* **Laboratory results:**
* **Plan for return of results to participants:**
* **Types of results to be returned to participants:**

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

# **Study Population**

## **Inclusion Criteria:**

## **Exclusion Criteria:**

## **Screening:**

# **Vulnerable Populations**

## **Vulnerable Populations:**

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

# **Local Number of Participants**

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

# **Local Recruitment Methods**

## **Recruitment Process:**

## **Identification of Potential Participants:**

## **Recruitment Materials:**

## **Payment:**

# **Withdrawal of Participants**

## **Withdrawal Circumstances:**

## **Withdrawal Procedures:**

## **Termination Procedures:**

# **Risks to Participants**

## **Foreseeable Risks:**

## **Reproduction Risks:**

## **Risks to Others:**

# **Potential Benefits to Participants**

## **Potential Benefits:**

# **Statistical Considerations**

## **Data Analysis Plan:**

## **Power Analysis:**

## **Statistical Analysis:**

## **Data Integrity:**

# **Health Information and Privacy Compliance**

## **Health Care Component:**

Are any research personnel working on this study part of the Health Care Component (HCC)?

[ ]  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.

[ ]  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)**:

[ ]  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:**

[ ]  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.

[ ]  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 (**Explain what, how, authority, appropriate exclusion)**:

[ ]  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.

[ ]  I will receive a de-identified data set from another institution.

[ ]  Other. Describe:

## **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:**

## **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.

[ ]  Communication may require the use of interpreter service(s) or translation service(s).

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

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

## **HST Device Number:**

**Other non-HST managed devices:**

[ ]  UMP Computer(s)

 [ ]  Store [ ]  Analyze [ ]  Share

[ ]  Fairview Computer(s)

 [ ]  Store [ ]  Analyze [ ]  Share

[ ]  Other non-HST managed device(s):

## **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:

 [ ]  Store [ ]  Analyze [ ]  Share

[ ]  Other. I will use a server not previously listed. Describe:

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

## **Data Ownership (Check all that apply):**

[ ]  UMN

[ ]  UMP

[ ]  Fairview

[ ]  Sponsor:

[ ]  Third-party university:

[ ]  Other (specify):

## **Links to identifiable data:**

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

## **Storage of Documents:**

## **Disposal of Documents:**

# **Confidentiality**

## **Data Security:**

## **Data Sharing:**

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

## **Safety Plan:**

## **Data Integrity Monitoring:**

## **Data Safety Monitoring:**

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

## **Protecting Privacy:**

## **Access to Participants:**

# **Compensation for Research-Related Injury**

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

## **Contract Language:**

# **Consent Process**

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

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

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

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

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

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

## **Adults Unable to Consent:**

### **Permission:**

### **Assent:**

### **Dissent:**

# **Setting**

## **Research Sites:**

## **International Research:**

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

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

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

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

# **Multi-Site Research**

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

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

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

## **Communication Among Sites:**

## **Communication to Sites:**

# **Coordinating Center Research**

## **Role:**

## **Responsibilities:**

## **Oversight:**

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

# **Resources Available**

## **Resources Available:**

# **References**