**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** |  |
| **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?** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

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**

# **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**