**DATA and/or SPECIMEN ONLY PROTOCOL**

**GENERAL INSTRUCTIONS:**

* Use this template to prepare a protocol for a study that will only involve use of data or specimens, and does not include any direct interaction or intervention with human research participants.
* This template **should not be used** for prospective studies where samples are collected solely for research purposes (for example: collection of research specimen by biopsy).
* There is a streamlined application process for research accessing retrospectively collected data via the [CTSI Best Practices Integrated Informatics Core (BPIC) service](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic). Follow the instructions on this template to determine if your research is eligible. If eligible, you will only complete a small portion of this protocol template.
* As you are creating your protocol, remove all instructions and guidance text (including these) so that they are not contained in the final version.
* Pg. 2-3 includes guidance regarding retrospective and prospective review and consent requirements. Additional guidance can be found in the [Investigator Manual (HRP-103)](https://research.umn.edu/units/irb/toolkit-library/manuals) regarding the use of information and/or specimens for research purposes (see Appendix B-2).
* Complete Appendix A, to indicate the types of materials/specimens that will be collected, used, or studied in this research study.
* Complete Appendix B to indicate whether any, some, or all identifiable information will be collected, used, or studied in this research study.

**Data Review Guidance:**

***What is the difference between a retrospective and prospective review?***

* A Retrospective Review evaluates participant data that exists at the time the study is submitted to the IRB for initial review.
* A Prospective Review evaluates participant data that does not yet exist at the time the project is submitted to the IRB for initial review.

***What type of consent should I request?***

* *Waiver of Consent:* Waiver of consent is often appropriate for both retrospective and prospective reviews. In order for the IRB to approve a waiver of consent, the IRB must be satisfied that the following criteria in “[CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)](https://research.umn.edu/units/irb/toolkit-library/checklists)” are met:
* The research involves no more than minimal risk to the participants;
* The waiver or alteration will not adversely affect the rights and welfare of the participants;
* The research could not practicably be carried out without the waiver or alteration; and
* Whenever appropriate, the participants will be provided with additional pertinent information after participation.
* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

*Waiver of Documentation of Consent:* This type of consent is not usually requested for a data review. Under a waiver of documentation of consent, an investigator must still obtain consent from the participant. However, the investigator does not need to obtain a signed consent form from participants if the IRB agrees that the criteria in “[CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)](https://research.umn.edu/units/irb/toolkit-library/checklists)” are met:

* The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether she or he wants documentation linking her or him with the research, and the participant's wishes will govern; or
* The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
* *Written Consent:* The IRB may determine that written consent is required if the investigator is unable to justify why it is impracticable to conduct the research without a waiver. This is often the case for prospective review studies, but may occur in retrospective review studies. For example, if an investigator wishes to review the data of all of the patients he refers onward for a colonoscopy to collect outcome measures, the IRB may determine that the investigator should obtain written consent because he will have the chance to obtain consent from the patients during their clinic visit with him.

**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* |
| [ ]  **Yes**[ ]  **No** | Require Scientific Review? Not sure? See guidance in the [Investigator Manual (HRP-103)](https://drive.google.com/uc?export=download&id=0B7644h9N2vLcOWtzU2FmSU5oS0U). | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| [ ]  **Yes**[ ]  **No** | Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobaccoNOTE: CPRC review is not required for Retrospective Chart Review, Retrospective Sample Review, or Prospective Specimen Repository studies. | *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) | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) | **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) as a study location or MR at Masonic Institute for the Developing Brain (MIDB) as a study location? | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| [ ]  **Yes**[ ]  **No** | Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents? | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| [ ]  **Yes**[ ]  **No** | Include the use of human fetal tissue, human embryos, or embryonic stem cells? | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| [ ]  **Yes**[ ]  **No** | Include the use of a controlled substance?  | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) | **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** | Use data from CTSI Best Practices Integrated Informatics Core (BPIC) Formerly the AHC Information Exchange (IE)? | *See instruction within this template.**Contact:* *bpic@umn.edu* |
| [ ]  **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 may conduct a review of this protocol.**Contact:* *privacy@umn.edu* |
| [ ]  **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 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:* *kmmccorm@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** | 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: |
| **Biospecimens and/or Data** |  |
| **Number of Records and/or Specimens** | N# of Records:      N# of Specimens:       |
| **Version Number/Date:** | Include the current version number and date of this protocol. |

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

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**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**

* 1. **Purpose:** Describe the purpose, specific aims, hypothesis, or objectives.

# **Background**

* 1. **Significance of Research Question/Purpose:** Describe the relevant prior research and gaps in current knowledge for your research question.
	2. **Preliminary Data:** Describe any relevant preliminary data (if applicable).
	3. **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.

# **Procedures Involved**

* 1. **Study Type (check all that apply):** Indicate if this is study is 1) retrospective, 2) prospective or 3) both retrospective and prospective.

[ ]  Retrospective Review

Note: To qualify as retrospective, the data and/or specimens must exist when the study is submitted to the IRB for initial review.

[ ]  Prospective Review

Note: If the data and/or specimens do not exist when the study is submitted to the IRB for initial review and is collected for non-research purposes (such as medical treatment or diagnosis or data collected from unrelated research studies), it is defined as prospective.)

[ ]  Both: Retrospective and Prospective Review

* 1. **Identify the Source of the individually identifiable information (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.

If this project requires only **RETROSPECTIVE REVIEW** and **ALL DATA** will be made available to you by CTSI Best Practices Integrated Informatics Core through the information Exchange you do not need to complete the remainder of this protocol (3.3 – 10, Appendices).

* Upload a copy of your BPIC consultation form with this protocol in ETHOS if you are using the abbreviated process.
* HIPCO and Fairview ancillary reviews are waived for these projects
* The BPIC ancillary review approval must be documented in ETHOS prior to completion of IRB review.
	1. **Date Range:** Describe the date range of data / specimens to be obtained for this study. If this is a retrospective review, the end date must be before the IRB submission date.
	2. **Approximate number of records required for review:**

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 BPIC to retrieve data from the Information Exchange

* 1. **Research conducted with populations with additional protections:** Indicate whether records will be associated with populations that require additional protections (pregnant women, prisoners, children, etc.).
	2. **Informed Consent:** Clarify whether informed consent for research use of records was ever obtained for the records you intend to utilize for research purposes or whether records where patients “opted out” will be excluded from the record set. Describe whether informed consent should be obtained for the purposes of this research (for information on whether consent is required, see the Appendix B-2 of the Investigator Manual (HRP-103)).
	3. **Study Design:** Describe and explain the study design.
	4. **Study Procedures:** Provide a description of all research procedures being performed and when they are performed. For research involving data, describe how the data will be selected and who will define the data selection.
	5. **Individually Identifiable Health Information:** Identify whether the research study involves the use of individually identifiable health information. Also complete Appendix B. If this research will involve the use of individually identifiable health information, either collecting or having access to, complete Section 4 below. 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.

# **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.

## 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:

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 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 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 – 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.

## 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/Data:

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**

* 1. **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).

* 1. **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).

# **Data/Specimen Management & Analysis**

* 1. **Data Analysis Plan:** Describe the data analysis plan, including any statistical procedures and who will conduct the analysis. Indicate the minimum number of records and/or specimens necessary to carry out the objectives of your study.
	2. **Power Analysis:** Provide a power analysis, if applicable.
	3. **Data Integrity:** Describe any procedures that will be used for quality control of collected data.
	4. **Existing Specimens (if applicable):** Describe the type(s) of specimens that will be used. Complete Appendix A. Indicate whether you will use specimens under the control of BioNet. If you are not using [BioNet](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement/tissue-procurement-facility), identify the biobank that you will utilize for this study. In addition, explain where the specimens will physically reside during the study.
	5. **Specimen Storage and Access:**

Describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the data/specimens. Indicate if[BioNet](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement/tissue-procurement-facility)will be used for specimens. State the person or group that will be the custodian of the specimens. Explain the purpose of storing specimens and define how they will be used. Clearly indicate where the specimens will be stored and clearly state for how long. If you are using BioNet for these purposes, you can include the following statement, “BioNet will maintain and store the specimens for this study. [BioNet](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement/tissue-procurement-facility)retention procedures will be followed.

* 1. **Data associated with specimens:** Specify which data will be associated with specimens.
	2. **Plans for Identifiers on Specimens (if applicable):**

Explain whether anyone, including the investigator, can identify the participant based on any information on the specimen.Explain whether there will be a unique code on the specimen that can be used to identify the participant but that will not, by itself, reveal who the participant is. If there will be a unique code, explain whether the researchers on this study will have a link to who the participant is. Explain how all specimens will be labelled.

* 1. **Release/Sharing:**

Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain specimens, and the data elements to be provided. Describe any plans for sending specimens outside the University of Minnesota including to whom, where, and for what purpose. Indicate whether a[Data Use Agreement](https://policy.umn.edu/contracts/categories/OT/240/253)is in place.

* 1. **Destruction of Specimens:** Describe how data/specimens will be destroyed when no longer needed.

# **Study Population**

* 1. **Inclusion Criteria:** Describe the criteria that define who will be included in your final study sample.

Research involving pregnant women, prisoners, or children must be reviewed by the IRB in accordance with Subparts B, C or D of the federal regulations. If it can be presumed that the participants are not pregnant, incarcerated, or under the age of 18 during the conduct of the study, the subparts do not apply. If, however, during the course of the study, the investigator becomes aware that the participant(s) meet one or more of these conditions, the PI must either exclude the participant(s) from the dataset or the IRB must promptly re-review the study in accordance with the requirements of Subparts B, C or D.

* 1. **Exclusion Criteria:** Describe the criteria that define who will be excluded in your final study sample.
	2. **Age Range:** Describe the specific age range that will define who will be included in the study population.

# **Consent Process**

* 1. **Consent Process (when consent will be obtained written or orally):** 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.
	2. **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, complete all items below:
		+ 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.
	3. **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.

# **Risks**

* 1. **Risks:** Include any known potential risks of this study. For example, a risk can include the breach of confidentiality.

# **Benefits**

* 1. **Benefits:** Describe any benefits. Generally, these studies do not have a direct benefit to participants. However, the study should have some benefit for the purpose of knowledge and benefit to others in the future. For example, the protocol could include the following statement:

The participants are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.

# **Setting**

[ ]  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.

[ ]  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.

**Appendix A. Types of Materials**

This list does not include all possible materials that will be collected, used, or studied. The following are examples (in red). Add or remove materials that will be collected, used, or studied. Adjust the final list font to black.

|  |  |  |
| --- | --- | --- |
| **Material Type** | **Material Quantity or Volume** | **Preservation Format (Specimens)** |
| Whole Blood  |  |  |
|  Plasma |  |  |
|  Serum |  |  |
|  Buffycoat/Lymphocytes |  |  |
| Isolated DNA/RNA |  |  |
| Specific Organ(s): |  |  |
| Specific Tissue Types(s) (i.e. Skin, Pancreas, etc.)  |  |  |
| Urine |  |  |
| Saliva |  |  |
| Ascites |  |  |
| CSF |  |  |
| Nail Clippings |  |  |
| Hair Clippings |  |  |
| Breast milk |  |  |
| Stool |  |  |
| Photographs |  |  |
| Journals or Diaries |  |  |
| Questionnaires (i.e., Quality of Life), Surveys, or instruments (depression scales) |  |  |
| Long Term Follow Up Surveys |  |  |
| Intake form(s) |  |  |
| Counseling record(s) |  |  |
| Lab report(s) |  |  |

**Appendix B. List of Identifiable Data Elements**

Indicate whether any of the following identifiable data elements will be collected, used, or studied. The following are identifiable data elements per HIPAA. Select Yes or No for each element.

|  |  |
| --- | --- |
| **Identifiable Data Element** | **Included in this research study?** |
| Names | Choose an item. |
| Dates, except year | Choose an item. |
| Telephone numbers | Choose an item. |
| Geographic data | Choose an item. |
| FAX numbers | Choose an item. |
| Social Security numbers | Choose an item. |
| Email addresses | Choose an item. |
| Medical record numbers | Choose an item. |
| Account numbers | Choose an item. |
| Health plan beneficiary numbers | Choose an item. |
| Certificate/license numbers | Choose an item. |
| Vehicle identifiers and serial numbers including license plates | Choose an item. |
| Web URLs | Choose an item. |
| Device identifiers and serial numbers | Choose an item. |
| Internet protocol addresses | Choose an item. |
| Full face photos and comparable images | Choose an item. |
| Biometric identifiers (i.e. retinal scan, fingerprints) | Choose an item. |
| Any unique identifying number or code | Choose an item. |