**Development of a Research Database, Registry, and Specimen Repository Protocol**

**GENERAL INSTRUCTIONS:**

* Developing and managing a database, registry, or repository requires an established infrastructure, standardized protocols, and databases. Consider collaborating with [Biomedical Informatics and Data Access](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic) or the [Biorepository and Laboratory Services (BLS)](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement) before developing an independent database, registry, or repository.
* This template is to prepare a protocol **to store** data and/or specimens for future research use. This template should not be used for the development of a Quality Improvement or Quality Assurance database. For more information about the differences between QA/QI and research, see “How does quality improvement differ from research?” in the [Investigator Manual (HRP-103)](https://drive.google.com/open?id=0B7644h9N2vLcOWtzU2FmSU5oS0U).
* This template **should not be used** to describe specific hypotheses or planned future analyses.
* Each request **to use or analyze identifiable** data or specimens for research should be submitted separately to the IRB using HRP-595 Data and Specimen Protocol.
* For more information about requirements and expectations, see [WORKSHEET: Databases, Registries and Repositories (HRP-337)](https://research.umn.edu/units/irb/toolkit-library/worksheets) and the [Investigator Manual (HRP-103)](https://drive.google.com/open?id=0B7644h9N2vLcOWtzU2FmSU5oS0U).
* This protocol has 2 sections. All proposals to develop a database, registry, or repository must complete Part 1. If you plan to prospectively collect directly from interacting or intervening with research participants, specimens or identifiable information, for the purpose of the database, registry, or repository complete Part 2. If Part 2 is not relevant, it can be removed.
* Before submitting the protocol to the IRB, be sure to remove all instructions and guidance text (including these) so that they are not contained in the final version.

**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) as a study location 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?  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:ics@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* |
| **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. |
| **Protocol Type** |  |
| **Prospective Collection Directly From Interacting with Research Participants** |  |
| **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]

**PART 1 (For Database, Registry, or Repository)**

# Purpose and Significance

* 1. **Purpose:** Describe the purpose, specific aims or objectives for creating this database, registry, or specimen repository.
  2. **Significance:** Provide any relevant background, evidence, or information that supports the importance or justification and scientific value of creating this database, registry, or repository.
  3. **Scope of research focus:** Indicate the intended scope of research focus (i.e., diseases, conditions, or processes) that the database, registry, or repository will support.

# Governance and Oversight

* 1. **Resourcing**: Describe the key personnel positions that will be in place to ensure proper oversight and function of activities necessary to create and maintain the database, registry, or repository.
  2. **Continuing Operations:** Describe the plan for continuing operations in the absence or departure of the PI.
  3. **Quality Assurance Oversight:** Indicate who will be responsible for assuring the quality and integrity of the data / specimens in the database, registry, or repository. Describe how the quality and integrity of the data/specimens will be evaluated.
  4. **Honest Broker of Identifiable Information:** Indicate the individual within the institution that will have the authority and responsibility to act on behalf of the database/registry/repository to remove the link to research identifiers and clinical identifiers in order to provide data, specimens or images to researchers without revealing the identity of participants. The honest broker cannot be a member of a research team that plans to request use of the database/registry/repository. Identify the position/person assigned as the honest broker and outline the policies and procedures that enable the honest broker to perform his/her function.
  5. **Custodian of Specimens:** Identify the individual that is responsible for the management of a biospecimen resource. Describe how the custodian will work with other key stakeholders in the management of the resource including the tracking of all relevant documentation for the resource and for ensuring that policies regarding access to the resource are in place and implemented according to appropriate guidelines.

# Data and/or Specimen Collection

* 1. **Specimen or Material Types:** Information about the types of specimens that will be collected should be listed in Appendix A. See Appendix A for a complete list of material and/or specimens types.
  2. **Data Elements:** Provide a list all of the identifiable data elements that will be collected and stored in the database, registry, or repository in Appendix B. See Appendix B for a complete list of identifiable data elements.
  3. **Medical/Health Records:** Indicate whether you will include information from medical or health records that are outside of the Informatics Consulting Services Information Exchange. How will you verify that records where patients have opt-ed out of research or change their opt-out status? Will the registry or database gather information from medical records that will exist in the future (prospectively, after the creation of the registry or database)? Identifiable information or data elements from the medical records may be stored should be listed in Appendix B.
     1. If accessing health records, include justification for a waiver of HIPAA as outlined in [HRP-441 HIPAA Waiver of Authorization](https://research.umn.edu/units/irb/toolkit-library/checklists).
  4. **Transfer of Existing Data or Specimens:** Describe where the pre-existing data or specimens are currently stored and how those will be transferred to the database, registry, or repository. Include each specific research protocol (including IRB Protocol ID or Submission ID) from which the data or specimens were originally collected, and indication in the original informed consent document that allows for banking.

|  |  |  |
| --- | --- | --- |
| Study Title | IRB Submission ID | Original Informed Consent Language Allowing Banking? |
| Enter study title | Enter submission ID | Indicate whether original informed consent allows banking. |
| Enter study title | Enter submission ID | Indicate whether original informed consent allows banking. |
| Enter study title | Enter submission ID | Indicate whether original informed consent allows banking. |

* 1. **Access to Existing Specimens:** If accessing specimens as part of this registry/repository, please request a consent waiver or type “N/A” and delete the bullet below. Otherwise, complete 3.5.1.
     1. 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
  2. **Follow-Up Data:** If you will collect any follow-up data, describe how this data will be collected (i.e., through routine standard of care visits; additional blood draws, follow-up phone calls, surveys, or questionnaires).
  3. **Non-U.S. Specimen and/or Health Information Sources:** If specimens and/or health information will be included that derives from persons living outside the United States, provide a justification for their inclusion and outline the international laws that permit such a transfer of specimens and/or health information. Review [General Data Protection Regulation (GDPR)](https://privacy.umn.edu/general-data-protection-regulation-gdpr) and the [Research Compliance Office](https://research.umn.edu/units/rco) for more information.

# Data and Specimen Storage and Retention

* 1. **Storage**: Describe how and where data and/or specimens will be stored and maintained. Reference any relevant storage standard operating procedures developed for the database, registry, or repository. Indicate whether the database will be maintained in Redcap, Qualtrics, or Box.
  2. **Withdrawal**: Indicate whether participants will be able to withdraw samples and/or data stored in the repository. If so, what is the process for doing so.
  3. **Destruction**: Indicate whether the data/specimens will be destroyed at any time point and how that will be done.

# Data/Specimen Access and Release

* 1. **Describe researchers who may be granted access or to whom information may be released:** Will only researchers who are agents of the institution have access? Will external researchers be able to request access?
  2. **Identifiable data or specimens release:** Describe the process for requesting and associating IRB approval documentation with all such releases.
  3. **Prohibitions on uses of data/specimens:** Describe any prohibited use (e.g. attempt to clone a human being) you will communicate to all investigators receiving data or specimens from the database/registry/repository.
  4. **Release/Sharing:** Describe the procedures to request and release data or specimens, including: the process to request a release, approvals required for release and who will check for those approvals before release, who can obtain data or specimens, how fund exchanges will work (if applicable), and the data elements to be provided. For research involving specimens, 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.
  5. **Preparation for Release/Sharing:** Explain how data/specimens will be prepared for sharing – if they will be de-identified, coded, or anonymized provide specific information about how those processes will be conducted.

# Data Security

* 1. **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.
  2. **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. [Review the University’s Privacy Office guidance on securing and de-identification of data](https://www.healthprivacy.umn.edu/research). 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).

# 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.

* 1. **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

* 1. **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. Please upload in ETHOS the Data Use Agreement you will use for this transfer of information. (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](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 whether the data / specimens 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/Data:**

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.

# Risks

Describe any potential risks related to the specimens and/or information collected and stored in the database, registry, or repository. For example, are there potential risks related to privacy or confidentiality? If information was unintentionally released, could reasonably place participants at risk of criminal or civil liability or be damaging to the participants financial standing, employability, insurability, reputation, or be stigmatizing.

# Population Characteristics

# Inclusion Criteria:

Describe the inclusion criteria for data or specimens to be included in the database, registry, or repository. For example, will data or specimens be collected from individuals of a specific age or individuals with a particular disease or condition? Specimens and/or data collected should reflect the demographic characteristics and diversity of the population appropriate to the scientific goals of the database, registry, or repository.

# Exclusion Criteria:

Describe the criteria that define data or specimens that will be excluded from the database, registry, or repository.

# Age Range:

Describe the specific age range, if any, of the individuals that data or specimens will be obtained from for the database, registry, or repository. If the age range is undefined or broad, indicate whether both children and adult information or specimens will be collected.

**PART 2 (Prospective Collection)**

**If you plan to prospectively collect directly from interacting or intervening with research participants, specimens or identifiable information, for the purpose of the database, registry, or repository complete Part 2. If Part 2 is not relevant, it can be removed.**

# 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.

* 1. **Vulnerable Populations:** Identify which of the following populations will be allowed to participate in this database, registry, or repository. You may not include members of the populations below as participants in your research unless you indicate this in your inclusion criteria above. If you are prospectively collecting data or specimens from research participants, inclusion of an individual from one of these groups will require the investigator to develop additional safeguards (Section 1.2) 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 primary focus of the research (targeted), included but not the focus of the research 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. |

* 1. **Additional Safeguards:**

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 1.1 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 your child becomes an adult (turns 18 years old) while they are still actively participating in this research, we will request that he or she provide their consent (agreement) to continue their participation in this study.
    - 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.
  1. **If research includes potential for direct benefit to participant, provide rationale 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 Recruitment and Compensation Methods

If you are prospectively collecting data or specimens from research participants for the database, registry, or repository, provide the following information about the recruitment process.

* 1. **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?
  2. **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., Health Sciences Information Exchange (AHC-IE).
  3. **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.)
  4. **Community Outreach:** Outline any community education efforts planned to inform and educate the general community about specimen or data database, registry, or repository collection and use activities as well as the scientific value of its use, especially if the collection will occur without participant knowledge or consent (such as, thru collection of de-identified tissue from hospital pathology).
  5. **Compensation:** Describe the amount, timing, and type of any compensation 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://drive.google.com/open?id=0B7644h9N2vLcVmwxR2dOZFRGSDg)).

# Consent Process

* 1. **Prospective Collection 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.
     + State whether you will ask participants if they wish to be recontacted for future research studies for which they might be eligible (Note that this should align with the consent form, if applicable.)
  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.
  1. **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?”) 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.
  1. **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.
  2. **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.
  3. **Adults Unable to Consent:**
     1. **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).”
     2. **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.
     3. **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.
  4. **Re-Consent or Re-Contact:** Indicate whether participants will ever be re-contacted regarding information in the database, registry, or repository. If so, describe your plan. Indicate whether the participants will be contacted in the future regarding use of data or specimens in the database, registry, or repository. If so, ensure the consent form adequately informs participants of the intention for future contact and includes a statement to opt-in to future contact.

# Provisions to Protect the Privacy Interests of Participants

* 1. **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.

* 1. **Access to 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.)

# Sharing of Results with Participants

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.

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.

**Appendix A. Types of Materials**

This list does not include all possible materials. Only include the materials that will be collected and stored in the repository. Add materials that will be collected and stored in the repository that are not included on this list. 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 and stored in the database, registry, or repository.

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