

Health Information Privacy & Compliance Office (HIPCO) Survey Response for ETHOS Submissions (Printable Template)

Instructions:

Questions highlighted in green must be completed by everyone.

Questions highlighted in blue are only required in some conditions. These conditions are included in the question prompt. When completing the online survey, these questions will only be displayed to those who must complete them.

This form must be completed as part of the ancillary review process by the Health Information Privacy & Compliance Office (HIPCO) for research involving individually identifiable health information or Protected Health Information of research participants (collectively referred to as PHI). The responses you provide should be consistent with the information you provide in your protocol template regarding confidentiality, data management and protecting research participant privacy. To complete this form, you should know:

- How you will gather your research data;
- What elements your research data will consist of;
- Where you will store your research data;
- Where you will analyze your research data;
- How you will share research data among your research team; and
- How you might communicate with research participants.

You may save an in progress survey by copying the unique URL address of this page. You may then restore your in-progress answers by visiting that URL on the computer you are currently using. In progress responses are automatically deleted after one week of inactivity. Responses cannot be edited after completion.

After you complete this form, you must use the form's link to download a PDF summary of your answers, and upload it under Supporting Documents in the ETHOS SmartForm with your IRB submission. If your research includes a HIPAA Disclosure Authorization Form or a Data Use Agreement, those documents should also be uploaded under Supporting Documents in the ETHOS SmartForm. If you have any questions about this form, please contact the Health Information Privacy and Compliance Office by e-mail at privacy@umn.edu, or by phone at 612-624-7447.

Note on storing PHI: Research data involving PHI must be handled in accordance with HIPAA requirements and UMN policy. Storing research data or links to research data on a password protected PC is insufficient to meet HIPAA or UMN standards. Appropriate methods of handling PHI include use of any of the following:

- The University's Clinical Data Repository available through CTSI, also referred to as the Information Exchange (<https://www.ctsi.umn.edu/researcher-resources/clinical-data-repository>)
- REDCap (<https://www.ctsi.umn.edu/researcher-resources/tools-and-software/redcap>)
- OnCore (<https://www.ctsi.umn.edu/researcher-resources/clinical-trial-management-system>)
- The University's Box Secure Storage (<https://it.umn.edu/technology/box-secure-storage>)
- An AHC-IS Server (<https://hub.ahc.umn.edu/technology-information-systems/server-operations>)

IRB Protocol Number for this research (if available):

Descriptive name of this research study:

Name of the Principal Investigator for this research:

E-mail address for Principal Investigator:

Contact telephone number for Principal Investigator:

Under the HIPAA Privacy Rule, research studies at the University are permitted to use and disclose protected health information with the authorization of the research participants, or without individual authorization in limited circumstances.

Please select which of the following is applicable to your research:

- I am requesting that all research participants sign the University's standard HIPAA Disclosure Authorization to participate in the research, or another form approved by the University's Health Information Privacy & Compliance Office.
- I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.
- An external IRB (e.g. Quorum) is reviewing and we are requesting use of the authorization language embedded in the template consent form in lieu of U of M stand-alone HIPAA Authorization, Note: External IRB must be serving as privacy board for this option.

If you are requesting that all research participants sign the University's standard HIPAA Disclosure Authorization to participate in the research, or another form approved by the University's Health Information Privacy & Compliance Office:

Please upload the HIPAA Disclosure Authorization Form that you will be using for this research to Supporting Documents with your ETHOS submission. The form you upload should have all appropriate fields completed.

Please identify the source of the PHI you will be using for your research (check all that apply):

- I will use the Informatics Consulting Services (ICS) available through CTSI (also referred to as the University's Information Exchange (IE) or data shelter) to pull records for me
- I will collect information directly from research participants.
- I will use University services to access and retrieve records from the Bone Marrow Transplant (BMPT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database
- I will pull records directly from EPIC

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

- 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 the Data Use Agreement you will use for this transfer of information here.

If you do not have a Data Use Agreement in place, you may continue with this survey, however, you must complete a Data Use Agreement before you can receive the Limited Data Set. If you have questions about Limited Data Sets, please refer to <http://www.healthprivacy.umn.edu/policies-procedures/creating-limited-data-set>, or contact the privacy office at (612)-624-7447, or by e-mail at privacy@umn.edu.

- Other (please describe on the next page)

If you have selected "Other (please describe on the next page)":

Please describe other sources of PHI you will be using for your research:

Please provide the approximate number of records you intend to review:

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 ICS to retrieve data from the Information Exchange.

The Information Exchange supports researchers by offering secure access to the electronic records of patients. You can request a consultation with the Information Exchange experts by visiting:

<https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting>.

Please provide additional details below about the PHI you will be collecting and/or using for your research:

If you will gather, store, or analyze any information using vendor devices, technology, systems or applications, please describe these below:

Please identify where you will store your 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>)
- In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) database
- In REDCap (recap.ahc.umn.edu)
- In Qualtrics (qualtrics.umn.edu)
- In OnCore (oncore.umn.edu)
- In the University's Box Secure Storage (box.umn.edu)
- In an AHC-IS supported server

If you will store research data in an AHC-IS supported server, please provide the folder where you will store the data so we can ensure that the data is in a properly encrypted server. The path should be in the form of "\\vp.ahc.umn.edu\vp\Research\Study0004"

- In an AHC-IS supported desktop or laptop

If you will store research data in an AHC-IS supported desktop or laptop, please provide device numbers of all devices where such information will be stored so we can ensure the devices are properly encrypted:

- In some other manner (describe on the next page)

If you will store your research data in some other manner, please respond to the following questions:

Please describe how you will store your research data:

If you will have any links (mapping to identifiable data) for your research data, please indicate how you will generate the links, how you will store these links, and how and when you will destroy these links:

What kind of paper documents will you generate during this research study? Where will these be stored, and how will you dispose of them?

Please indicate where you will analyze your research data:

- In the data shelter of the University's Information Exchange (IE)
- In REDCap
- In Qualtrics
- In the University's Box Secure Storage

In an AHC-IS supported server If you will analyze research data in an AHC-IS supported server, please provide the folder name you will be using so we can ensure that the data is in a properly encrypted server:

- In an AHC-IS supported desktop or laptop

If you will analyze research data in an AHC-IS supported desktop or laptop, please provide device numbers of all devices where such information will be stored so we can ensure the devices are properly encrypted:

- In some other place (describe on the next page)

If you will analyze your research data in some other place, Please describe where you will analyze your research data:

Please indicate how you will share research data among research team members:

Will you at any time during the research download research data to a server, desktop, laptop, or external drive that you have not already identified in the preceding questions?

- Yes
- No

If you responded yes, please provide the physical location of the server, desktop, laptop or external drive, along with the name of your IT support person and any device numbers you have:

Device #	Location (Campus/Bldg or other)	Name of IT Support Person

Please indicate how you will share research data among research team members. Acceptable methods of sharing data include transferring data using the University's Box instance, and/or sharing data with an AHC-IS supported shared folder.

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. If you anticipate using e-mail, please read the University's Policy on E-Mail and PHI at <http://policy.umn.edu/operations/phi-appa>, which requires encryption of out-going emails. More information on the University's encryption tool is available at <http://it.umn.edu/technology/proofpoint-secure-email-center>.

This is the final page of the survey. You may complete the survey by using the "Forward" button.

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