How do I submit to the IRB?

All submissions should be routed using the University-wide IRB system, AURA. Please log in to the IRB module in AURA through the AURA website: http://aura.uchicago.edu

How do I select or determine the level of review?

Many new protocols require a full review, but if you believe your new research project qualifies for expedited review, please complete the Expedited Review section on the electronic submission form.

Alternatively, if you believe your study can be **exempted** from review, request "Exempt" review and fill out only those sections of the electronic submission form that appear in AURA. Please also upload any necessary documentation (e.g. a copy of the survey). The IRB office will then notify you if indeed your study qualifies as exempt or if you will need to complete the entire protocol submission form.

The IRB will make the final decision regarding level of review.

Incomplete submissions will not be reviewed until all necessary materials have been received regardless of the date the initial submission was received.

Is there a template available for a protocol document?

The BSD/UCMC IRBs require a protocol document to be submitted with all non-exempt new submissions. A sponsor protocol document used by multiple sites can be submitted, or, for a single-site study, the investigator should prepare a local protocol document. The protocol document, "protocol narrative," or "protocol" is submitted with the original submission of the protocol and revised versions, as necessary, with amendments. There is no required format, but the document must be sufficiently detailed to permit the IRB to evaluate the soundness of the procedures proposed and the potential risks and benefits to research subjects. The sample protocol narrative outline prepared by the IRB office demonstrates content that is generally requested by the IRB.

Protocol narrative outline *updated Feb 2025*

For **non-interventional** studies, such as chart reviews and specimen repositories, a sample template is also provided below:

Non Interventional Protocol Document

Please also see the Forms and Templates page.

I am writing a new protocol and I need assistance in protocol design or determining number of subjects. Are there resources available?

The Biostatistics Clinic, part of the Biostatistics Laboratory in the Department of Public Health Sciences, offers free, short term statistical consultation. This might include discussion on protocol design, sample size calculations, or other assistance. For further information, please visit: https://health.uchicago.edu/research/biostatistics-laboratory .

What is HIPAA and how does it apply to human subjects research?

To improve the efficiency and effectiveness of the health care system, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), included Administrative Simplification provisions that required the Department of Health and Human Services to adopt national standards for electronic health care transactions and code sets, unique health identifiers, and security. At the same time, Congress incorporated into HIPAA provisions that mandated the adoption of Federal privacy protections for individually identifiable health information. https://www.hhs.gov/hipaa/index.html

The Health Insurance Portability and Accountability Act (HIPAA) at 45CFR160 and 45CFR164, also known as the Privacy Rule, is the federal law that sets rules for health care providers and health insurance companies about who can look at and receive patient health information. It defines certain identifiers as protected health information (PHI) and requires an individual to provide written permission, known as an authorization, before a HIPAA Covered Entity such as UCMC can use or disclose the individual's PHI. Use means accessing PHI for internal use within the Covered Entity; disclose means sharing any element(s) of PHI outside the Covered Entity with an external entity, such as a research sponsor.

Because HIPAA applies to all uses of patient health information by a Covered Entity, HIPAA regulations must be considered when using patient health information in a research study.

Authorizations for use and/or disclosure of PHI for research must be reviewed and approved by an IRB or Privacy Board to determine that required elements are present and prohibited elements are not included. Under certain circumstances, the Privacy Rule permits a Covered Entity to use or disclose PHI for research without an individual's authorization. One way a Covered Entity can use or disclose PHI for research without an authorization is by obtaining a waiver of the authorization requirement by an IRB or Privacy Board. Other uses not requiring authorization include use of PHI preparatory for research and research on decedents; researchers must notify the Privacy Board or IRB of these intended uses (https://biologicalsciences.uchicago.edu/irb/irb-forms-and-templates).

An update to the HIPAA Privacy rule effective on June 25, 2024 recognizes certain prohibitions about how Reproductive Health Care Information may be used or disclosed for certain non-health care purposes and additional written attestation requirements. These non-health care purposes are related to health oversight activities, judicial or administrative proceedings, or law

enforcement or regarding decedents, when disclosures are made to coroners and medical examiners.

Authorizations and waivers of authorizations will only permit the use or disclosure for the specific research study for which they were obtained.

Definitions

Covered Entity: Covered Entity is a health plan, a health care clearinghouse, or a health care provider who conducts standard health care transactions electronically.

Health Information: Any information, whether oral or recorded in any form or medium, that (1) is created or received by a Covered Entity; and (2) relates to the past, present, or future physical or mental health, condition or future payment of an individual for the provision of health care to an individual.

Individually Identifiable Health Information (IIHI): IIHI is a subset of health information, including demographic data, that relates to an individual's past, present or future physical or mental health or condition, the provision of health care to the individual, or the past, present, or future payment for the provision of health care to the individual, AND that identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.

Protected Health Information (PHI): PHI is individually identifiable health information transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. HIPAA defines 18 distinct elements of PHI (see FAQ entitled "What is Protected Health Information (PHI)?" on this page).

De-Identified Health Information: Health Information from which PHI has been removed. De-identified Health Information neither identifies nor provides a reasonable basis to identify an individual. Please see Clinical Research Policy CR_POL_117, "Creation of De-identified Data or Limited Data Sets for Research Purposes."

Limited Data Set: A Limited Data Set is a dataset from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed (16 out of 18 elements of PHI as defined by HIPAA). A Limited Data Set may be used and disclosed for research, health care operations, or public health purposes, provided the recipient of the Limited Data Set enters into a data use agreement signed by an Institutional Official. Please see Clinical Research Policy CR_POL_117, "Creation of De-identified Data or Limited Data Sets for Research Purposes."

What is Protected Health Information (PHI)?

Protected health information ("PHI") is any information that might directly or indirectly identify an individual, including

- Physical or mental health information
- Past, present, or future information
- Information collected, created or received
- Information in any medium: electronic, paper, oral

Inclusion of any of the below listed items, alone or in combination, is considered use of protected health information.

- Name – including the use of initials
- Address – All geographical identifiers smaller than a state, except for the initial three digits of a zip code
- Names of relative(s)
- Names of employer(s)
- Dates – any specific date, including date of discharge and date of birth, and including year-month combinations (year of event alone, without month or day, is not PHI)
- Telephone number
- Fax number
- E-mail address
- Social Security number
- Medical record number
- Health Plan or Account number
- Certificate or license number
- Vehicle or device serial number
- Web URL
- IP Address
- Voiceprints
- Fingerprints
- Photographs - full face
- Code
- Any other unique identifying number, characteristic, or code

I believe my study is exempt from IRB review. Can I go ahead?

Per local policy, the IRB reviewer must make the final determination regarding exemption status. **Never commence any study procedures until receiving notification of exemption or approval from the IRB**. Investigators should submit an exemption request through AURA with enough detail to determine whether the protocol meets exemption requirements. You should be notified within a week of the status of your exemption request.

If you make changes to an existing study that has previously been determined to be exempt, a new request for exemption should be submitted, as research activities may have changed such that the exempt requirements are no longer met.

Please contact the IRB staff for further information regarding specific studies that may be exempt from IRB review.

In addition, if you have received approval or exemption from a non-University of Chicago IRB, please contact the U of C IRB office to determine approval or exemption procedures at our site.