What is the Institutional Review Board (IRB)?

Federal regulations require an Institutional Review Board (IRB) to review research on human subjects if the research involves federal funding. The University of Chicago has determined that all research undertaken at this institution, or by those persons affiliated with this institution, must undergo a similar level of review as research that falls under federal regulations. The University has obtained a Federalwide Assurance (FWA), which signifies that the University and the University of Chicago Medical Center are in compliance with the Federal requirements for the protection of human subjects. For details on the University's FWA, please visit the IRB home page or the University Research Administration's website.

The University of Chicago currently has five IRBs: the Social and Behavioral Sciences Division IRB, the Crown Family School of Social Work, Policy, and Practice and Chapin Hall Institutional Review Board (Crown-CH IRB) Institutional Review Board, and 3 Biological Sciences Division IRBs (known as Committees A, B, and C). Each IRB is fully constituted with the appropriate number of scientific and non-scientific, affiliated and non-University-affiliated members, as well as members from different genders and ethnic backgrounds, as required by federal regulations. For current BSD IRB rosters, please see the OCR intranet site.

The Biological Sciences Division (BSD) Institutional Review Boards are administered by the Office of Clinical Research. The BSD IRBs are responsible for all biological or medical research conducted at the University of Chicago and/or the University of Chicago Medical Center and all human subjects research conducted by UCMC faculty, unless review has been ceded to an external IRB. If you are a BSD faculty member, the IRB submission system, AURA, will automatically route your submission to the BSD IRBs for review, regardless of the nature of the research and/or subject population. For more information on the Crown-CH IRB or Social and Behavioral Sciences IRB, please follow the links above.

What is research?

“Research” is defined by the Department of Health and Human Services as “a systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(l)).

Research studies may involve a variety of invasive or non-invasive procedures, including removal of body tissues or fluids, administration of drugs, exposure to various forms of radiation, alteration of diet or environment, interviews, surveys, simple observation, administration of questionnaires, or review of records.

Note that research is **systematic**, and thus the writing up of a single case report would typically not be considered "research." On the other hand, some quality improvement and quality assurance activities are systematic, but are not designed to contribute to **generalizable** knowledge (that is, those overseeing the project are not planning to share results outside this

institution or results are not generalizable to a larger group). These quality assurance activities would therefore not be research and would not require review by the IRB.

Please see the following topics in this section for further information.

What is a human subject?

"Human Subject" is defined as of January 21, 2019 as "a living individual about whom an investigator (whether professional or student) conducting research (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens" (45CFR46.102(e)(1)).

Interventions may be physical procedures by which data are gathered or manipulations of the subject or the subject's environment that are performed for research purposes. "Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes." (45CFR46.102(e)(2)) "Interaction includes communication or interpersonal contact between investigator and subject." (45CFR46.102(e)(3))

Obtaining identifiable private information may include a review of medical records or collection of data from surveys or from existing databases. 45CFR46 clarifies that "private information" includes "information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place" and information "that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. a medical record)." (45CFR46.102(e)(4))

If an investigator obtains data about a living individual in such a way that she or he has no identifiable private information about the subject, then the project is not considered to involve human subjects. In this case, the data must be coded or anonymous, and the investigator conducting the research, as well as the entire research team, must have no access to any code which links the information or material used in the research back to specific individuals.
If investigators have created the code between identifiable information and study data or will have access to the code, the project may qualify for an exemption from IRB review. However, it is still considered human subjects research and some type of submission to the IRB is necessary in this case.

Please see further guidance below for definitions of "coded" versus "de-identified" data.

What about deceased individuals?

The regulations for the protection of human subjects in research at 45CFR46 do not apply to research on deceased individuals. Similarly, BSD/UCMC policies typically do not apply to research on deceased individuals. However, while most regulations concerning humans in

research refer to "living" individuals, the HIPAA regulations at 45CFR164 apply to all persons, whether living or no longer living. As a result, activities that may not be subject to IRB review because all subjects are deceased may still require a minimal submission process to the IRB office because HIPAA regulations still apply. The IRB at the University of Chicago is designated to perform this HIPAA-related function.

Investigators pursuing a research project involving solely deceased individuals should fill out the form for a "Request for Research on Decedents."

What does it mean to be "engaged" in research?

Per OHRP guidance, "OHRP recognizes that many institutions and individuals (e.g., the principal investigator, statistical centers, community physicians, educators, data repositories) may work together on various aspects of a human subjects research project. However, not all participating institutions and individuals need to be covered by an FWA or certify IRB review and approval of the research to the HHS agency conducting or supporting the research. This guidance aims to assist institutions in determining whether they must meet those requirements, that is, whether they are *engaged* in activities covered by the regulations."

Please see the 2008 OHRP guidance "Engagement of Institutions in Human Subjects Research" for help in determining whether an individual or institution is engaged in research:

https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html

Institutions not "engaged" in research would not be required to submit for IRB review. For questions about whether external sites or individuals are considered "engaged" in research, please contact the IRB Reliance team at IRBReliance@bsd.uchicago.edu

How do I get more information about upcoming IRB deadlines or events?

The Office of Clinical Research maintains an email mailing list for IRB contacts through University IT Services. This mailing list will allow researchers and support staff to receive information on upcoming IRB training and meeting dates. Researchers and support staff will also be updated on new or revised policies, forms, or procedures for submitting to the IRB through this mailing list.

As you sign up for the list yourself, you have the freedom to remove yourself from this list at any time.

To sign up for the list, please go to this website:
https://lists.uchicago.edu/web/info/irbcontacts

Once you sign up at this website, you will receive an email to confirm your subscription.

Where can I get more information?

If you have a specific question about a submission in process, please contact the person listed as the "IRB Administrator" on the workspace for that submission in AURA. Contact information for IRB administrators can be found here on the IRB Contacts page.

If you have a general question or are unsure whom to contact, you can contact the IRB administrator on call for the day according to the monthly schedule posted at the above address. (Click on the link to "On Call Schedule" for that month)

The BSD/UCMC IRB office has also established a general email address to which questions or comments may be sent by the research community. The email address is:
bsdirb@bsd.uchicago.edu

Emails sent to this address will be answered within 1-3 business days. If you have a general question about IRB policies, questions about a planned IRB submission, or a question about other IRB-related issues, please consider contacting this email address. If you do not know the specific IRB administrator to contact about a particular submission, you can also use this address and your email will be directed to the appropriate person to respond.

If you have a question about IRB Reliance Agreements and/or single IRB of record, please email IRBReliance@bsd.uchicago.edu