

IRB FAQ's

We hope that this FAQ will acquaint you with the basic policies and procedures of the IRB review and approval process. It is available to researchers from the Columbia College Chicago IRB. Although we serve as a regulatory function, we take a collegial approach to consultation with researchers and their staff. Feel free to call on us as you navigate the process. We are happy to respond to your questions.

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What is the IRB?

- The Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects.
- The primary purpose of the IRB is to protect the rights and welfare of the human subjects.

What research has to be reviewed by the IRB?

The IRB reviews and monitors human subjects research conducted by Columbia College Chicago faculty, staff, and students.

What is research?

- Research contributes to generalizable knowledge.
- Research is designed in advance.
- Research utilizes a systematic approach.

What is a human subject?

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f))

What kinds of IRB review are there?

- There are three levels of IRB Review: full board, expedited, and exempt. The level is determined by the nature of the protocol, level of potential risk to human subjects, and the subject population.
- The determination of level of review applicable to a particular study is made by the IRB.
- Regardless of the kind of review, all applications use the same submission form.

Full Board IRB review

- Any study involving greater than minimal risk requires a review by the convened IRB. This includes studies with vulnerable populations and sensitive questions as well as studies with the possibility of physical risk.
- The IRB is scheduled to meet monthly September thru May and has ad hoc meetings during the months of June and August.
- Studies assigned to full board review are reviewed by members ahead of time, and then discussed at the meeting. The Committee then votes on whether or not to approve the study.

Expedited IRB review

- Only research involving no more than minimal risk to subjects may be considered for expedited review.
- An expedited review is conducted by an individual reviewer or a few reviewers, rather than going to the full board.
- There are federal guidelines as to what can be considered expedited research.

Exempt from continuing IRB review

- Research with very minimal risk to human subjects as determined by regulatory guidelines may be exempted from review at the discretion of the IRB.
- An exemption is granted by the IRB upon review of the application.
- Exempt reviews are effectively “exempt from continuing review.”

What about student research or class projects?

- Some student work is clearly research and requires IRB approval but other student class activities present a challenge to know if they fall under IRB governance. Columbia’s “IRB Guidance for Student Research and Class Projects” is intended to help you decide.

How do I apply?

- Submit a completed IRB Protocol Application for Social and Behavioral Research form to the Office of Academic Research, 218 S. Wabash, 7th floor along with an electronic submission to irb@iris.colum.edu.

Do I have to get consent from study participants?

- The standard expectation is that all subjects will sign a document containing all the elements of informed consent.
- The informed consent process gives potential subjects a description of the study that is clear and complete enough for the individual to judge whether she or he wants to participate.
- The consent form should provide readily understandable information in an amount appropriate to the level of risk in participating.
- Some or all of the elements of consent, including signatures, may be waived under certain circumstances.

Does Columbia have a consent form template?

- Yes, Columbia’s IRB does have a consent form template.

What information must be included in a consent form?

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others that may be reasonably expected from the research;
- A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained;
- For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research related injury to the subject, if relevant. Typically, questions concerning a research project should be referred to the Principal Investigator (PI) for that project, whereas questions concerning the rights of human subjects should be referred to the IRB.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- Other requirements may apply.

How do I obtain consent from Non-English speaking participants?

- Researchers should take great care when obtaining informed consent from individuals who do not speak English or whose understanding of the language is limited.
- Researchers should be fluent in the subject's language or an interpreter should be available during the consent process and throughout the subject's participation as needed.
- Consent forms should be prepared in the language understandable to potential subjects.

What are the exceptions to informed consent requirements?

- The IRB may waive the requirement for written consent if the consent document is the only link between the subject and the research and the principal risk of harm would come from a breach of confidentiality.
- The IRB may waive consent if:
 - o The research involves no more than minimal risk to the subjects;

- o The waiver will not adversely affect the rights and welfare of the subjects;
- o The research could not practicably be carried out without the waiver;
- o If appropriate, the subjects will be provided with additional information after participation.
- Consent may also be waived for some types of research regarding public service programs.

What if I need to review medical records in order to identify subjects for recruitment?

- You may request a limited waiver of authorization for recruitment purposes as part of your application process. To do so, answer the following questions in your application:
 1. Will the information collected be limited only to that necessary to contact the subjects to ask if they are interested in participating in the study?
 2. How will confidentiality/privacy be protected prior to ascertaining desire to participate?
 3. When and how will you destroy the contact information if an individual declines participation?

What does it mean for data to be "de-identified"?

- A de-identified data set may not include any direct identifiers of the individual or of the individual's relatives, employers, or household members.

Where do I send the application?

- Send all IRB applications and correspondence to:
Office of Academic Research/IRB
Location: 218 S. Wabash, 7th floor
Mailings: 600 S. Michigan Avenue
Chicago, IL 60605

What happens after submission?

- Your study will be assigned an IRB number that should be used on all correspondence relating to the study until the study is closed.
- The IRB will determine the level of review.
- The IRB will conduct the review and take one of the following actions:

Approval of research

- Research may proceed on receipt of written documentation of IRB approval.

Stipulated minor changes or clarifications required prior to approval

- It is common for the IRB to request some changes to the consent form or protocol prior to approval. These are called “stipulated changes.”
- If there are stipulations, you will receive a communication from the IRB with details.
- You should respond to the communication in writing.
- If your response is acceptable, your project will be approved and you will receive an approval letter.

Disapproval (full board action only)

- If the IRB determines that the research cannot be conducted at Columbia College Chicago or by employees or agents of the University or otherwise under the auspices of the College, the project, as proposed, is disapproved and may not go forward.

Exemption

- The IRB may determine that your study is not subject to continuing review. How long does it take?
- An expedited or exempt review typically takes about 10 business days.
- Studies requiring full board review are scheduled for the first available meeting. An application submitted by the published deadline will generally be assigned to that meeting. There may be circumstances when this is not possible, in which case it will be assigned to the next available meeting.
- Correspondence from the IRB is sent to the Principal Investigator within one week of full board review.
- The PI has a significant influence on length of time between submission and approval.
 - o Well prepared applications result in fewer requests for stipulated changes.
 - o Rapid response by the PI to requests for changes speeds the approval process.

What happens after I receive approval?

You may begin your research.

You have a responsibility to report problems or adverse events that may occur during the research to the IRB.

- “Adverse event” or “adverse experience” (AE) is an undesirable and unintended, though not necessarily unanticipated, injury or physical or emotional consequence to a human subject.

- “Unanticipated Problems” (UPs) may or may not include specific events experienced by individual subjects, but are developments within the research activity that suggest a potential for increased risks to subjects or others.

All projects are subject to renewal, usually annually.

- No approval is for longer than one year from the initial review.
- If the research is continuing or data analysis is not yet completed, request renewal of approval using the IRB Re-Approval/Completion Form (form IRB-2).
- Projects are subject to continuing review through the data analysis phase. At completion of this phase, inform the IRB that your project is completed so the IRB does not continue to inquire about renewal.
- Projects that the IRB determined to be exempt from further review receive an exemption notice, and no renewal is required. However, the IRB needs to review and approve any modifications to the study in advance.

What if I want to modify the study?

- Once the project is submitted to the IRB, you may not make changes to the study until the IRB has completed the approval process for your original submission.
- Once your study is approved, you may submit modifications.
 - o All protocol changes must be approved by the IRB prior to implementation.
 - o All changes to documents used with subjects (consent forms, questionnaires, recruitment materials, etc.) must be approved by the IRB prior to use.
 - o Use Amendment Review Form (form IRB-3) to explain to the IRB how you want to change the protocol, and to request approval of the changes.
 - o The review of the amendment request may be expedited or may require full board review.

Where do I get more information?

- We are happy to respond to your questions. Feel free to call 312-369-7384 or email us at irb@iris.colum.edu.