



Drexel Institutional Review Board FAQs

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General Questions

Q.1. What is an Institutional Review Board?

An Institutional Review Board (IRB) is an administrative body that is responsible for ensuring protections of the rights and welfare of human subjects that are recruited into research studies which are being conducted through the institution in which it is affiliated. All human subjects research projects must be reviewed by the IRB where the board has the responsibility to approve, disapprove, conditionally approve, renew, suspend, or terminate research conducted by the institution.

The IRB follows the ethical principles of the Belmont report and federal regulations including the Common Rule (45 CFR 46), and the human subjects research regulations from the FDA (21 CFR 50 and 56).

Q.2. What is the Common Rule and the Revised Rule?

The Common Rule refers to the federal regulations for human subjects research, 45 CFR 46 “Protection of Human Subjects”, which investigators must comply with when conducting studies that involve human subjects research. The Revised Rule, which became effective on January 19, 2019, was a revision to the Common Rule to reduce administrative burden related to minimal risk studies and added protections for human subjects. Studies involving human subjects approved prior to January 19, 2019, follow the Common Rule, while studies approved after this are reviewed under the Revised Rule.

Key changes in the Revised Rule were the elimination of continuing reviews for expedited studies, new exemption categories, the requirements for a Single IRB of Record, limited IRB reviews for exempt studies, and new requirements for informed consent.

Most executive branch agencies have signed on to the Revised Rule meaning that research sponsored by these agencies would be reviewed under the Revised Rule. Agencies that have not signed on to the Revised Rule include the Department of Justice (DOJ) and the Food & Drug Administration (FDA) where studies sponsored under these agencies would still be reviewed under the Common Rule.

Q.3. What is human subjects research?

The Department of Health and Human Services (DHHS) has specific definitions for research and human subjects that determines whether a study needs IRB review:

- **Research** - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Human subject** – a living individual about whom an investigator (whether professional or student) is conducting research and obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.



Q.4. What are some examples of projects that are not human subjects research?

- Case reports (fewer than 3 subjects) that will be collected retrospectively.
- Publicly available information, data or biospecimens.
- Classroom projects do not need IRB approval as long data collected from the research will not be taken outside of the classroom setting and is exclusively being done for the purpose of completing a course requirement.
- Quality Improvement (QI) projects, or program evaluation projects limited to improving a department or hospital and program evaluations limited to improving the program. QI and program evaluation projects can be disseminated and shared in publication, however they cannot be referred to as research.

If you are unsure if your activity requires IRB review, or have questions please contact us at HRPP@drexel.edu

The DHHS has specified that the following activities are NOT human subjects research and do not need IRB purview:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

Drexel IRB has process for documenting and acknowledging studies that do not involve human subjects research. A Letter of Determination (LOD) request can submitted to the IRB when a research team needs documentation of a 'Not Human Subject Research' determination from the IRB as may be required in grant applications or provided to publications.



Q.5. Do you have templates or other resources that researchers can use when submitting?

Yes, we have various researcher resources that can be used with your application and IRB submission. Please visit our website to see our [templates and resources](#) to make sure you are using the most up to date versions of our templates.

ORI also has a newsletter, where the HRPP will communicate any changes or important information with our researchers. All Drexel Faculty, Staff, and Graduate Students receive the newsletter automatically. You can also find past newsletter information [here](#).

Application Process

Q.6. What projects need to be submitted to the IRB for review?

The IRB is required to review all research activities that involve human subjects in a systematic investigation designed to develop or contribute to generalizable knowledge.

A formal application can be submitted via Coeus for all research regulated under the exempt, expedited and full board procedures.

The IRB also reviews non-research activities such as case reports (less than 3 patients), quality improvement, program evaluation, and requesting to analyze secondary de-identified data or publicly available information. An Letter of Determination (LOD) form can be submitted via Coeus to receive a formal determination.

Q.7. What do I need to submit with my IRB?

The forms and templates can be found on our [website](#). When submitting a standard initial application to the IRB the following will need to be done:

- Complete the Application Form – Standard or HUD in CoeusLite
- Submit a HRP 504 – Protocol Template (choose the template that is applicable to your study).
 - If your research involves no more than minimal risk, please use the protocol for minimal risk template.
 - If the research is solely a chart review then please complete the Protocol Template for Chart Review.
 - If your research is not minimal risk please use the standard protocol template.
- Make sure that all research personnel complete CITI training or the equivalent.
 - If research personnel are external they are required to only submit a Human Subjects Research course they have completed through the CITI system or the equivalent.



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- Submit [Financial Conflict of Interest form \(FCOI\)](#) for all research personnel. **Please note that a disclosure will need to be submitted for each protocol that you submit.** If you have specific COI questions, please contact the COI office at fcoi@drexel.edu or visit their website: <https://drexel.edu/research/compliance/coi/>
- Submit all recruitment materials that are going to be used in the study. This includes any participant facing documents that will be used for recruitment.
- Submit all data instruments that have been created specifically for the study.
- If the study will consent subjects then it is a requirement to submit a Consent Form or Information Sheet.
- If your research is conducted in a covered entity and access to medical records is needed, then a HIPAA Authorization or Waiver may be required.

IRB Submission System

Q.8. How can a project be submitted to the IRB??

There is a guide on how to submit to the IRB through Coeus Lite at the Drexel University HRPP website located here under the “How to Submit” section:

<https://drexel.edu/research/compliance/human-research-protection-new/researchers/>

Once a study has been submitted to the IRB there will be a process where the Protocol will route for approval. This process typically includes a sequence for routing is that it comes to the principal investigator to the department level and then comes to the IRB level to approve routing. On the Protocol page in Coeus Lite there is an “Approval Routing” tab which shows the sequence of the routing for the specific study and where the study currently is in routing if it has not yet been accepted by the IRB for review.

If you need support or help with Coeus, please contact: [Coeus Help](#)

Please visit the [Electronic Research Administration](#) site for COEUS support and information

Exempt Procedures

Please refer to the [Exempt FAQ Sheet](#) and the Exempt Information Sheet

You will need a protocol and your supportive documents with your submission.

Expedited and Full Board Procedures

Human research that is greater than minimal risk is required to be reviewed at meetings of the Full Committee and human research that is minimal risk can be reviewed by a single IRB staff member that are designated by the Committee that would be reviewed at either an expedited or exempt level of review.

Study Specific Information

Q.9. What if my research involves data from student work or student information?

Faculty that plan to use information from student course materials from classes they teach would be considered a data source that consists personally identifiable information (PII) under FERPA law. There are different requirements depending on what happens to PII being used from the course materials:

- If faculty will not be recording PII that personally identifies students from the course materials for research purposes then there only needs to be a description in the study Protocol that makes it clear that PII is not being used for the study.
- If faculty will be using PII from course materials for research purposes then the following is required for the study:
 - The parent or adult student must sign and date a written consent form.
 - Consent disclosures must include the educational records that may be disclosed, the purpose of the disclosure, and the party or class of party for whom the disclosure of educational records may be made.
 - The study must have a process where upon request of a parent or adult student, the educational agency or institution will provide him or her with a copy of the records disclosed.
 - The study must have a process where upon request of the parent of a non-adult student requests, the agency or institution will provide the student with a copy of the records disclosed.

Q.10. What is an amendment?

Amendments are required when a study has received approval from the IRB and there will be revisions made that will make changes to the currently approved study documents or add new study documents.

Addition and removal of research personnel on studies also need to be made through amendments that are submitted to the IRB. Amendments are required so that the IRB can assess the following:

- The modifications that are being made and the reasons for these changes.
- The increase or decrease of risk of harm to subjects in the study.
- Determine whether the amendment would affect the informed consent form that is presented to potential subjects and if communication with current subjects about the changes being made is necessary.



Q.11. When are continuing reviews needed?

Continuing Reviews are required in the following circumstances:

- Studies require continuing reviews if the studies were initially approved prior to January 21, 2019 when the Revised Common Rule became effective.
- Studies that are reviewed from the Fully convened IRB that are above minimal risk or are deemed to be minimal risk with the condition that there be continuing reviews for the study.
- Studies that are funded by the Department of Justice (DOJ) or Food & Drug Administration (FDA) require continuing reviews.

Q.12. How do I add new research personnel to a study?

The addition of new research personnel who are engaged in research requires submitting an amendment to the IRB. If you are unsure if someone needs to be added, please contact the IRB at HRPP@drexel.edu for assistance. The following information will need to be included with your submission:

- Describe the personnel changes in the amendment summary.
- Complete the HRP 213 Modification for Approved Research Questionnaire.
- Have the new research personnel complete all necessary CITI training.
- Submit Financial Conflict of Interest forms (FCOI) for all new research personnel.
- If new research personnel are external then the following would need to be explained:
 - What is their role in the study.
 - Will the researcher have access to the Drexel University data or subjects identifiers.
 - Does this potentially involve another institution.
 - Does the researcher have permission from their institution to take part in a Drexel University research study.

Q.13. What should I do if the PI is leaving Drexel University?

When an active study changes in the principal investigator, this requires submitting an amendment to the IRB.

The research team will need to complete the HRP 207 Form – Change of Principal Investigator and submit a Financial Conflict of Interest Form again for the incoming PI. All study documents that reference the principal investigator will also have to be updated to reflect this change.

Q.14. What if I am part of a multi-site study?

When more than one institution is involved in a research study, Drexel HRP follows the NIH single IRB policy for. If another IRB is reviewing the research and Drexel investigators would like to cede review to an external IRB, Drexel HRP has detailed information on our website under [Reliance Agreements](#)

Q. 15. What is the Just in Time (JIT) process to receive federal funding?

The JIT process allows a PI to receive documentation from the IRB to secure federal funding. This letter will serve as documentation for a study's proposed use of human subjects. Once the PI has secured funding and is ready to submit a protocol and other study documents to the IRB, an amendment will need to be submitted before any research involving human subjects can take place.