Institutional Review Board FAQ

Please note: Any reference to the "2018 regulations" is referring to the revised Common Rule regulations with the implementation date of January 21, 2019, including any provisions that were put into effect during the delay period (between July 19, 2018 through January 20, 2019). Any reference to the "pre-2018 requirements" is referring to the original Common Rule regulations.

Contents

Who must apply for review by the Institutional Review Board (IRB)?

Anyone who intends to conduct research that involves human subjects must apply for and receive IRB approval before beginning the research. This applies to ALL research involving human subjects. Social science, behavioral, historic, linguistic and marketing research studies must be reviewed by, and receive approval from, the IRB (this is a representation of likely studies, and not an exhaustive list). Check with the IRB Administrator or the IRB Chair if in doubt about the need for IRB review.

What is the definition of research?

Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge

The new regulations identify four activities that are deemed as not being research:

- Scholarly and journalistic activities, including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Certain public health surveillance activities limited to those necessary to identify, monitor, assess, or investigate conditions of public health importance
- Collection and analysis of information, biospecimens, or records for criminal justice or criminal investigative purposes.
- Authorized operational activities for national security purposes.

When can I begin my research?

Research can only begin once you are notified that your project has been approved by the IRB administrator. Therefore, subjects should not be contacted or recruited before the approval notification is obtained.

Do students undertaking class projects need to obtain IRB approval?

Research activities such as class projects, with the goal of providing research experience to the students, by definition, research practica, are not intended to add to generalizable knowledge and thus do not meet the federal regulatory definition of research. For more information to help you determine whether or not your project is considered research according to the federal definition, please see the Who Must Apply section.

How do I know if my research study falls under the revised Common Rule regulations?

All studies initiated after January 21, 2019 must comply with and will be reviewed according to the 2018 regulations.

Any study initiated prior to January 21, 2019 will fall under one of two categories:

a. Studies transitioned during the delay period (July 19, 2018 through January 20, 2019), which includes new studies that began after 8/15/19, or studies that came up for continuing

review and processed the removal of continuing review requirement. Studies in this category will be immediately transitioned to the new regulations.

b. Any study active prior to January 21, 2019 that did not adapt the new continuing review requirements. Studies in this category will not immediately transition to the new regulations. As studies come up for continuing review, they will be given the chance to implement the removal of CR and as such, transition to the new regulations.

The IRB will contact all Principal Investigators as studies transition. Please reach out to irbadmin@ursinus.edu if you have any questions about a specific study.

What are the different categories for review?

The IRB will review research under one of the following categories: Full-Committee review, Expedited review, or Exempt review.

Full-Committee Review

Studies are reviewed by a fully-convened IRB meeting each semester. The Board discusses the study and makes a decision about the approval of the study. This type of review is carried out for studies greater than minimal risk to subjects and any study that recruits subjects under a category of vulnerable populations.

Expedited Review

Studies are reviewed by IRB Chair (or an experienced reviewer designated by the chairperson) and one other member of the board. Members review the appropriate materials and consults with the PI, if necessary, to come to a decision about the approval of the study. This type of review is carried out for studies that involve minimal risk to subjects and fit into an expedited review category of research (see Review Categories). These reviews are conducted on an ongoing basis.

Exempt Review

Certain categories of human subject research (for instance: non-sensitive and anonymous survey and some pedagogical research) are exempt from federal human subject research regulations. Those wishing to undertake such exempt research should still obtain confirmation of the exempt status by submitting the Exemption Request.

When will I hear from the IRB about approval of my study?

The length of time a study will take to be approved depends on the type or level of review required. Listed below are approximate times for approval.

Exempt Review (from application submission to granting of exemption): 7 - 10 business days

Expedited Review (from application submission to primary review): 14 business days

Full-Committee Review (days after the committee meeting): 7 days

Note on approval time: These times are averages for studies that are not assigned stipulations by the IRB or require additional information. Studies that are assigned stipulations will take an additional

amount of time depending on how fast these stipulations are met and when they can be reviewed, either through expedited review or full-IRB review.

What is the category of limited IRB review?

Limited IRB review is a process that is required only for certain exemptions, and does not require an IRB to consider all of the IRB approval criteria. In limited IRB review, the IRB must determine that certain conditions, which are specified in the regulations, are met. Limited IRB review may be done via the expedited review mechanism, that is, IRB Chair (or an experienced reviewer designated by the chairperson) and one other member of the board. Continuing review is not required.

Under what circumstances is limited IRB review used?

There are four exemptions that may require limited IRB review: Exemptions 2, 3, 7, and 8. (Please see the section on Exempt Research for more details on each exemption.)

1. Under Exemption 2, limited IRB review is required only if the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. The limited IRB review in this case serves to make the determination that:
    a. Adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
2. Under Exemption 3, limited IRB review is required only if the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. The limited IRB review in this case serves to make the determination that:
    a. Adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
3. Under Exemption 7, limited IRB review is required to make the determination that:
    a. broad consent was properly obtained,
    b. broad consent was appropriately documented or waived,
    c. and if changes are made in the way that identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
4. Under Exemption 8, limited IRB review is required to determine that:
    a. Adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data,
    b. the research to be conducted is within the scope of the original obtained broad consent (and said broad consent was properly obtained and documented, or waived),
    c. and the investigator does not include returning individual research results to subjects as part of the study.

How do I submit a change in protocol to the IRB?

If you are only adding or removing Faculty or Student PIs then you should complete the Add/Remove/Change IRB Personnel Form.

Other changes/additions require filing the Revision/Addendum/Amendment form. Please remember to highlight all changes to documents (Protocols, Consent Form, Study Instruments).

A change in protocol will be reviewed by the same method in which the study was first reviewed, either by the full-committee or through the expedited review process unless the change is minor and can be managed through expedited review.

When is continuing review required?

The IRB shall conduct continuing review of research requiring review by the convened IRB no less than once per year.

Unless otherwise determined, continuing review of research is not required in the following circumstances:

a. Research initially approved under expedited review.
b. Research reviewed in accordance with the limited IRB review (see explanation of limited IRB review).
c. Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
    i. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    ii. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Is informed consent required for all research?

Informed consent is used to provide potential subjects with the necessary information to make a decision about whether or not to participate in a research study.

Informed consent must be obtained, and documented, from the subject or the subject's legally authorized representative before involving a human subject in research.

The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, which includes providing the information in a language they understand. Informed consent should be obtained only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence

What are the required elements for informed consent?

Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. Information must be presented in sufficient detail relating to the research, and must be organized and presented in a way that facilitates understanding of the reasons why one might or might not want to participate.

The following elements are required as part of an informed consent document to be presented to the prospective subject or legally authorized representative:

a. a research description, which should include an explanation of the purposes of the research, the expected duration of the subject's participation, and a description of the procedures to be followed;
b. a description of any reasonably foreseeable risks or discomforts to the subject;
c. a description of any benefits to the subject or to others that may reasonably be expected from the research;
d. a disclosure of appropriate alternative procedures or courses of treatment, if any;
e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
f. for research involving more than minimal risk, an explanation as to whether any compensation will be given if injury occurs and, if so, what they consist of, or where further information may be obtained;
g. an explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
h. a statement that participation is voluntary, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
i. one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens
    a. a statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies, if this might be a possibility; or
    b. a statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

What are the additional elements for informed consent?

The following elements are required, only as appropriate, as part of an informed consent document to be presented to the prospective subject or legally authorized representative:

a. statement that the particular treatment or procedure may involve risks to the subject that are currently unforeseeable;

b. anticipated circumstances under which the subject's participation may be terminated by the investigator;
c. any additional costs to the subject that may result from participation in the research;
d. the consequences of a subject's decision to withdraw from the research;
e. a statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;
f. the approximate number of subjects involved in the study;
g. a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
h. a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
i. for research involving biospecimens, whether the research might include whole genome sequencing.

Under what circumstances can informed consent be waived?

Under certain circumstances, the IRB may waive the requirement to obtain informed consent for research or may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent

In order for an IRB to waive or alter consent, the IRB must find and document that:

a. The research involves no more than minimal risk to the subjects;
b. The research could not practicably be carried out without the requested waiver or alteration;
c. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
d. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
e. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Informed consent may also be waived or altered in research involving public benefit and service programs conducted by or subject to the approval of state or local officials under certain circumstances.

What is broad consent?

Broad consent is a new type of informed consent provided under the revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for nonresearch purposes.

Is broad consent required?

No, broad consent is only an option for conducting secondary research as an alternative to traditional informed consent or a waiver of informed consent. Broad consent is an option only for secondary research use of identifiable private information or identifiable biospecimens.

If identifiable private information or identifiable biospecimens were collected with broad consent, then exemptions 7 and 8 may apply. Exemption 7 may apply for the storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use. Exemption 8 may apply for the secondary research use use of identifiable private information or identifiable biospecimens.

If individuals were asked, and refused, to provide broad consent, the IRB cannot waive informed consent to use the subject's identifiable information or biospecimens in a secondary study. Use of thse materials without identifiers is still allowed.

Other options for doing secondary research remain, such as conducting secondary research suing nonidentifiable private information and nonidentifiable biospecimens, using the provisions under exemption 4, getting an IRB waiver of informed consent, or returning to the subjects and obtaining the standard informed consent.

If you are considering using materials for secondary research use, please use the IRB as a resourse to help determine what steps you may need to take.

What are the required elements of broad consent?

Under the revised Common Rule, broad consent includes some of the elements of informed consent that are required in the standard informed consent and additional elements specific to broad consent. All required elements of broad consent include:

a. any foreseeable risks to the subjects;
b. reasonably expected benefits to subjects or others;
c. the extent to which confidentiality will be maintained;
d. a statement that participation is voluntary and may be discontinued without penalty;
e. when appropriate, a statement about commercial profit and whether subjects will or will not share in it;
f. when appropriate, whether research might include whole genome sequencing;
g. a description of the types of research that may be done, with sufficient information that a reasonable person would expect the broad consent would permit the types of research conducted;
h. a description of the identifiable private information or identifiable biospecimens that might be used, whether they might be shared, and the types of institutions or researchers that may conduct research with that information or biospecimens;
i. a description of the period of time the identifiable private information or identifiable biospecimens may be stored, maintained, or used for research purposes;

j. a statement, if applicable, that subjects may not be informed about specific research studies that may use their information and that they might have chosen not to consent to some of these studies;
k. a statement, if applicable, that clinically relevant research results might not be disclosed to the subject;
l. and an explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research related harm.

Please note that if broad consent is used, none of these elements can be waived.

Can broad consent for future research be requested at the time of obtaining standard consent for a present study?

Yes, broad consent for secondary use may be obtained when standard informed consent from subjects is obtained for the initial primary research. Investigators who anticipate that they or others may want to use information or biospecimens collected through the primary research for unspecified secondary research may consider this option.