

Human Subjects Research: An Overview for Researchers

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This information is provided by the Human Subjects Office (HSO) to help researchers recognize when Institutional Review Board (IRB) approval is necessary and how to obtain approval for human subjects research.

What is an Institutional Review Board?

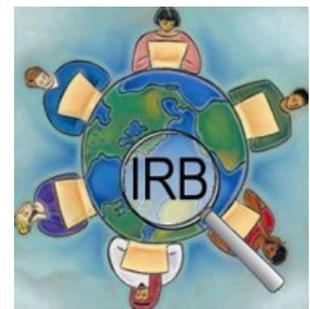
An Institutional Review Board (IRB) is an ethical review committee charged with reviewing, approving and monitoring biomedical and behavioral research involving humans. The underlying purpose is to protect the rights, safety and welfare of research subjects. The Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS) sections of the Code of Federal Regulations ([21 CFR 50](#) and [45 CFR 46](#)) mandate the establishment of an IRB at any institution that receives federal funding for human subjects research.

Board membership consists of University of Iowa (UI) faculty and staff, Veterans Affairs Health Care System (VAHCS) who have either a scientific or non-scientific background. In compliance with the federal regulations, the IRBs also include members who are not affiliated with either the UI or VAHCS.

What are the University of Iowa Institutional Review Boards?

The University of Iowa (UI) has three IRBs:

- [IRB-01](#) reviews biomedical research
- [IRB-02](#) reviews social/behavioral research
- [IRB-03](#) reviews research conducted at the Veterans Affairs Health Care System (VAHCS) or using VA resources



IRB membership includes over 60 UI faculty and staff and VA employees (on IRB-03) with appropriate expertise to review the types of studies submitted to the board on which they serve. In compliance with regulatory requirements, each board includes scientists and members with a non-scientific background as well as community members who do not have a professional connection with the institution.

The UI IRB may also enter into reliance agreements for UI investigators to rely on another commercial or academic IRBs, or for external investigators rely on the UI IRB. Sometimes called a "[central or external IRB model](#)," these reliance agreements allow for a single IRB for multi-site studies as required by National Institutes of Health (NIH) policy.

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What is the Human Subjects Office (HSO)?

The Human Subjects Office (HSO) is the administrative office that supports the three University of Iowa IRBs. HSO staff review electronic IRB application forms, monitor ongoing research and provide education and assistance to University of Iowa and VAHCS researchers. The Human Subjects Office is one of the compliance units under the Vice President for Research and Economic Development and is not affiliated with a specific college or department.

What projects need IRB approval?

According to institutional policy, the University of Iowa IRB must review all research conducted by UI faculty, staff and students and VA employees that meets the definition of human subjects research (see definitions below). IRB review is required prior to the conduct of any research activity (such as recruitment and data collection). According to UI IRB policy, IRB review and approval is necessary regardless of the funding source or location of the research activities (on- or off-campus).



The following definitions come from the Department of Health and Human Services (DHHS) section of the Code of Federal Regulations for human subjects research ([45 CFR 46](#)). The IRB uses these definitions to determine whether IRB approval is required.

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The key components of this definition:

- A “systematic investigation” means data are collected in a systematic manner, i.e. the same questions or procedures for all subjects.
- Research is “designed” to answer question(s), test hypotheses, or find themes or patterns in the data gathered.
- Research results “contribute to generalizable knowledge” when a researcher draws conclusions or makes generalizations based on the information collected.

Human Subject: A living individual about whom an investigator conducting research:

- (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

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What projects need IRB approval? (cont.)

Key points in the definition of human subject:

- “Intervention or interaction” – Information is gathered directly through taking measurements, giving a drug or treatment, or manipulating the subject or their environment (intervention) or through interpersonal communication or contact (interaction).
- “Identifiable private information or identifiable biospecimens” – Working with existing data or biospecimens can be human subjects research if the records or data set contain subject identifiers that allow the identity of the subject to be readily ascertained, even if a researcher never interacts with a subject. “Identifiers” can be the individual’s name, address, contact information, date of birth, etc. or an ID code linked to those identifiers.

IRB approval is required for any project that meets this definition of human subjects research. The definition does not limit ‘human subject research’ to when the researcher plans to publish or present the results at a professional meeting. A study could meet the definition of human subjects research even if it is never published or presented. Journals and professional organizations typically require documentation of IRB approval to publish data or present findings at professional meetings.

IRB approval must be sought and obtained before beginning any research activity or study procedures, including identification of potential subjects, recruitment efforts, data collection or any interaction with potential subjects for research purposes. The IRB cannot retroactively approve research activity.

How to ask if IRB approval is necessary?



There is a form in the electronic HawkIRB system to ask whether IRB approval is necessary. The *Human Subjects Research Determination (HSRD) Form* gathers basic information about the planned study. A researcher may submit an HSRD form prior to completing the CITI training. [For additional information about CITI training, see page 5, “What are the requirements for a Principal Investigator (PI)?”]

An IRB Chair will decide whether the proposed project requires IRB review. HSRD forms are typically reviewed within 1-2 business days after submission in HawkIRB.

- If the proposed project meets the regulatory definition of human subjects research: A determination memo will be attached to the (HSRD) form. Also, a HawkIRB New Project form will be started in the Principal Investigator’s HawkIRB Inbox. This form must be completed and submitted for IRB approval before any research activity can begin.
- If the proposed project does **not** meet the regulatory definition of human subjects research: A determination memo will be attached to the (HSRD) form documenting that IRB approval is not necessary for the project as described. As long as the project is conducted exactly as described in the HSRD form, the project does not require further IRB review and approval and other requirements for human subjects research do not apply.

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What are the types of IRB Review?

Some human subjects research must be reviewed by the full, convened IRB. Other types of research may be reviewed by a single IRB Chair. The type of review depends on the level of risk to subjects participating in the research.

- **Full Board** – Review by the full, convened board is required for research that is more than minimal risk (see definition below) and for studies that cannot be approved through Expedited Review procedures (see below).
- **Expedited Review** – For minimal risk research (see definition below) the IRB review may be conducted by a single person rather than the full board. An IRB Chair or Chair Designee may *approve* research but may not *disapprove* a study. If s/he can't approve the study it must be referred to the full board for review. There are seven categories of research that may qualify for expedited review. Note: The regulatory term 'expedited review' does not refer to the *speed* of the IRB review process.
- **Exempt Research** – The Revised Code of Federal Regulations (effective January 21, 2019) describes eight categories of research that meet the definition of exempt research. University of Iowa policy requires an authorized reviewer other than the Principal Investigator to make determinations of whether an activity fits into any of the exempt categories. This determination does not mean that the research is exempt from IRB review. After the determination is made, the research is exempt from some of the requirements for human subjects research, such as continuing review by the IRB or the amount and type of information provided to subjects at the time of enrollment.

Minimal Risk: According to the Code of Federal Regulations (45 CFR 46.102(j)) a minimal risk study is one in which “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” There are potential risks to subjects associated with any type of research. There is no such thing as a “no risk” research study. In addition to physical risks, subjects may face emotional, psychological, financial, legal or social risks from research study participation. Subjects in a minimal risk study such as a web-based survey or a medical record review face risks from a breach of confidentiality of research data. All possible risks to subjects must be described in the IRB application and disclosed to subjects in the Informed Consent Document.

The key components of this definition are:

- The likelihood (probability) and severity (magnitude) of harm from any risk subjects face from participating in the research
- The amount of risk the subject faces in his/her everyday life. This level of risk may vary for subject populations in different studies or even for subject groups within a study.

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What are the requirements for a Principal Investigator?

A Principal Investigator (PI) is the UI faculty, staff or student or VA employee responsible for the conduct of the research study. According to UI IRB policy, the PI must have the necessary skills and expertise to oversee and supervise the research.

- **CITI Training**



To serve as the PI, or to be research team member, an individual must complete the UI-required modules of an online training course (CITI training) in human subjects protections. Click on the CITI Program logo on the Human Subjects Office (HSO) [web site](#) and follow the instructions to complete the correct course. The *Certified Investigator Database* on the HSO web site includes everyone who has completed the UI- or VA-required modules for CITI training. For UI researchers this is a one-time training requirement. VA employees must take a CITI refresher course on a regular basis. If you already completed CITI training at another institution, you do not need to complete the entire course again. Log in with your previous username and follow the directions to affiliate with the University of Iowa.

- **Financial Disclosure**



The PI and all key personnel must complete the annual financial disclosure in the electronic conflict of interest ([eCOI](#)) system. This process is overseen by the [Conflict of Interest in Research Committee \(CIRC\)](#).

- **IRB Approval**



HawkIRB is the web-based system for IRB application and review. The link to the system is at the top of the menu bar on the Human Subjects Office (HSO) web site. You can find the HSO web site from the UI home page using the A-Z search (under "Institutional Review Board" or "Human Subjects Office").

- **New Project Form** - Researchers must prepare and submit a HawkIRB New Project application to request IRB approval. The Principal Investigator and all research team members must complete CITI training before the New Project application can be submitted. The research should not begin until IRB approval has been granted and notification received by e-mail. An IRB approval memo is attached to each HawkIRB form in the "Form Approval" tab.
- **Modification Form** - Principal Investigators must submit a HawkIRB Modification form to report any changes in the research design or study procedures. IRB approval is required prior to initiation of any changes in the conduct of research activities, unless the change is made to prevent an immediate hazard to subjects.
- **Continuing/Biennial Review Forms** - Federal regulations and institutional policy require IRB review and approval at least once a year for all research that is more than minimal risk. Minimal risk research may qualify for a Biennial Review. If applicable, Principal Investigators must submit a HawkIRB Continuing Review form to request IRB review and approval to continue the study activities. The HawkIRB system sends reminder messages with the deadline for submitting a Continuing Review or Biennial Review forms. These reminders are sent to the PI, the PI's delegates and all contact persons on the research team. The PI may submit a combined Continuing Review/Modification form to revise the study design or procedures at the time of a Continuing Review.

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Requirements for a Principal Investigator (cont.)

- **Assurances**

In order to submit a HawkIRB application, the PI makes some agreements with the IRB about the oversight and conduct of the research study. These agreements are called “assurances.” An Assurance Document is available on the Attachment page of the HawkIRB New Project application. The document includes assurances from the PI and the Department Executive Officer (DEO) or Department Head. The signed Assurance Document is attached to the HawkIRB New Project form.

The UI IRB allows graduate and undergraduate students, residents and postdoctoral fellows with appropriate expertise to serve as Principal Investigator of a study. They must have a faculty advisor who is included in their research team. The faculty advisor will need to complete the online CITI training in human subjects protections and sign a section of the Assurance Document agreeing to oversee and supervise the student researcher.

Are there additional requirements for research off-campus or outside the United States?

There are some additional approvals and documents required for research that is conducted off-campus or outside the United States. The UI IRB needs to review and approve (or defer to another IRB) all research conducted by UI faculty, staff and students and VAHCS employees. However, research outside of the state of Iowa or in another country will also need to comply with local rules and regulations. Approval by a local ethics committee may also be necessary.



- **HawkIRB Attachments** – Start a draft New Project application providing a thorough, detailed response to all of the questions. Sections will open on the Attachment Page to indicate the required documents. Wait to submit the application to the IRB until you obtain and attach all necessary permissions or ethics committee approvals.
- **Letter of Agreement** – Whenever research is conducted off-campus or outside the U.S., an attachment category opens in the HawkIRB New Project application to provide documentation of permission to conduct the research. If the research will be conducted in a facility (school, agency, clinic, etc.) for which permission must be obtained to conduct the research, that letter of agreement must be obtained prior to submission of the HawkIRB application to the IRB. The facility may provide the letter to the researcher on paper or by e-mail, but it must indicate that the person providing permission:
 - Is associated with the agency (letter on letterhead or an e-mail address associated with the agency)
 - Has the authority to grant permission for the research to be conducted in the facility
 - Has knowledge of the study design and procedures

The signature block on the letter or e-mail message must include their name, title and affiliation with the agency.

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Additional requirements for research off-campus or outside the U.S. (cont.)

Attach the letter of agreement to the HawkIRB application. The letter of agreement attachment category may be left blank if the research will not be conducted in a facility for which permission is necessary (i.e. in subjects' homes, in a public place)

- **Obtain Outside Approval**

- **Ethical Review Committee Approval** – The U.S. Department of Health and Human Services (HHS) maintains an international compilation of human research standards that lists over 1,000 laws, regulations and guidelines for the conduct of human subjects research in over 100 countries. HHS also maintains a compilation of countries that have ethical review regulations or standards for social/behavioral research. (<http://www.hhs.gov/ohrp/international/index.html>). Consult with a local researcher and the HHS compilation of research standards to determine whether additional ethics review is required. In some cases, there are ethical review requirements for the country or a specific region. In other cases the local facility may have its own ethical review requirements. The country may also have a Ministry of Health that must approve the research in addition to in-country ethical review or UI IRB review.

-OR-

- **Local Context for Research** – If the country or facility to not have an ethical review committee, the UI researcher must identify a local expert who is willing to evaluate the study proposal in terms of the local standards for conducting human subjects research. There is a form/letter for this expert to complete providing information about local context to the IRB. The template letter is available on the attachment page of the HawkIRB New Project form, in the Miscellaneous Attachments drop down menu.

This step can take a considerable amount of time. Plan accordingly.

What resources are available for researchers?

- **Guide for Human Subjects Research at the University of Iowa** – The Guide provides an overview of UI IRB policies and procedures and guidance on best practices for the conduct of various aspects of research activity. The Guide is posted on the HSO web site under “UI Investigator’s Guide.”
- **Frequently Asked Questions (FAQ)** – There are a variety of topics covered, including an IRB overview, requirements for IRB approval, starting a HawkIRB application, assigning delegates in the HawkIRB system, and many more.



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Resources for researchers (cont.)

- **Education and Training**

- **HawkIRB Training Sessions** - HSO staff present a three-part series on how to use the HawkIRB system. The first two sessions provide an overview of the system and covers the HawkIRB New Project application. The third session covers HawkIRB forms a researcher might submit after initial IRB approval (Modifications, Continuing Reviews, Reportable Events and Project Closure). There is a fourth HawkIRB Training for external IRB review applications.
- **IRB Office Hours** - Human Subjects Office staff are available several days a week during the fall and spring semesters and once a week in the summer. The schedule is posted on the HSO web site under “Education and Training”.
- **Recorded Presentations (IRB ICON Course)** - There are a number of research-oriented recordings, including the HawkIRB training sessions, available in the *IRB ICON Course for Researchers*. The portal for this course is on the HSO web site, under “Education and Training.”
- **IRB Connection Newsletter** - The monthly newsletter highlights IRB policies, federal regulations and guidance, answers to frequently asked questions and much more. The newsletter is posted on the HSO web site and distributed electronically to the UI and VA research community.
- **HawkIRB Help Messages** ⓘ - There are guidance messages associated with most of the questions in the HawkIRB New Project application. These messages were designed to help researchers provide the required content in response to questions in the application.
- **Human Subjects Office Staff** - HSO staff and IRB Chairs are available to assist researchers over the telephone, by e-mail or by appointment.

Contact the Human Subjects Office by phone: 319-335-6564 or e-mail: irb@uiowa.edu.

