

CWRU IRB Frequently Asked Questions

Where is the CWRU IRB Administrative Office located?

The administrative office is located in the Office of Research Compliance (ORC), Sears Library Building, 6th Floor mail code: 7230. Please contact the IRB office at (216) 368-6925 or (216) 368-4514 with any questions that you may have.

Who are the Members of the CWRU IRB?

To comply with the federal regulations regarding human study participants in research (45 CFR 46), the CWRU IRB must consist of at least five (5) members. These members are appointed by the University Provost's office and aim, "...to promote complete and adequate review of research activities commonly conducted" at the University. In addition to faculty members with expertise in scientific areas, the IRB includes at least one member whose primary concerns are in a nonscientific area. Also, at least one member must be from the community, and must not be affiliated with the institution. The IRB Administrative Office (IAO) Head, in consultation with the IRB Chair, is responsible for ensuring that each meeting is appropriately convened as follows: (1) at least one non-affiliated member must be present, (2) at least one non-scientific member must be present, and (3) more than half of the members must be present.

The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB; these consultants, however, do not vote with the IRB.

When is IRB approval required?

If your project involves "research" and "human subjects" as defined by 45 CFR 46, you must submit an application to the CWRU IRB for approval prior to the recruitment of study participants and the collection of data. Human study participant research for student theses and dissertations always requires prior IRB approval. Data collected before approval is obtained cannot be used for research.

Who may act as a Responsible Investigator?

To serve as the principal investigator on an IRB protocol, he or she must also meet all of the following criteria:

- CREC-certified
- CWRU Faculty member

o Faculty has to be classified as such by the University's Human Resources Department as reflected in the Faculty Senate Handbook.

o At the discretion of the IO, he or she may determine whether a researcher, not defined as a faculty member, is able to serve as the principal investigator on a case by case basis.

Note: Even if a study is student-driven, students cannot act as principal investigators, they can only be listed as a co-investigator or research staff/assistant. This applies to all levels of students, undergraduate and graduate.

What are the education requirements?

The Continuing Research Education Credit (CREC) Program was created to provide documented training for all Responsible Investigators, regardless of sponsorship, as well as those Key Personnel listed on NIH grants. Investigators must meet the “Core” CREC requirements before the IRB will grant approval, and must obtain a specified number of points over a specified time to retain CREC certification. For the CREC program description and a link to the program specific to non-biomedical researchers, please see <https://research.case.edu/Education/CREC.cfm>

What is the faculty member’s role in student research?

“A faculty member assigning research projects involving human subjects must take an active role in assuring that the subjects of student research are adequately protected. The University expects that advisors will take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of IRB applications. After protocol approval the advisor should meet regularly with the student in order to review their work and progress. While a student serves as the primary researcher for the protocol, the faculty advisor is ultimately responsible for the protection of human subjects. A faculty member’s signature on the application indicates their willingness to comply with all administrative and federal regulations” (University Policy on the Involvement of Human Participants in Research). To comply with this policy, the faculty member who is acting as the Responsible Investigator is required to educate and mentor the research team, and is also responsible for maintaining research records as required by law or University policy.

What is the difference between Exemption, Expedited Review, and Full Review?

An **exemption** is a determination that the human study participant research in question meets the federal requirements to waive IRB review. According to University policy, investigators are prohibited from making exemption determinations themselves. Rather, all research involving human study participants must be submitted to the IRB for a determination of exemption.

Expedited review means that the research in question can be reviewed and approved by one or more members of the IRB because it meets the criteria listed in 45 CFR 46.

Full review means that a quorum of IRB members is required to meet, discuss, and vote on the research in question in order to obtain IRB approval. All research that the IRB does not exempt or expedite requires full review.

If applying for a grant, how would I obtain the FWA numbers?

The institution’s FWA number can be found in the ORA website, <http://case.edu/research/>, under “Popular Resources → Commonly Requested Information.”

What is the role of the IRB Administrative Office (IAO)?

The IAO is responsible for making determinations of exemption, pre-reviewing protocols, answering investigator questions, facilitating IRB review of protocols, maintaining records, providing required written documentation of IRB actions, and acting as a member of the IRB Advisory Committee (IAC). Kim Volarcik is the Executive Director of Research Compliance, and Sue Ambro is the Associate Director of Research Compliance and the Manager of the CWRU Institutional Review Board. If you have any questions about human study participants' research or CWRU IRB procedures, please feel free to contact Ms. Volarcik or Ms. Ambro via email at cwru-irb@cwru.edu or via phone at 216-368-0134 (Volarcik) or 216- 368-4514 (Ambro).

As per federal regulations at 45 CFR 46.103(b)(2) and the Common Rule require CWRU to provide its IRB with sufficient meeting space and to support the IRB's review and record-keeping responsibilities. The IRB shall include the administrative personnel to manage the processing of the application to the IRB and managers to establish operating procedures to promote consistency and efficiency. The staff receives mentoring and training on the job. They also participate in the CREC training program required of the IRB members and investigators. Additionally, the IRB administrative staff attends national meetings.

Each staff member is appointed to his/her position and receives periodic performance evaluations at least on an annual basis by the Assistant Vice President of the Office of Research Compliance.

What are common problems that can delay the review of my protocol?

- Failure to meet educational requirements.
- Failure to fully answer all the questions on the application.
- Failure to provide a completed signature page.
- Failure to include a consent document that includes all required information.
- Failure to provide accurate contact information. For example, listing an e-mail address that you don't normally use.
- Failure to provide IRB approval letters or letters of cooperation from institutions outside our Federal Wide Assurance system.
- Failure to submit a proposal in a timely fashion.

Once an application has been submitted to the IRB office, when can research begin?

No research may be initiated until the CWRU IRB has given your protocol full approval with no revisions. **You must wait to receive this approval in writing before initiating your research. Verbal approval is not acceptable. Any data collected before obtaining written approval cannot be used for research purposes.**

Why does full board review seem to take so long?

The full CWRU IRB meets once per month. If an investigator does not submit a protocol requiring full board review before the monthly deadline date, the review will automatically take more than four weeks. It is important to keep the deadline dates in mind in order to avoid these types of delays.

Some protocols are delayed because they require multiple full board reviews due to poorly written protocols that require substantial revision or additional information. The IRB cannot approve protocols that are lacking required information or that are unclear. Careful preparation of the application by the investigator helps to avoid such delays.

Why does the IRB require a copy of the translated consent when the research involves Non-English speaking study participants?

The IRB must ensure that the consent is appropriate for the study participant population in question, and must maintain a copy of the exact consent document to be used. The copy to be used is stamped in the file as “approved.”

Where can I find 45 CFR 46 and 21 CFR 56?

45 CFR 46 can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

21 CFR 56 can be found at <https://www.ecfr.gov/cgi-bin/text-idx?SID=d0ed3b44c393bde807b7dfd68b321f97&mc=true&node=pt21.1.56&rgn=div5>

Where can I go to learn more about human study participants’ protections?

To learn more about human study participants’ protections, please visit the CWRU Office of Research Compliance Education webpage at <http://case.edu/research/faculty-staff/education/crec/>, at which you can discover educational opportunities, including the annual seminar series on human study participants’ protections.

The DHHS Office for Human Research Protections (OHRP) also has a webpage that includes educational materials, policy guidance, and workshop information: <http://www.hhs.gov/ohrp/>