

Research and IRB Review FAQs

Who sits on the Institutional Review Board (IRB)?

The Chair of the IRB is Nicole Michels, PhD, and she can be reached via email at: nmichels@rvu.edu or by calling: 720-874-2436. The Vice Chair is Dr. Brad Thornock, and he can be reached at: bthornock@rvu.edu or by calling: 435-222-1265

The IRB Compliance Administrator is Laura Dement, and she can help you get started if you have questions. She can be reached at: ldement@rvu.edu or: 720-874-2481.

How do I know if I am conducting research with human subjects?

The definition of human subject is “a living individual about whom an investigator, whether professional or student 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.”

Intervention includes both physical procedures by which data are gathered, manipulations of the subject or the subject’s environment for research. *Interaction* includes communication via surveys, emails, phone calls, in-person, etc. or any interpersonal contact between investigator and subject.

When am I required to submit a proposal involving research with human participants to the IRB?

All research projects that will involve human participants must be submitted for review and approval before beginning the study. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

I am just doing a simple survey; do I need to submit my proposal to the IRB?

Yes, if the study meets the definition for research with human participants, as explained above. RVU Federalwide Assurance (FWA) with the U.S. Department of Health and Human Services states that all research being conducted under the auspices of this institution is subject to review and approval by the IRB. Written approval from the IRB must be in place before any interventions or interactions with human participants (e.g., recruitment) actually begin.

I am not collecting any identifying information in my human participant research project. Do I need to submit my proposal to the IRB for review?

Yes, if your research project involves active data collection. Federal regulations and RVU policy require that ALL research involving intervention or interaction with human participants, regardless of whether or not identifying information is being collected, must be submitted for review prior to beginning the research study. However, if your research project involves use of existing information collected from human participants (e.g., secondary datasets, existing biological samples), but there are not any identifiers linking individuals to the data/samples, then the activity may not require IRB review.

Can researchers be subjects in their own studies? Does self-experimentation require IRB review?

Yes, researchers can be subjects in their own studies. However, RVU policy regards this type of research (investigator self-experimentation) as research with human participants, and generally requires the same review and approval as research that recruits other people as subjects.

Though investigator self-experimentation may not raise the conventional ethical concerns outlined in the [Belmont Report](#), all human research projects should undergo ethical review to assure the safety of people involved and the integrity of the research at the university. While researchers may be aware of the risks of self-experimentation, they may also be more willing to accept risks that are ill-advised. Application for review with the IRB office allows a neutral third party to raise concerns and/or propose measures to promote the welfare of researchers.

If my research qualifies as Exempt, does this mean that I don't have to submit a protocol for review?

No. The Federal Regulations do make certain categories of research exempt from IRB review. However, RVU policy does not allow investigators to self-exempt their human participant research projects. Instead, determining if a project is Exempt from IRB review is an administrative review process handled by the IRB staff.

I will be collaborating with another institution. Do I need to submit to RVU's IRB and the other institution?

If you are a member of the RVU faculty or staff, or a RVU student, and you are the person responsible for the conduct of the study (PI), you must get RVU IRB approval to conduct your research regardless of where the research takes place. Investigators should contact the IRB office whenever collaborative research is occurring. Separate applications for each institution may be necessary; however, in order to avoid duplicate review, an IRB Authorization Agreement may be

arranged with the other institution to establish one IRB as the designated IRB to review and approve the research.

My research will be done in another country. Do I have to obtain IRB review and approval from RVU?

Yes. If you are a member of the RVU faculty or staff, or a RVU student, and you are the person responsible for the conduct of the study (PI), you must get RVU IRB approval to conduct your research regardless of where the research takes place. You should also be aware that your project may need local (that country's) IRB approval (or the equivalent ethical review) in addition to RVU.

I want to conduct a study that involves the use of deception. Is this allowed? What do I need to consider?

The use of deception in research is not prohibited by either the federal regulations or RVU. However, because at some level the use of deception in research violates the trust that the participant puts in the researcher, this method should be considered carefully. Deliberate deception of participants may occur only in situations where withholding information about the nature of the study is necessary to ensure valid results, and never to get participants to do something that they would not do if the information was fully disclosed to them.

Researchers should describe for the IRB the method, rationale, and the process of informing participants of the purpose of the research as early as is feasible, preferably at the conclusion of an individual's participation (but no later than at the conclusion of data collection) to permit participants to withdraw their data. Additionally, researchers should provide a justification for the deception techniques and document that there are no equally effective non-deceptive techniques available. Please refer to the American Psychological Association's [Ethical Principles of Psychologists and Code of Conduct](#) for further guidance.

I am planning to do an oral history project; do I need to submit my proposal to the IRB?

Some research involving the collection and use of oral histories or life histories meets the federal definition of 'human subjects research' and requires an application to the IRB office, while other research using the same methods does not. When in doubt, please check with an IRB member.

I am developing case studies; do I need to submit my proposal to the IRB?

Studies that use multiple case studies to draw conclusions that are applicable in a generalizable context, or to address a hypothesis, meets the federal definition of 'human subjects research' and requires review by the IRB office. Other case studies may not require IRB review.

When may I begin data collection for my study?

You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis. A memo will be sent to you via e-mail when your project has IRB approval.

How long will it take for me to obtain approval to do my study?

That depends on the nature of your study and the characteristics of the people you intend to recruit. Research projects that involve only minimal risks are eligible for Exempt or Expedited review, wherein you should allow 2-3 weeks for IRB review.

Research projects that involve greater than minimal risk to participants will need to go through a fully convened IRB meeting, wherein you should allow at least 4-6 weeks for review and approval of your study. The IRB Compliance Administrator should be able to give you an approximate review date.

Can the IRB approve a project retroactively?

No. There is no provision in the federal regulations that allow for IRB approval of research that has already been conducted. If data was collected for purposes that the IRB determines to be non-research (e.g., program evaluations for library or educational programs not initially intended to be used for research), IRB approval can be sought for the data analysis going forward.

Who can I talk to if I have a question about my research project involving human participants?

The IRB staff is available to provide assistance to investigators who are engaged in research with human participants. The Compliance Administrator is your resource for any general questions at: ldement@rvu.edu