

IRB FAQ:

Getting Started:

1) What is the Institutional Review Board?

The IRB is a committee comprised of faculty, staff and community members authorized to review and ensure the safety of human subjects in research.

2) Does my research project need IRB Review?

Before submitting a research project for review, please consider the following:

a. Is my project considered human subjects research?

If your study involves human subjects and a research question, it is considered human subjects research and must be reviewed by the IRB before data collection can begin.

b. What are human subjects?

A human subject is a living individual *about* whom an investigator conducting research obtains data through intervention/interaction with the individual or collecting identifiable private information. Collecting information from a person that isn't private data does not count.

c. What is considered intervention?

Intervention involves any manipulation to the participant or the participant's environment during the course of a research study. Intervention also includes physical procedures to collect data.

d. What is considered interaction?

This includes communication or interpersonal contact between the participant and an investigator.

3) What training is required to work with Human Subjects?

Any member of the research team who obtains informed consent, interacts with subjects, or has access to private, identifiable information needs to complete the required CITI [training](#) courses.

4) How do I apply for IRB review?

Appalachian IRBIS Information

Please log into the IRBIS system to begin the application process. You will need to attach any relevant supporting documents.

5) What happens after I submit an application?

The reviewing process for a research project may take any time from a week to a month, depending on the study. Please allow ample time for your research project to be reviewed and approved.

General Questions:

1) Can I compensate human subjects who participate in my research project?

Yes. Consider what amount is reasonable to reimburse a participant for his/her time and effort to be in your research. It is recommended to say 'you will be compensated for your participation in this research project' in your communications. Please refer to the Paying Human Subjects section of the Office of Research department for further information.

Paying Human Subjects

2) Can I offer extra credit for participation in my research project?

Credit is allowed for study participation but an *alternative means* that does not involve research participation must also be provided. See your department's policies for details.

3) How do I report an adverse or unanticipated event?

Log into the IRBIS system. On the left hand column select unanticipated problem. Follow the instructions listed.

IRBIS Unanticipated Problem

4) How do I modify my research project?

Log into the IRBIS system. On the left hand column select modification. Follow the instructions listed.

IRBIS Modification

5) How do I add, change or remove personnel from my research project?

Depending on the personnel, submission of a modification form might be necessary. For changes other than a PI or a specially trained personnel, send an email to irb@appstate.edu

6) Can I be a Principal Investigator (PI) on a research project if I am a student?

Yes, but you are required to lost a Faculty Advisor. Confirm that your advisor understands what your research project entail and that they have completed the necessary CITI training courses.

7) What is the process for collaborating with a researcher from another university or institution?

Usually one IRB conducts the review and the other “relies” on that review. To initiate a reliance agreement, log into IRBIS and start a new study.

8) What are the necessary steps to become a researcher at Appalachian if I have been approved to be a researcher at a different university or institution?

Researchers who were previously approved will need to affiliate their CITI training courses with Appalachian.

9) How do I close my research project?

Log into the IRBIS system. On the left hand column select closure. Follow the instructions listed.

IRBIS Closure

10) What are the requirements for storing identifiable data?

Security requirements depend on the data classification. Please consult the data management standard for more information

Appalachian Data Management

11) What is the difference between de-identified, coded and anonymous data?

De-identified data is data that has all identifiable information removed but could be re-identified with approval from the IRB.

Coded data is when no direct participant identifiers, but is linked to identifiable information through coded data.

Anonymous data is when identifiable information cannot be recovered or was never collected.

Forms and Templates:

1) What consent form should I use?

Remember that the language used in a consent form should be at the level of a local student in 6th to 8th grade.

If the participants are part of a focus group, please add that participants should not share private, identifiable information about others (i.e.,

participants will not share the conversation or others' responses outside of the group).

2) When should I use an assent form?

If a participant is under the age of eighteen and not enrolled in college, an assent form must be used in order to obtain consent.

3) What consent form should I use for non-native English speakers?

If the participant does not clearly understand the consent form, translate the consent form into the participant's native language.

4) Do I need a LOA (Letter of Agreement)?

When transferring materials between laboratories for non-commercial research purposes, a LOA would be needed.

Research Project Resources:

1) How can I share files securely?

FileLocker is a service provided through Appalachian to share files with people both inside and outside of Appalachian State University. It is a secure means of sharing files with collaborators inside and outside Appalachian.

FileLocker

2) How can I build secure online surveys and databases?

REDCap is a service provided through Appalachian to provide a secure way to create and store surveys and databases.

If you are collecting data for the purposes of human subjects/ research, review and approval of the project is required by your Institutional Review Board.

Appalachian REDCap Information

REDCap Overview

Qualtrics is the survey provider supported by IT. In your survey draft, select "Edit Survey" from the tabs. Choose "Survey Options," then "Survey Termination." Check the box called "Anonymize Responses" which will make Qualtrics delete the IP address once the survey is completed.

Appalachian Qualtrics Information

Please visit security.appstate.edu for more information on how to manage data storage and security.