

Guidelines on Students Conducting Medical Education Investigations

How can medical students participate in educational investigations?

Medical students may be involved in education research or evaluation through a variety of different paths. They may conduct research through participation in the Medical Education Distinction Track, serve as research assistants on formal projects, or collaborate with faculty on evaluation or quality improvement projects as part of an elective or independent study.

Do all educational investigations qualify as “research”?

The projects students are involved in may or may not qualify as human subjects research, as that term has been defined by the Code of Federal Regulations for the purposes of conducting research with human subjects. **“Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not that are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.” (CFR §46-102.d).**

Some educational evaluation or quality improvement projects might not meet the federal definition of research. For example a project might not use a research design that supports the generalizability of the findings to other settings (e.g., control/comparison groups, random selection). It might be designed to provide only locally relevant information to local stakeholders.

If you have any questions about whether or not your project is research contact the [Human Subjects Protection Program \(HSPP\)](#). The HSPP has also implemented a “Determination of Human Subjects Research” form to help investigators determine whether or not their project is human subjects research. The form can be found [here](#).

Why is some research considered exempt?

If a student is included on an educational project that has been determined to be human subjects research by the University of Arizona Human Subjects Protection Program then the project and the student must abide by all institutional guidelines as well as the standards outlined in the IRB application. It is the responsibility of the Principal Investigator to ensure this compliance.

A research project also may receive “exempt” status when it meets one of the federal definitions of exempt research. Studies conducted in an established or commonly accepted education setting is an exempt category, as are studies involving educational tests or survey procedures. A research investigation still must submit the appropriate application for research to the HSPP. This application will detail the ethical guidelines the investigation must adhere to.

What would prevent an educational research project from being exempt?

The HSPP will not classify a human subjects research investigation if it collects sensitive information. The Code of Federal Regulations (CFR) indicates that studies are not exempt when they collect data that “is recorded in such a manner that [human] subjects can be identified, directly or through identifiers linked to the subjects and b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.” [Code of Federal Regulations 45 CFR 46.101\(b\)\(2\)\(1\) Categories of Exempt Research.](#)

Do we have to follow ethical standards when studies are exempt?

Even if a project has received exempt status from the OCRC, it still should abide by all ethical standards concerning research outlined in the project application. These expectations are outlined as well in the Collaborative Institutional Training Initiative (CITI) modules.

In addition, we strongly recommend that all faculty and students involved in research review the ethics guidelines from the [American Educational Research Association](#) and the [American Evaluation Association](#).

The Office of Medical Student Education recommends the following for students participating in education evaluation or other investigations that are not research:

If a student is included in an educational evaluation or quality improvement project in the educational environment that is **not research** they should:

- Complete the CITI course and maintain an up-to-date certificate.
- Abide by all ethical guidelines outlined in the CITI training especially concerning participant privacy and protecting the confidentiality of data.

If a student is included in an educational evaluation or quality improvement project in the educational environment the supervising faculty member should:

- Have current CITI certification for conducting studies involving human subjects in educational settings.
- Be responsible for oversight and ensuring all ethical standards are upheld.
- Ensure that the privacy and confidentiality of the data is protected, to include defining how the student is able to interact with project data. Please see this guidance from the HSPP office on data [storage](#).

Medical Students should only:

- Have access to de-identified student level data for analysis (all unique identifiers should be removed from the dataset). Examples of unique identifiers in data may include names (first and last), addresses, email addresses, online user names, birth dates, telephone numbers, IP addresses, and social security numbers or other unique numbers that can be traced back to the identify of participants. In the instance of health related human subjects research there is a list of the 18 personal health identifiers which can be found [here](#).

- Save project related data on University of Arizona or College of Medicine computers with appropriate security protections required by the supervising faculty member and/or described in the study protocol. CAUTION: Personal devices should never be used to store project data.

If you have any questions about this guidance, please contact Bryna Koch, the Director for Program Evaluation and Student Assessment in the Office of Medical Education, at brynak@medadmin.arizona.edu. You may also consult with the Human Subjects Protection Program. The email address is VPR-IRB@email.arizona.edu.