

FREQUENTLY ASKED QUESTIONS

1. **What is the Institutional Review Board (IRB)?** The IRB is a diverse group of scientific and non-scientific individuals who conduct the initial and ongoing review of research studies in order to ensure the protection of the rights, safety, and well-being of human subjects participating in those studies. The federal code of regulations governs the composition and conduct of the IRB. (Title 45: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>)
2. **Does my project need to be reviewed?** The IRB is only charged with reviewing research that involves people as research participants. Your project needs to be reviewed if it meets the following criteria:
 - a. The research is a **systematic** investigation (including development, testing, and evaluation) designed to discover or contribute to a body of **generalizable** knowledge.
 - b. **It involves human participants.** Human participants include those who are actively involved in the research process (being interviewed, filling out surveys, etc.). They also include those who may not be in front of us: those who provided medical samples, left records of their activities through applying for marriage licenses, etc. The IRB reviews research that involves living individuals (1) about whom "an investigator conducting research obtains data through intervention or interaction with the individual" or (2) which obtains "identifiable private information"(Title 45 CFR, Part 46.102.f). Secondary data analysis of existing datasets where participants are individually identifiable should be reviewed by the IRB.
3. **Can I begin my research before I receive IRB approval?** No. Research must be approved by the IRB before research can be conducted.
4. **Who do I talk to if I'm not sure if my project needs to be reviewed?** Please contact The Research Regulatory Compliance office at irb-review@andrew.cmu.edu or 412-268-1901.
5. **Where do I send my completed proposal?** Please send it electronically to the IRB, Research Regulatory Compliance Administration office at irb-review@andrew.cmu.edu, If necessary a hard copy can be sent to Warner Hall, Room 413 or faxed to 412-268-6279.
6. **Where do I get training in the ethical treatment of human research participants?** [NIH Online Training](#) (Human Participant Protections Education for Research Teams)
7. **What are the types of IRB review?** There are three types of IRB review: Exempt, Expedited and Full Board. The level of review depends on the risk to the human participants. The IRB makes the determination of level.

- a. Exempt - Studies that meet explicit criteria set forth by the federal regulations.
- b. Expedited - Studies that involve minimal risk and meet explicit criteria set forth in federal regulations.
- c. Full - Studies that do not meet criteria for Exempt or Expedited Review and are usually greater than minimal risk are reviewed by the Full Board. Examples are studies that involve vulnerable populations or questions of a sensitive nature.

8. **What is Exempt review?** Research projects that involve human participants and meet the criteria for exempt review. Examples of studies in this category are anonymous questionnaires or surveys that do not involve a sensitive topics, research being conducted in educational settings involving normal curriculum, and research on archival data. The following criteria for exemption set forth in Federal regulations (45 CFR 46).

- a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside of the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observations of public behavior that is not exempt under category (b) of this section, if: the human participants are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or indirectly through identifiers linked to subjects. (NOTE: According to the Office of Human Rights Protection (OHRP), "to qualify for this exemption, the data, documents, records, or specimens must be in existence before the project begins.)
- e. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits under those programs; (iii) possible changes in

or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- f. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection of the U.S. Department of Agriculture.
9. **What is Expedited review?** Expedited review protocols are studies that pose no more than minimal risks to the participants and meet the criteria for Expedited Review under 45 CFR 46.10. Examples include studies using questionnaires, surveys, and interviews that are not anonymous. Applications may be submitted at any time.
 10. **What is Full Board review?** Full review protocols involve more than just minimal risks, vulnerable participants or questionnaires/surveys on a sensitive topic. These protocols are reviewed by the Full IRB at the monthly board meetings (the first Wednesday of each month). Applications should be submitted at least three (3) weeks prior to the meeting.
 11. **What is the average turn-around time for a protocol to be reviewed?** The Full Board meets the first Wednesday of each month to review protocols that are above minimal risk. Expedited Reviewers review protocols that meet the criteria for Exempt or Expedited status with an average turnaround time of three (3) weeks. Please note that turn-around time is dependent on the completeness of the application submitted and the PI's responsiveness to questions and requests from the reviewers.
 12. **If I submit a grant proposal, do I have to propose and submit a protocol?** You can submit an IRB protocol at the time you submit a grant proposal. Depending upon the sponsor, you may also wait until you know if you will receive the award. Please note that the Office of Sponsored Programs will not release the funding until there is an approved protocol.
 13. **Do students' academic research projects require IRB approval?** If human subjects are involved, yes. Student research that involves human subjects, whether of a biomedical or social-scientific nature, requires approval or granting of exemption by the IRB prior to initiation. Please note: student researchers are required to work with a faculty advisor for each research project.
 14. **Why do you talk about "human research participants"? Is this the same as "human subjects"?** The phrases "human subjects" and "human research participants" can be used interchangeably. "Participant" is the preferred term.
 15. **Who can sign the consent form on behalf of a minor or other subject incapable of giving consent?** A minor participant or a participant considered mentally incapable of consenting on their own behalf requires consent by a legal representative. This can be a parent, court

appointed guardian or individual with power of attorney. When minors participate in research consent must be given by a parent or legal guardian and often assent must be given by the minor.

16. Is an English consent document acceptable when enrolling non-English-speaking subjects?

Study participants must be given a copy of the consent to be used as a reference document and to reinforce their understanding of the study. Regulations require that the consent document must be in language understandable to the participant. When the prospective participant is fluent in English, the consent document should be in English. However, when the participant is non-English-speaking, the PI should submit a translated consent form for IRB review along with a certification from the translator that the English and non-English versions are the same. While a translator may be used to facilitate conversation with the participant, routine ad hoc translation of the consent document may not be substituted for a written translation.

17. How do you obtain consent from someone who speaks and understands English but cannot read? Illiterate persons may have the consent form read to them and "make their mark." Regulations require a signature of a witness to the consent process and signature of the person conducting the consent interview. Investigators should not enroll participants who may not truly understand what they have agreed to do.

18. If I make any changes in my protocol does the IRB have to review and approve it again?

Yes. Any changes to your protocol must be reviewed and approved by the IRB prior to the implementation of those changes. In many cases this can be done quickly. Highlight the changes on the application and send the application along with a Request for Modification to the IRB, Regulatory Compliance Administration office at irb-review@andrew.cmu.edu.

19. Does the IRB continue to review projects once they have been approved? Yes. The IRB is required by law to conduct continuing review of research. Requests for Continuing Review must be filed each year.

20. Do I need IRB approval if my work will be conducted outside of the campuses? Do I need IRB approval if my study is already approved by another IRB? Yes. To ensure that investigators comply with federal and University regulations, it is important that the University, through the IRB, be aware of where and by whom such research is being done, even if it is done in a foreign country. Formal approval still must come from a human subjects review panel in the host institution or country. This approval must then be received and approved by CMU's IRB.

21. What happens if I conduct human research without IRB approval? You will be out of compliance with Federal requirements for human subject research. This can result in Federal or CMU actions that will prevent you from conducting human subject research and will jeopardize the CMU human research certification.