FAQ

Q: How long have IRBs been in existence?
A: In the United States, IRBs are the product of the National Research Act of 1974. They were created as a response to publicized cases of research abuse including the Tuskegee Syphilis Study. Their principles can be traced back to the Nuremberg Code, created at the end of World War II in response to horrifically unethical research conducted by the Third Reich.

Q: What is the authority of the IRB?
A: (a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §46.116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when in the IRB’s judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with §46.117.
(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
(e) An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Department of Health & Human Services, Title 45: Part 46, Protection of Human Subjects)

Q: What is a “human subject”? 
A: Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains
(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information.

(Department of Health & Human Services, Title 45: Part 46, Protection of Human Subjects)
Q: Is any research on human subjects exempt from IRB approval?

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) 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 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.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   (i) The human subjects 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.

(4) 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 through identifiers linked to the subjects.

(5) Research and demonstration projects which 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 or services 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.

(6) 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 and for a use found to be safe, or agricultural chemical or environmental contaminant 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 Service of the U.S. Department of Agriculture. (Department of Health & Human Services, Title 45: Part 46, Protection of Human Subjects)
Q: If I believe that my research is exempt from the need for IRB approval, can I make that determination myself?
A: During the academic year, it should take only a week to receive a formal decision by the IRB concerning proposed research. It is best to submit an initial request and allow for the IRB to make that decision.

Q: What if I have IRB approval from a different institution’s IRB?
A: The Jefferson College IRB will review previous IRB approvals, but must individually and independently assess any research proposals involving human subjects at Jefferson College.

Q: What is the required membership on an IRB?
A: (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.
(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution’s consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
(c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.
(d) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
(e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

[21 CFR 56]

Q: Who is currently on the Jefferson College IRB, and how do I contact them?
A: 2014-15
Chair--Dr. Michael Booker, Division Chair-Communication & Arts
Dr. Amy Kausler, Professor-Psychology
Dr. Cindy Rossi, Professor of Business Management
Ms. Heather Lawyer, Outreach Coordinator, St. Louis University Hospital
Nick Marmaduke, Student

Ex Officio: Ms. Julie Fraser, Associate Vice President of Student Services

Q: What happens if I propose research and do not receive IRB approval?
A: In most cases it will be possible to modify the research in order to satisfy the IRB. The IRB will discuss such changes with the researchers. If the research is not approved by the IRB, researchers will be denied access to the students, records and grounds of Jefferson College and its satellite sites. A researcher who conducts research on human subjects without Jefferson College IRB approval will be escorted from campus if a non-employee, or, if an employee of the College, subject to administrative action due to violation of Board of Trustees Policies and Procedures.

Q: How much will IRB approval cost?
A: Members of the IRB volunteer their time for the benefit of Jefferson College and the local community. There is no cost.