



ALMA COLLEGE

Human Subjects Research INSTITUTIONAL REVIEW BOARD Policies and Procedures

To assist researchers in protecting the rights and welfare of all human subjects, Alma College has established an Institutional Review Board (IRB). All research involving living human subjects must be approved in advance by this board.

Ethical Principles for Research

IRB members and researchers should familiarize themselves with the Belmont Report's three ethical principles of Respect for Persons, Beneficence, and Justice, and the accompanying application guidelines. (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>).

Although the Belmont report makes clear that no fixed set of rules can ever ensure safety and ethical treatment in all situations, it teaches that the primary concerns of the working IRB are that:

- participation is truly voluntary.
- subjects understand what is going to happen to them and what risks they face.
- people are not harmed (mentally, physically, or in any other way)
- participants are protected with respect to rights such as privacy and access to knowledge or other benefits generated by the research.

The Institutional Review Board

The IRB's sole responsibility is to protect the rights and safety of research subjects, which involves ensuring that potential risks to subjects are minimized while potential benefits from the research, both to the subjects and to society, are optimized. In doing so, it will also be protecting researchers, the College, and the place of research in our society. The board will try to ensure that research conducted at Alma College or by College personnel is consistent with the principles of the Belmont Report and all applicable laws. Ultimately, however, responsibility for the welfare of research subjects rests with the individual researcher.

The Institutional Review Board, appointed by the Provost, will be composed of a minimum of 7 members: 5 faculty (one of which must be from outside the sciences), an institutional representative, and one community member who is not employed by or in the immediate family of anyone employed by Alma College.

All applications will be distributed to the IRB. The IRB will separate applications into one of three review categories: exempt, expedited, or full board. Applications will be exempt or expedited if deemed eligible by the IRB chair. Exempt projects will be reviewed only by the IRB chair, and expedited projects will be reviewed by the IRB chair and one IRB member chosen by the chair. If a project is approved as exempt or expedited, the full board will be so informed, with no further action required. Applications deemed to require full board review will be distributed to the committee at least

two weeks in advance of the next IRB meeting and discussed at that meeting. All meetings are open to all employees and students of the College. The IRB will attempt to respond to applications deemed exempt or expedited within two weeks of receipt. Board members will recuse themselves from deliberations concerning their own research. If the IRB judges that a project is too risky and/or poses little to no benefit to subject or society, it will withhold approval and work with the researcher until it is deemed safe and of value. The chair will promptly notify the researcher of committee action. In addition to approving or withholding approval, the IRB may, when risks are substantial, give contingent approval or provisional approval subject to periodic re-review.

After approval, researchers are expected to report immediately to the IRB any substantial change in the research procedures as well as any unforeseen problems or dangers to subjects.

Continuing review

Approved projects remain approved until finished unless they are funded by Federal Agencies or are of a type that is subject to additional regulation by a specific Federal Agency (such as the FDA's regulation of the testing of new drugs). Federally funded or regulated projects will need to have their approval renewed at the end of each year. Unless there have been significant changes in procedures, or the initial review found more than minimal risk, this renewal will not require submission of a new application and will typically be handled by expedited review.

The chair of the IRB is responsible for reporting to the researcher, and for federally funded projects, the funding agency and OHRP, any board action or suspension of approval due to unanticipated problems or serious non-compliance with regulations. A record of IRB actions will be kept by the office of the Provost for a period of seven years.

Who can submit study applications to the IRB?

All individuals employed as full-time faculty/staff members or those currently employed as adjunct faculty or part-time staff at Alma College can serve as principal investigators and submit study applications to the IRB, provided that the study is completed during their employment period.

Current Alma College students must follow the same guidelines as all other research. Students cannot serve as principal investigators on research but can serve as co-investigators. Student research projects must be conducted under the supervision of a full-time or currently employed adjunct faculty member, who assumes the role of principal investigator on the study. The faculty supervisor must submit the IRB application and any continuing review documents required by the IRB and retain all research records (e.g., signed informed consent forms, data) following completion of the study.

When research activities are to be conducted by students as part of routine course or laboratory work, the principal investigator may choose to submit a single application containing a description of the range of anticipated activities and procedures. If approved, they will then be responsible for monitoring individual student projects, referring to the IRB any procedures which raise concerns of more than minimal risk or which deviate substantially from this approved range.

Categories of Research

1. Research that Qualifies for Exemption from IRB Review

Exempt from review is most research concerning education practices and studies that use only existing, publicly available data or records (e.g., NHANES). Being exempt from review does not excuse the researcher from responsibility to follow all ethical guidelines.

2. Research that Qualifies for Expedited IRB Review

Research activities involving no more than minimal risk may be reviewed by the IRB through the expedited review process. Risk is considered minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests.

Examples of activities that may qualify for expedited review include: Collection of data with commonly used medical instruments, non-invasive collection of biological specimens, most studies of behavior, perception or cognition, identity, communication or beliefs, and most research employing surveys or interviews. Also eligible are studies using the same methods as previously approved studies judged to contain minimal risk

3. Research Requiring Full-Board IRB Review

- All research that involves more than minimal risk to the subjects
- All research involving the deception of subjects
(Use of deception requires justification and post-experiment debriefing)
- Sensitive behavioral research (such as research relating to illegal activity or sexual activity)
- Research involving children, prisoners, or people with impaired decisional capacity (see OHRP for additional guidelines for protecting people in special or vulnerable populations)

Collaborative Institutional Training Initiative (CITI) Training

All individuals who conduct or oversee human subjects research must complete CITI training prior to beginning a project. Alma College has an institutional subscription to CITI training, so there is no cost to students, faculty, or staff to complete training. Faculty/staff conducting human subjects research must complete either the Biomedical Research or the Social & Behavioral Research training course (see below for information on accessing these training modules) and score at least 80% overall on the quizzes following the training modules. Students who conduct or assist with human subjects research must also complete CITI training prior to being able to begin a project. Students conducting human subjects research must complete the Undergraduate Student Researchers training course. For faculty/staff, CITI training is good for a period of 3 years, after which researchers must complete a training refresher course. For students, CITI training is good for the duration of their time at Alma College. The following steps provide instructions for accessing the CITI training website, registering with Alma College, and completing the required training courses:

1. Go to citiprogram.org and select "Register" at the top right.
2. In Step 1, type in "Alma College" and, once selected, check the two checkboxes which appear, and click on the "Continue To Create Your CITI Program Username/Password" button which appears. Do not select anything under the "Independent Learner" Registration area.
3. In Step 2, enter name and your Alma College email address. A secondary email address is optional.
4. In Step 3, create a username and password and select a security question.
5. In Step 4, type in your country of residence.
6. In Step 5, check the "No" box for the question asking about interest in being able to pay for CEU credits. Then, answer the final two questions regarding your preferences on if CITI can contact you for research participation or marketing.
7. In Step 6, complete all required questions and as many of the optional questions as desired. For "Department", students should list the department of their main faculty research supervisor. For

"Role in Research", students should select "Student Researcher - Undergraduate", faculty/staff overseeing or leading research projects should select "Principal Investigator", and faculty/staff who do not conduct human subjects research but serve on the IRB should select "IRB Member".

8. In Step 7, Question 1 requires individuals to select the most appropriate area under which their research falls.
 - Faculty/staff conducting human subjects research in the fields of biology, chemistry, IPHS, and many other natural sciences would most likely select "Biomedical Research Investigators".
 - For human research in the fields of education, economics, political science, sociology, psychology, anthropology, and history, "Social & Behavioral Research Investigators" will be the most likely choice.
 - Faculty/staff in nursing can choose either depending on the focus of their research question.
 - Students conducting or assisting with human subjects research select "Undergraduate Student Researchers".
 - Once a selection is made for Question 1, click the "Complete Registration" button at the bottom of the page.
9. Questions 2-10 contain many more optional training courses which can be taken if desired, but these are not required to be able to complete human subjects research.
10. When ready to complete all or a portion of the training modules, click "View Courses", and the course should appear under "Courses Ready to Begin" or "Active Courses". Complete all required modules and any desired supplemental modules. When completed, there is an option to print a hardcopy or PDF completion certificate. Save this certificate as proof of completion of the CITI training.

Submission of Research Applications to the IRB

All applications (new applications, revisions, continuing review, and study modifications) must be submitted through Qualtrics, which is accessed at the following link: https://alma.co1.qualtrics.com/jfe/form/SV_6Ps2KutrYQUartP. All required questions must be answered, and at the end of the application there are places to upload the Informed Consent document and any other supporting documentation for the study (e.g., child assent forms, questionnaires). This application can be saved and returned to later, but it is recommended that answers to all questions be completed outside of Qualtrics in a format that can be saved (e.g., Microsoft Word, Google Docs) and, when ready, copied and pasted into Qualtrics. A Word document with all questions asked in the Qualtrics link can be accessed here: [LINK TO BE ADDED].