

**Barton College**  
**Institutional Review Board for the Use of Human Subjects in Research**

## ***1) What Research/Activity Must Be Reviewed?***

All research or data collection at Barton College that involves humans or records gathered on human subjects requires IRB review. This is true regardless of its funding source or area of research.

Research that requires IRB review includes any research on human subjects that

- is conducted by College faculty, staff, or students;
- involves College patients, students, staff, or faculty as subjects;
- is performed on the premises of the College;
- is performed with, or involves the use of, facilities or equipment belonging to the College;
- satisfies a requirement imposed by the College for the award of a degree or for the completion of a course of study; or
- is certified by a dean or department head to satisfy an obligation of a faculty appointment at the College, including clinical or adjunct appointments.

In addition, the following circumstances require IRB review.

- Affiliated faculty research is subject to IRB review.
- Research conducted by "affiliated faculty" (including professors who hold clinical or adjunct appointments) is also subject to IRB review
- Research conducted at another institution does require IRB review.
- Research projects conducted at other sites should be reviewed by the Barton College's IRB as well as by the other institution's IRB.
- Research that is part of multicenter clinical trials - Approval of a document at the national level is not sufficient to bypass approval at the local level. Therefore, documents must also be submitted for IRB review.
- Research in foreign countries - Research conducted by College researchers in foreign countries falls under College guidelines. Although they cannot be imposed on other cultures, the standards for ethical conduct cannot be lowered. Human subjects in foreign countries deserve the same level of protection as subjects in the United States.
- Research conducted in courses is subject to IRB review.
- Courses in research methods and class assignments involving research with human subjects require IRB approval
- Faculty-supervised student research - Faculty must take an active role in ensuring that research projects are conducted in accordance with the IRB's requirements.
- Research at a pilot or feasibility stage - Pilot and feasibility studies, even those with only one human subject, require the same review as full-scale research projects. Applications to the IRB for pilot studies should be identified as such, and subjects must be told during the consent process that the study is a pilot.
- Research involving secondary use of data - Projects that use data on human subjects gathered in earlier projects and in which individual identifiers are present require IRB

review. If, however, the data is gathered by someone who has legitimate access to the records and who gives the investigator only "blinded" data (meaning the investigator is unable to identify the subjects), the research project may qualify for an exemption from full review.

- Research projects in which the researcher is a consultant under contract with the College does require IRB review.

IRB review is not required if the researcher has a strict consulting relationship in which

- the researcher is hired on his or her own time,
- the researcher holds no rights in the work, and
- neither the researcher nor the College retains any data.

*All three of these criteria must be met, or the IRB will need to review the project.*

### **In Summary:**

**A project requires IRB review if**

- 1) human participants are involved and**
- 2) the activity generates new knowledge or generalizable knowledge for publication or**
- 3) the project involves skills or knowledge to be applied outside of the immediate classroom.**

## ***2) What Type of Review Is Required?***

Review Categories: There are three categories (or types of review) for projects that are submitted to the IRB. These are as follows.

1. Exempt from further review – Investigator uses the “IRB Exemption Request” form.
2. Subject to expedited review – Investigator uses an “IRB New Submission” form. See information on the next page to know which new submission form to use.
3. Subject to full review – Investigator uses an “IRB New Submission” form. See information on the next page to know which new submission form to use.

Institutional studies for planning and assessment purposes do not require IRB review.

Proposals for expedited (administrative) review and proposals for full review are made using the same forms and processes. Determination of the type of review (expedited or full review) will be made by the chair of the IRB upon consideration of the submitted materials. If the chair sends the proposal for an expedited review, and the reviewers determine that there should be a full review, the chair will then submit the proposal for a full review.

Exempt Review: Studies may be determined by the IRB to be exempt if they fall under the following categories and have no more than minimal risk.

1. Normal educational practices and settings
2. Anonymous educational tests, surveys, interviews, or observations
3. Identifiable subjects in special circumstances

4. Collection or study of existing data
  5. Public benefit or service programs
  6. Taste and food evaluation and acceptance studies
- \* The term "exempt" review may create confusion because it does not mean exempt from IRB review. Rather, it is a request for a type of review that requires a briefer proposal form, called an "IRB Exemption Request."**

Expedited (Administrative) Review: Expedited review will typically be conducted on those projects that involve no more than minimal risk. Expedited review involves review by two or three committee members. Review of a project in the expedited review category may take two to four weeks from initial submission. Proposals submitted for an expedited review use the "IRB New Submission" form, as described on the next page.

Full Review Studies: Full Board Review involves the whole IRB committee and may take four to six weeks from initial submission. Proposals submitted for a full review use the "IRB New Submission" form, as described on the next page.

### ***3) Which Type of Form Do I Use?***

If you are submitting a request for a review of a new study, whether you think **it needs a full review or an administrative review**, you will use one of the following forms:

- **IRB new submission-Barton FAS and Student Researcher- 4-08**
  - Use this form for any research involving a student as a researcher
- **IRB new submission-Barton FAS - may include outside investigator-4-08**
  - Use this form for research involving a person from the outside (such as another institution) as the primary investigator and a Barton faculty/staff as the secondary investigator and Barton sponsor (principal investigator of record.)
  - Outside investigator must also complete and sign the IRB Unaffiliated Investigator Agreement
- **IRB new submission-2 Barton Faculty and/or Staff Co- Researchers-4-08**
  - Use this form for research involving a Barton faculty or staff member as the primary investigator – Research may also include a second Barton faculty/staff member or an outside investigator as a secondary investigator.

Use the **IRB Exemption Request Form** for projects that you think meet **one of the following exemption categories**:

1. Research conducted in established or commonly accepted educational settings and 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 45 CFR46.101, 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. Not applicable
6. Taste and food quality evaluation and consumer acceptance studies, if (i) wholesome foods without additives are consumed, or (ii) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe or an agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration or that is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.