

## **Policy & Procedures for Institutional Review of Human Research**

Bridgewater College recognizes the importance of conducting research using human participants to further the knowledge base of the academic and larger community. The college accepts the responsibility to assure that research conducted under its auspices protects the rights and welfare of human participants in accordance with federal regulations and ethical standards. The Institutional Review Board (IRB) will oversee this process by reviewing research involving human participants conducted by faculty, staff, and students.

The mission of the IRB is to ensure that human participants are treated with the utmost respect and fairness throughout the research process as stipulated by the [Belmont Report](#), [Title 45 Code of Federal Regulations, Part 46 Protection of Human Subjects](#), and [Virginia Code 32.1-162.16-20](#). The goal of IRB review at Bridgewater is to help the researcher examine the research design so that 1) human participants are recruited and treated ethically, 2) participants feel their consent to participate is fully informed, 3) the data gathered is confidential, and 4) the relationship of risks and benefits to participants is fully considered.

### **Research Activities Applicable for IRB Review**

The Bridgewater College IRB does not seek to define what constitutes research within any discipline. These decisions are rightfully left to each individual discipline to decide. However, the IRB does need to define what research activities will be subject to IRB review. Adopting the Federal Regulations definition of research applicable for review entails a systematic investigation (including research development, testing, and evaluation) designed to develop or contribute to generalizable knowledge which involves human participant(s) ([46.102](#)).

Based on this definition of research, classroom projects, which involve students engaging in research activities, most often fall outside the purview of the IRB because they are conducted as part of standard educational practice and the findings are not intended to contribute to generalizable knowledge. However, instructors still need to ensure that the rights of human participants are adequately protected. Therefore, instructors incorporating these types of projects are encouraged to discuss research ethics with students prior to data collection. Additionally, if instructors have questions about the ethical treatment of human participants in a classroom project they are encouraged to contact the IRB chairperson.

All students conducting honors or independent projects that are subject to IRB review should seek IRB approval with their faculty mentor.

If a research activity qualifies for IRB review an application should be submitted and approved prior to data collection.

## **Who May Submit an IRB Review**

Any faculty, staff, or student may be designated as a principal investigator on the IRB application. When a student or staff member is listed as a principal investigator, a faculty member must provide assurance and advise the project. Every faculty member should be familiar with the [Belmont Report](#) and the [Title 45 Code of Federal Regulations, Part 46 Protection of Human Subjects](#).

## **Application for Research Project Review**

A formal application (See the Application for IRB Review) should be submitted for every research project that qualifies for IRB Review (See Decision Table). However, the type of review will be based on the nature of the research and the potential risk to participants. It is highly recommended that principal investigators submit applications in a timely fashion to ensure no delays in data collection.

### Excluded from Review

Activities that are not considered research activities applicable to IRB review (noted in the previous section) are excluded from review. For further assistance in determining whether the activity is excluded see the IRB Decision Table. If it is excluded, no IRB Review application is necessary. All other review categories require IRB Review application.

### Exempt Review

Upon submission of application, the IRB will provide exempt review for proposed research that is considered exempt from federal regulation guidelines as stated in 45 CFR 46, Protection of Human Subjects ([46.101](#)). For specific details regarding whether exemption is appropriate for your research activities see the IRB application.

Researchers submitting an exempt review will submit two copies of the application to the IRB. Two members of the IRB will review the research project and application and provide a written response within approximately 10 working days.

### Expedited Review

The IRB will provide expedited review for those projects that are not considered exempt yet only present a minimal risk to human participants (i.e., the probability of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests occurring as a result of participation in a research study – [45 CFR 46.102i](#)). For specific details regarding whether expedited is appropriate for your research activities see the IRB application.

Researchers submitting an expedited review will submit six copies of the application to the IRB. All members of the IRB committee will review the research project and application and provide a written response within approximately 10 working days.

### Full Review

Proposed research projects, which place the human participant at more than minimal risk, involve vulnerable populations (i.e., prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults) as participants, or does not fall into either exempt or expedited review, will be considered for full review by the IRB. Under a full review, researchers will submit six copies of the application to be considered by the entire IRB during its regularly scheduled meeting.

### **Cooperative Research**

When collaborating with researchers at other institutions it is important to note that each institution is responsible for safeguarding the rights and welfare of human participants. Therefore, if approval has been obtained from another institution these documents should also be submitted to the IRB requesting an exempt review (see application for details).

### **Informed Consent Procedures**

The process of informed consent is based on the principle of respect for the rights of others to make informed decisions concerning participation. Procedures for informed consent provide research participants with sufficient knowledge about the purpose of the research and the type of involvement in the study and the potential risks and benefits. Based on this knowledge participants can then make an informed decision as to whether they would like to engage in the research project. All investigators, submitting Exempt, Expedited or Full Reviews, are requested to secure oral and written informed consent of the participant or the participant's legally authorized representative (see below for waivers to informed consent). Basic elements to include in the informed consent form are presented below:

1. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a basic description of the procedures to be followed (not including manipulations or deception), and identification of any procedures which are experimental;
2. a description of any reasonably foreseeable risks or discomforts to the subject;
3. a description of any benefits to the subject or to others which may reasonably be expected from the research;
4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. a statement describing the extent to which confidentiality of records identifying the subject will be maintained;

6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. an explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled ([45 CFR 46.116a](#)).

Every effort should be made to construct a consent form that uses non-technical language or jargon. Researchers may elect to orally explain elements of informed consent; however, participants are still requested to sign a consent form. If the participant is not a native English speaker then the consent form will be translated into their native tongue. If the participant is a minor, consent must be obtained from the legal guardian and the minor, who is capable of reading and understanding a simplified version of the consent form, must sign an assent form. For guidance on the creation of an informed consent form see the Sample Consent Forms.

Within some cultural settings it may be necessary to first obtain consent from community leaders or family members. However, this should not preclude obtaining consent from individual research participants.

#### Waivers of Written (Not Oral) Informed Consent ([45 CFR 46.116c-d](#))

The IRB may waive part of the normal consent requirements if: a) the research involves no more than minimal risk to the participants; b) the waiver or alteration of normal consent procedures will not affect adversely the rights and welfare of the participants; c) the research could not be carried out effectively without the waiver or alteration; and d) whenever appropriate, the participants will be provided with additional pertinent information after participation. This category of waiver includes those cases in which the researcher desires to withhold from the subject some information about the project that, if known by the subject, would bias the results of the study. Ordinarily, the researcher would plan a debriefing session after completion of the subject's participation in order to provide the subject with the missing information, and give the subject the option of including his/her data in the study or having it destroyed. In no case should a researcher seek to withhold information about the research or the subject's role in the research solely to reduce the chance that the subject will refuse to participate.

The IRB may waive the requirement for written consent if it finds that a) the only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from breach of confidentiality; or b) the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. This type of waiver applies especially to anonymous interviews (including face-to-face and telephone interviews) where the researcher's sole knowledge of the identity of the subject would come from the consent document. Waiver of

written consent procedures does not imply waiver of the researcher's responsibility to obtain consent from the subject. In all cases, the researcher must provide the subject with a statement describing the research that includes all relevant elements of informed consent. The IRB requires that when the use of written informed consent is waived, a cover letter be given to the participants outlining the purpose and procedures of the project and containing a statement such as "Completion and return of the survey [questionnaire, interview, etc.] indicates consent to participate in the study."

### **IRB Action**

The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy ([45 CFR 46.109](#)). When reviewing a protocol the IRB will use the following criteria to determine the approval of the project ([45 CFR 46.111](#)) (Note: Some of these criteria may not apply to certain research designs or review types):

- ❑ Minimal risk to participants
- ❑ Risks are reasonable in relation to benefits to participants and information gained from the project
- ❑ Selection of participants is equitable and appropriate considerations have been made for vulnerable populations
- ❑ Informed consent procedures are in accordance with federal regulations
- ❑ Researchers make adequate provisions for monitoring the data collection to ensure the safety of participants
- ❑ Provisions are in place to protect the privacy and confidentiality of the participant.

Following review, the IRB will take one of the following actions: (1) Approve the research as exempt (in which case no additional oversight is required by the IRB); (2) Approve the research as submitted; (3) Approve the research as contingent upon submission of minor revisions; (4) Request outside review and reconsider; (5) Request significant modification before approval; (6) Request the researcher to discuss problems with the IRB; (7) Disapprove the proposed research. The IRB will 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.

Additionally, research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution or outside community agencies or programs. However, those officials may not approve the research if it has not been approved by the IRB. Finally, research approved by the IRB may be suspended or terminated if it is believed that the research is not being conducted in accordance with Bridgewater Colleges IRB Policy and Procedures.

## **Appeal Process**

If the researcher does object to the disapproval, the researcher may resubmit a full review and request an outsider (related to the field of study) review the application. The outside reviewer and researcher will then meet with the full committee in a timely fashion.

## **Continuing Review**

A continuing review shall be performed once a year by the IRB for every non-exempt ongoing human subject research project. The IRB may determine that a human participant research project should be scheduled for more frequent reviews than annually. The category of review (expedited or full) will be the same as was used for the initial review and researchers will be asked to submit an application that documents the progress of the research (Complete the Application for Extension of Research Project). With each continuing review, the IRB will consider whether the project requires verification from sources other than the researcher that no material changes have occurred since prior IRB review.

## **Project Changes**

If changes need to be made to the research protocol previously approved by the IRB, the investigator should submit an Application for Amendments to Research Projects. A member of the IRB will review the proposed changes and provide a prompt decision regarding approval (no more than 10 working days). Note that project changes may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to participants.

Researchers who have received IRB project approvals should also advise the IRB promptly of any unanticipated problems involving risks to participants.

## **Adverse Events**

If there is an adverse event during the data collection phase of the study that has presented an unanticipated risk, and may have potential liability for the human participant(s), researcher, or institution, it must be reported as soon as reasonably possible, but no later than 5 working days subsequent to the adverse event, to the IRB using the Adverse Events Form. The completion of this form should be in addition to any notification that is required by an outside granting agency.

## **Reporting and Record Keeping**

Records (i.e., a list of IRB members, initial IRB applications, minutes of IRB meetings, continuing reviews, reports of adverse effects, copies of all correspondence between the IRB and investigators, and decisions rendered for each application) will be maintained by the IRB chairperson and stored in a secure central location for a minimum of 3 years (45 CFR 46.115).

However, researchers should maintain research records (consent forms, raw data, analysis procedures, etc.) in a secure location for a minimum of 3 years.

## **Questions**

Questions concerning the IRB policy or application procedures should be directed toward the chairperson of IRB.

## **Acknowledgments**

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## **Helpful Links**

Belmont Report

<http://ohsr.od.nih.gov/guidelines/belmont.html>

Title 45 Code of Federal Regulation 46 Protection of Human Subjects

[www.hhs.gov/ohrp/humansubjects/guidance/45dfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45dfr46.htm)

Virginia Code Regarding Human Research

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-162.16>

The FDA guidelines for informed consent and protection of human subjects

[http://www.access.gpo.gov/nara/cfr/waisidx\\_00/21cfr50\\_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr50_00.html).

President's Council on Bioethics

<http://www.bioethics.gov>