



Bellarmino University

Institutional Review Board (IRB) Handbook

Policies and Procedures for the

Review of Research Involving Human Subjects

Purpose & Mission

Human research oversight and compliance at Bellarmine University is administered by the Institutional Review Board (IRB). The IRB is composed of full-time faculty members and at least one non-Bellarmino associated member of the community. Members are appointed by and report to the Provost (or designee). Guidelines for IRB operations are outlined in [Title 45 Part 46 of the Code of Federal Regulations](#) and by the Office for Human Research Protections (OHRP), [U.S. Department of Health and Human Services](#).

The ‘Common Rule.’ On 6/18/91, 17 Federal Departments and Agencies adopted a common set of regulations known as the *Federal Policy for the Protection of Human Subjects*. This is often referred to as the “Common Rule.” The common rule requires that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that the research is reviewed and approved by the University’s Institutional Review Board. This is based on internationally recognized ethical principles originally published on 4/18/79 in the [Belmont Report](#). These principles are:

Respect for persons – this incorporates at least 2 ethical convictions: ‘first, that individuals should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection’ (Thus the need to obtain informed consent).

Beneficence – this anticipates that persons will be treated “Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Two general rules: 1) do no harm and 2) maximize possible benefits and minimize possible harms.”

Justice- this requires that the “benefits and burdens of research be distributed fairly” (particularly in the selection of research subjects).

As such, the mission of the Bellarmine University IRB is to protect the community and individual participants. In the process, the IRB ensures that the research activity of all Bellarmine University affiliates complies with federal regulations and meet the highest ethical standards. Any person participating as a subject in a research study is entitled to informed consent, privacy, and confidentiality with respect to the research data collected.

Definition of Research and Principal Investigator (PI)

Research is defined as a systematic investigation, including testing and evaluation, designed to develop or contribute to generalizable knowledge. All human subject activities meeting this definition are within the jurisdiction of the IRB. As such, research involving human subjects must be reviewed and approved. Exceptions to IRB approval would be those projects or activities that do not meet the federal definition of research based on the U.S. Department of Health and Human Services’ decision tree (see [Chart 1](#) also reproduced in Appendix B).

The Principal Investigator (PI) for Research involving Human Subjects, performed on the Bellarmine University campus or any affiliated facility, **must be a member of the faculty or full-time staff**. Students, graduate or undergraduate, are not allowed to serve as PI. They are welcome to serve as co-investigators, but all IRB forms must be approved, signed, and submitted by the PI. All formal communication regarding an IRB submission shall be handled through the PI.

The immediate and ultimate responsibility for managing these projects lies with the principal investigator (PI) and can be assisted by the IRB, other support offices, school or college dean and the departmental chairperson and staff.

Composition & Quorum

The IRB will be composed of no fewer than five members including the Chair and Vice-Chair. To ensure compliance with federal regulations and ensure broad representation of the campus community, the BU committee will include at least one regular member from the following 7 constituencies: 1) Sciences, 2) Social Sciences, 3) Education, 4) Nursing, 5) Physical Therapy, 6) non-science disciplines such as the arts, communications, and humanities, and 7) the

community at large. Note, one member may be able to satisfy more than one of these constituency requirements. As required by governing regulations, the community member (and/or any of their immediate family members) must not have a formal affiliation with the institution. The committee will appoint at least two alternates to assist with reviews in those situations where a potential conflict of interest might be identified or declared. Alternates will participate at the discretion of the Chair. Additionally, the IRB (or the chair, or an assigned expedited reviewer) may consult with outside experts in a given field in situations where a submitted protocol may be reasonably beyond the expertise of the member(s).

Quorum will be defined as no less than three participating members with at least one of the attendees being a non-scientist and one unaffiliated member of the community. In limited and extra-ordinary situations, IRB members may, with prior approval of the Chair and consent of the majority of IRB members in attendance, participate via teleconference to obtain a quorum. **A passing vote shall be defined as one receiving a simple majority of those members present.** The Chair and Vice-chair are voting members of the committee.

Appointment Procedures & Terms

The Office of Academic Affairs will solicit volunteers annually and membership will ordinarily be selected from the obtained pool of volunteers. Members and alternates will be appointed for two -year terms by the Provost (or designee). To ensure consistency, the terms will be staggered with at least three permanent members appointed in even years and at-least two members appointed in odd years. Alternates will be appointed in a similar fashion. Should a permanent member resign or be removed from the committee, the Provost (or designee) will consult with the IRB Chair prior to appointing a replacement. The Chair and Vice-Chair of the IRB will be appointed by the Provost (or designee).

Meeting Schedule

The committee will meet at least once per semester, and as needed (inclusive of a single July meeting on the second Tuesday of the month) to facilitate the review of protocols requiring full review. When and where electronic resources can be used to increase the efficiency of the review process, technology shall be used at the discretion of the IRB Chair insofar as the principles of committee composition and quorum are preserved and all regular members (or designated alternates, if appropriate) have the means to participate. Additionally, the IRB may deploy committee-approved practices associated with exempt or expedited reviews to increase efficiency as long as human subjects are protected.

Functions, Responsibilities, & Authority

The IRB will review and approve investigator protocols as well as exercise continuing review of ongoing research. As part of its review process, the IRB has the authority to recommend modifications prior to approval to ensure the safety of the public. Likewise, the IRB may vote to not approve proposed research as the risks may be deemed unacceptable. Additionally, the IRB is obligated to investigate non-compliance issues and has the authority to suspend research activities and may recommend sanctions related to research performance and/or misconduct to the Office of Academic Affairs.

The Chair has responsibilities for scheduling and chairing meetings of the IRB, assigning expedited reviews, and issuing decision letters. The University will provide the Chair with administrative support to ensure consistent record keeping and overall compliance with governing regulations. Additionally, the Chair may delegate duties to the Vice-chair, as needed.

Training Opportunities & Commitment Training

All IRB members and alternates are required to have completed human subjects training within 2 years of

reviewing IRB submissions. Likewise, all investigators are required to have completed human subjects training prior to IRB submission. The IRB is committed to ensuring training and no submitted protocols will be approved without a

verification certificate from one of the approved tutorials below. Certificates will be kept on file in the IRB office. All investigators are required to renew their human subjects training every 3 years. Please refer to the Bellarmine University IRB website for instructions and the link to the Collaborative Institutional Training Initiative (CITI) training modules. https://www.bellarmine.edu/academicaffairs/faculty_affairs_and_research/research-and-creativity/irb/

In addition to the tutorials above, investigators are encouraged to view training videos prepared by the US Office for Human Research Protections. The videos can be viewed at: http://www.hhs.gov/ohrp/education/training/ded_video.html

Informed Consent

According to federal regulations, informed consent must include the following basic elements and participant consent must be documented:

- “(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 description of the procedures to be followed, 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, if any, 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 is offered and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, who pays for such treatment, and where further information may be obtained;*
- (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' 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.”*

Source: 45 CFR 46.116

To assist investigators with meeting the informed consent requirements outlined above, the IRB has created two templates (copies can be found in Appendix A). The first template can be used for standard survey and interview research. The second template has been designed to address issues of informed consent associated with more complex studies involving interventions, biological sampling, and/or studies dealing with vulnerable populations. The Bellarmine University IRB has created a checklist that ensures all basic elements are included for the second consent form. This checklist must be filled out by the PI and included with the submission.

Assent & Vulnerable Populations. Documenting assent of vulnerable populations (such as minors, individuals with cognitive disabilities, and prisoners) following permission to recruit vis-à-vis the approved informed consent process is critical to protecting the rights and safety of all research subjects. The IRB requires the assent of participants be documented using a process that is developmentally appropriate and formal. “Assent” means an affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent ([45 CFR 46.402\(b\)](#)). Given the wide range of environments where research with vulnerable populations might occur, investigators are able to propose a variety of mechanisms or practices that are appropriate as documented in the recognized literature.

The IRB recognizes that the assent process will vary depending on the intervention type and population. For example, the process will vary for minors depending on the age, maturity, and psychological state of the child.¹

All investigators must present a protocol that articulates how vulnerable populations will be informed of their rights to participate or not (i.e., a proposed script). Note that nonmedical, minimal-risk studies (e.g., institutional or educational research) will sometimes not have an assent form, but instead use a verbal process or a signal for the child's assent, along with a written parental permission. In these cases, all investigators must: 1.) Provide a description of the resources, activities, or options available to non-participants; and 2.) Document the assent of willing participants (such as a summary list of participants with a reference to the total number of non-participants, participant sign up, or individual signatures on formal assent forms). As part of the assent process, all investigators must also articulate the options available to non-assenting individuals who will not participate. In the end, the objective of the IRB is to ensure that partner organizations (schools, prisons, or health care facilities), legal guardians, and vulnerable populations are protected and not exploited as samples of convenience.

Investigations of Non-Compliance, Reporting, and Actions

The IRB has a duty to investigate all cases of noncompliance in human subjects research. Notification of suspected noncompliance may occur during the review of submitted protocols, community reports, inadvertent disclosures, or report of an adverse event. Once the IRB has been made aware of potentially noncompliant research, the Chair must make an initial determination as to whether or not the noncompliance: 1) constitutes serious or continuing noncompliance with IRB rules and federal regulations, 2) poses immediate risk of injury to the community, 3) a significant adverse event has occurred; 4) continuation of the research exposes subjects to risk that exceeds minimal risk; or 5) the noncompliance is non-serious and poses only minimal risk. If the Chair makes a determination other than “non-serious” (#5), the Chair must report the noncompliance to the designated institutional officer and inform the PI to cease all study activities immediately.

In all cases, the Chair will: 1) Contact the PI and discuss the situation, 2) Endeavor to determine if noncompliance has occurred and resolve the non-compliance issue (i.e., situations best described as “non-serious and non-continuing” where submission of a new protocol or revision of an existing protocol would be appropriate and/or the non-compliance was minor and/or inadvertent), 3) If the noncompliance cannot be resolved informally or a full investigation by the Committee is warranted, the Chair will collect relevant documentation for presentation to the Committee, 4) the full Committee will review the documents and make a determination inclusive of assigning sanctions (if appropriate), and 5) the Committee will notify the PI of the outcome of the investigation and sanctions (if any). Sanctions may include termination of a study, suspension of study, preventing a PI from disseminating data collected, additional training, and/or the modification of a protocol. In addition to IRB action, the University may impose other appropriate sanctions consistent with the University Handbook.

¹ While protocols for documenting and obtaining assent may vary by discipline, the IRB generally recommends that assent be obtained from any child with an intellectual age of 7 years or more, in addition to obtaining written parental permission. A distinction can be made for assent protocols including children between the ages of 13 and 17 years (i.e., an adolescent written assent form including the same elements as in the adult consent form or parent permission form with age-appropriate language), between the ages of 7 and 12 years (i.e., a briefer, piloted written assent mechanism that may include large font, simple schemas, and pictures), and children under the age of 7 (i.e., a witnessed verbal assent form in some cases). Variations from the general strategies and methods outlined above should be documented by the investigator and cite the appropriate peer reviewed literature.

Any and all adverse events must be reported promptly (within ten days) to the IRB and investigated using the general process outlined above. According to the [Office for Human Research Protections \(OHRP\)](#), an adverse event can refer to any unanticipated problems or events that involve increased risk, a breach in approved protocol, or other injury associated with human subjects research. Serious adverse events include death or the combination of all of the following conditions: the event was unexpected, serious (physical injury, psychological disability, or other event requiring hospitalization), and possibly related to the research. Adverse events could result in the suspension or termination of an approved study or the modification of an existing protocol.

The IRB is required to report all adverse events and cases of noncompliance to sponsors and the Office of Human Research Protections that are: 1) serious or continuing noncompliance; 2) significant adverse events beyond minimal risk; or 3) associated with the suspension or termination of an IRB approved protocol.

Changing this document

Changes to this document (The Bellarmine IRB Handbook) may be made provided the suggestions are disseminated to all current members for their review and comment. After a 1-week period of review, the Chair may call for a vote. Changes shall be passed by a simple majority of the Committee members. The date of the latest revision should be noted in the footer.

Appendix A: IRB Submission Forms

The following forms are available on the IRB website for PI's wishing to submit their proposal for review. All relevant forms (including the Human Subjects Research Training certificate and CV's for all investigators) must be completed and submitted before formal IRB review will begin. A clerical screening will be performed by the IRB support staff and the PI will be informed of any omissions. Initial review by the IRB Chairman will only occur when the submission is complete.

1. Submission Checklist
2. IRB Submission Summary Form
3. Risks and Benefits Form
4. Conflict of Interest Form
5. Survey Consent Template
6. Consent Form Template
7. Consent Form Checklist
8. Amendment or Termination Form
9. nonBU IRB Submission Summary Form
10. Short App for Exempt Review

Appendix B: IRB Review Process by Type & General Timelines

- 1) **Clerical Screening:** Submissions are first checked for completeness and accuracy by the IRB support staff. The PI is alerted regarding any omissions.
- 2) **Initial Review by Chair (or designee):** Completed submissions are reviewed by the Chairman in order to determine...
 - a) Does the project qualify as Human Subjects Research?
 - If NO- inform the PI and keep record of the submission.
 - If YES- proceed to next step.
 - If UNSURE- Consult with other IRB members or Assistant Vice-President for Research and Academic Affairs
 - b) Does the Research involve '**more than minimal risk?**' (i.e. risks one would typically encounter in daily living)
 - If NO- Proceed to step c.
 - If YES- The study must be reviewed by the Full IRB Committee.** Have the file scanned and sent to the Committee with a meeting request. A Standard Informed consent will be needed unless the PI applies for an exemption per 45 CFR 46.116(d). The study will also need to be reviewed annually.
 - IF UNSURE- Consult with other IRB members or Assistant Vice-President for Research and Academic Affairs
 - c) Determine if the study meets the criteria for **Exempt Review or Expedited Review.**
 - Utilize the 11-page flowchart published by the OHRP on 9/24/04- OHRPdecisionFlowWcitations.pdf (attached at the end of this Appendix). Expedited Review can be performed by the Chair or the chair's designee. The submission should be scanned and sent to a member along with a Reviewer Decision Worksheet (copy attached at the end of this appendix). Consent forms (either Survey OR Standard Consent) are usually required unless the PI applies for an exemption per 45 CFR 46.116(d). The study will need to be reviewed annually.
 - Exempt studies are NOT exempt from review. They are simply exempt from annual review. All human subjects research must be reviewed by the IRB. However, research that is less than minimal risk may be reviewed by a short form (see form #10 in Appendix A).
 - d) If the Chair or the Committee suggests changes in the protocol or consent, the Chair shall alert the PI.
 - Once the Chair or committee are satisfied with the submission and approve the research, the Chair shall inform the PI (with cc to the Assistant Vice-President for Research and Academic Affairs). IF the work is not approved, the Chair shall inform the PI with cc to the Assistant Vice-President for Research and Academic Affairs. The submission and approval or rejection letter shall be kept on file in the IRB office.

Details on the Types of Reviews are included below:

Full Review

Full reviews require a completed IRB checklist, submission summary form, a comprehensive protocol description and an example of informed consent on Bellarmine letterhead. Full review is required in all cases where research exposes subjects to more than minimal risk. Examples may include (but are not limited to) research involving deception, individuals with cognitive disabilities, prisoners, or the infirmed, as well as any protocols where body specimens are obtained, or sensitive information requested. All full review of protocol must be approved at a scheduled meeting of the IRB. The IRB may vote to:

- 1.) Approve;
- 2.) Approve with minor revisions;
- 3.) Request additional information or clarifications for consideration at later meeting; or
- 4.) Not approve the research protocol.

Ordinarily, full reviews (not necessarily approval of the protocol per se) should be completed within twenty-eight (28) working days of receiving a completed submission, depending upon the timeliness of investigator responses to IRB (or IRB chair) inquiries. **Please note, protocols requiring a summer review will not be considered by the IRB until July.** As such, protocols requiring action prior to the end of the Spring semester should be submitted no later than mid-April.

If approved, the PI is required to submit an annual Progress Report. Any modifications or amendments to an approved research protocol require prior approval and an amendment form must be submitted to the IRB chair. The IRB chair or his/her designee may approve a modification or request the modification be reviewed at a scheduled IRB meeting.

Expedited Review

Expedited reviews require a complete IRB checklist, a submission summary form, a comprehensive protocol description and an example of informed consent.² Studies that entail non-exempt research involving minimal or less than minimal risk to subjects, or non-invasive research, may be eligible to undergo an expedited review at the discretion of the IRB chair and will be reviewed by the chair or an assigned IRB member. As part of the expedited process, the reviewer and/or the chair may make inquiries of the PI and suggest revisions prior to issuing a decision. The assigned reviewer may recommend to the chair that the protocol be:

- 1.) Approved;
- 2.) Approved with minor amendments; or
- 3.) Forwarded to the committee for a full IRB review.

Ordinarily, expedited reviews are completed within fourteen (14) working days of receiving a completed submission, depending upon the timeliness of an investigator to IRB inquiries.

If approved, the PI is required to submit an annual report to the IRB. Any modifications or amendments to an approved research protocol require prior approval and an amendment form must be submitted to the IRB chair. The IRB chair or his/her designee may approve a modification or request the modification be reviewed by at a scheduled IRB meeting.

Expedited reviews should be approached with caution when the reviewer feels they lack the appropriate expertise to judge the submission. The chair should be asked to redirect the review to a more qualified member of the committee. Independent, unaffiliated experts can also be consulted by the IRB chair or designee. In cases where uncertainty may still exist following investigator inquiries and/or an external consult, a full IRB committee review would be necessary.

Exempt Review

Exempt reviews require a PI to submit an *Exempt Short Form Application*. The short form is an abbreviated process whereby the PI can demonstrate the research meets the criteria for an exemption. The Chair or her/his designee may:

- 1.) approve the protocol;
- 2.) approve with minor revisions; or
- 3.) Request a full protocol be submitted pursuant to the expectations and requirements of either expedited or full review.

Ordinarily, an exempt review is completed within seven (7) working days of receiving a completed submission. Pursuant to the governing regulations, the exemption permits an on-going study to occur over a 12-month period and no annual report is required. Studies lasting longer than 12 months are required to submit an amendment of the study seeking a time extension. **Studies involving minors or other vulnerable populations are not normally eligible for Exempt Review except for as outlined in the exempt application as approved by the CFR language.**

Restarting a Protocol

A PI may restart a previously terminated study by submitting an Amendment form (form # 8 in Appendix A).

Participating in a Study that has been Approved by a nonBU IRB

A PI may participate in a study (e.g. as a satellite center) that has been approved by an IRB other than the Bellarmine IRB (a.k.a. a nonBU IRB) but prior to doing so, he or she must inform the Bellarmine IRB by submitting the following:

- 1) A signed and completed nonBU IRB Submission Summary Form (Form # 9 in Appendix A)
- 2) A copy of the protocol for the research
- 3) A copy of the nonBU IRB approval letter.

The Bellarmine IRB has the authority to ask for additional information and to decide if the nonBU IRB approval is acceptable or not.

Appendix C: Community-based Research & Partnerships

The IRB recognizes the increasing importance of community-based teaching, learning, & research. As such, the IRB may recognize, at its discretion, formal partnership agreements from which research might one day emerge as a result of public service or other academic activities. As part of this process, the IRB may permit a program (not an individual researcher) to develop a memorandum of understanding (MOU) associated with partnership activities (particularly in clinical and/or professional environments) where the risk is determined to be (or reasonably expected to be) minimal or less than minimal risk. The MOU must generally describe the scale and scope of approved activities. The proposed partnerships and resulting MOU must also be institutional and programmatic—and investigator specific. The intent of the MOU approach is to ensure compliance with human subjects research rules. As such, any activities that would ordinarily require a full IRB review cannot be covered by the MOU.

Appendix D: Class Projects & Student Research

The intent of class projects is to provide students with an important educational experience and not professional dissemination. As part of the educational process, students enrolled in courses that require minimal risk human subjects or related community-based research (i.e., interviews, surveys, program assessments, and so on) are not required to obtain IRB approval. Nevertheless, all students are expected to receive appropriate training and comply with the principles of informed consent. All course-based research projects must be approved by the instructor. All projects that exceed minimal risk and would ordinarily require expedited or full review (i.e., sensitive data, etc...) must receive IRB approval. Independent student research that involves human subjects (e.g., thesis, dissertation, culminating capstone experience, etc.) is not considered a class project, and IRB review and approval is required.

While non-IRB reviewed class projects cannot ordinarily be published or presented outside of the institutional context of Bellarmine University inclusive of community partnerships, minimal risk studies and subsequent research derived from prior class projects may be eligible for approval as existing data at the discretion of the IRB Chair (or full IRB) and provided both human subjects training of the students and informed consent of the participants are documented. Should the intent of a class-based or community-based project change from primarily educational to research as defined by the IRB, all project activity (i.e., surveys, interviews, etc...) would need to cease until such time as IRB approval is obtained.