



INSTITUTIONAL REVIEW BOARD

Policies and Procedures Related to the Use of Human Subjects in Research

Updated September 2021

The College of Saint Benedict, a liberal arts college for women, and Saint John's University, a liberal arts institution for men, are two nationally-recognized Catholic, Benedictine colleges. The colleges have a joint academic program led by a single provost, and students attend classes together on both campuses. Accordingly, the colleges have formed this joint Institutional Review Board to serve researchers at both institutions.

The United States Department of Health and Human Services has established regulations for the protection of human subjects according to the Code of Federal Regulations, Title 45, Part 46 (45 CFR 46). This document describes the policies and procedures of the College of Saint Benedict and Saint John's University Institutional Review Board (CSB-SJU IRB), organized for the protection human subjects in research in compliance with 45 CFR 46, and registered with the Office of Human Research Protections as IRB00009135. These policies and procedures apply to research and related activities conducted at College of Saint Benedict and Saint John's University, and/or by members of these institutions. Members of these institutions include students, faculty, and staff. The IRB is organized as a committee of appointed members of faculty, staff, and non-college community representatives. The IRB's policies apply to all human subjects research and research-related activities for which these institutions are responsible participants regardless of the source of funding or whether or not funding exists.

A. Purpose of the Institutional Review Board

1. Description of the Charge

The institutions affirm their policy to safeguard and respect the rights and welfare of human subjects in scientific research. In order to carry out this obligation, the institutions, through this joint IRB, conduct initial and continuing reviews of research protocols. Continuing review is conducted for full or expedited projects lasting longer than one year, and exempt projects lasting more than three years. Decisions regarding protection of human subjects in research submitted to the IRB are final as required by 45 CFR 46. No official in the institution may approve research protocols if it has not been approved by the IRB. The IRB reports to the CSB/SJU Vice Provost of Academic Affairs. It may consult with an identified IRB authority as needed to change or implement new policies. The IRB will also educate the college community about the research process and concerns for protection of human subjects. The chair will answer questions that faculty, students, and staff may have about the IRB process.

2. General Statement of Responsibility

All research involving human subjects must be reviewed at one of three levels. According to the Office of Human Research Subjects Protection (OHRP), human subjects research requiring IRB review is defined as "a systematic investigation, including research

development, testing and evaluation, designed to develop or contribute to generalizable knowledge." In order to approve research, the IRB shall determine that all of the following requirements are satisfied:

- a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- b. Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result.
- c. Selection of subjects is equitable.
- d. Informed consent will be sought from each prospective subject or the subject's legally-authorized representative. In some situations, it is appropriate to waive the signed consent form. The committee has authority to make the decision in these situations.
- e. Informed consent will be appropriately documented unless waived.
- f. Adequate provision is made to monitor data to ensure the safety of the subjects.
- g. There are adequate provisions to protect the privacy of subjects and confidentiality of the data, including no attempts to coerce subjects. (45 CFR 46.116)
- h. Documentation of support from the outside organization where the research is going to occur.
- i. Additional safeguards are put in place to protect vulnerable populations.

Investigators cannot begin research involving human subjects until a complete application has been submitted to the IRB, reviewed, and approved. The IRB will notify investigators in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval. If the IRB disapproves a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person and in writing.

The use of human subjects is a privilege granted to the investigator rather than a right. The policies and procedures of this board are designed to meet minimal criteria established by Federal law and Federal regulations. A project approved by the IRB that lasts longer than one year (for full or expedited reviews) is required to submit a written annual report to verify that no material changes have occurred since previous the IRB review. The IRB may require more frequent reviews at its discretion. Material changes in the study or in the consent form must be reported to and reviewed by the IRB before the changes may be implemented.

B. Definitions

1. Research

The Department of Health and Human Services (June 19, 2018, 45 CFR 46.102) defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge". Activities that meet this definition constitute "research" for purposes of the regulations, whether or not they are conducted or supported under a program that is considered research for other purposes. **All research involving human subjects must be reviewed at one of three levels (Full, Expedited, or Exempt) or through course approvals.**

Data collection that is not designed to develop or contribute to generalizable knowledge would not be defined as research. Examples include data collection only for assessment, program evaluation, quality assurance, quality improvement, fiscal or program audits, or similar uses.

In addition, for the purposes of this part of the Federal Register, certain specific activities "are deemed not to be research:

- a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions."

2. Human subject

"Human subject" is defined in 45 CFR 46 as "a living individual about whom an investigator (whether professional or student) conducting research" obtains data through intervention or interaction with the individual and uses, studies or analyzes the information; or obtains, uses, studies or analyzes identifiable private data. See 45 CFR 46 for the definitions of "interaction", "intervention", and "private information." Research not using human

subjects as defined here does not need to be reviewed by the IRB. If animal research is being conducted, please review Animal Use and Care Committee Policies.

3. Risk

“Risk” is the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both probability and magnitude may vary from minimal to significant.

4. Minimal risk

“Minimal risk” is defined in 45 CFR 46 as “the probability and magnitude 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.”

5. Informed Consent

An investigator may involve a human subject in research only if the investigator has obtained the legally-effective and informed consent of the subject or the subject’s legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The investigator must provide the information to the subject or representative in a written format that uses language understandable to the subject or representative. The investigator cannot include in the consent process, either through written or oral information, any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Please review the format for a consent forms and the checklist for essential elements of consent (<http://www.csbsju.edu/Institutional-Review-Board/Informed-Consent>).

C. Scope of Activities

All research (see Section B.1 for definition) involving human subjects (See section B.2 for definition) must be reviewed by the IRB. The IRB reviews applications at three levels, which are briefly introduced below. Researchers have the initial responsibility to determine the level of review of their project; however, the IRB has the ultimate responsibility to identify this level for committee review. Specific information about the nature of each level is located in the application policies found in the IRB website <http://www.csbsju.edu/Institutional-Review-Board.htm>.

1. Review for Exempt Status

Researchers who believe their research qualifies for the exempt category must submit the Exempt Review form to the IRB Chair, who verifies that the project meets the criteria for exemption. Research is reviewed for exempt status if it involves minimal or no risk procedures such as surveys/ interviews, observation of non-institutionalized adults, and educational tests. Many surveys may qualify for exempt review, except those in which a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and b) 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. (45 CFR §46.101 (b)(2)(i-ii) "Exempt" means the research is exempt from the federal regulations. The CSB-SJU IRB determines the Exempt status of a study. Specific information about the categories that qualify for Exempt status are listed on the IRB website (<https://www.csbsju.edu/institutional-review-board/exempt-categories>).

2. Expedited Review

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the IRB. Requests that qualify for this level of review require reading by at least three members of the IRB. The reviewers may exercise all the authorities of the IRB as follows:

- a. Approval as submitted
- b. Approval with suggestions
- c. Not approved until stipulations are met
- d. Refer to full committee for review

If the application is not recommended for approval, the full committee must review it. Only the full IRB can disapprove an application.

Research at the expedited level covers minimal risk procedures such as those involving small amounts of blood, dental plaque, moderate exercise (appropriate given the age, weight, and health of the individual), voice recordings, etc. See <http://www.hhs.gov/ohrp/policy/expedited98.html> for a more complete explanation of the types of research that *may* qualify for expedited review.

3. Full Committee Review

All research not falling into the other two categories and most research involving children, minors, or other vulnerable populations (such as prisoners, pregnant women, mentally disabled persons) requires full review because it places the subject at more risk than research that qualifies for exempt or expedited review. (See

<http://www.hhs.gov/ohrp/policy/populations> for additional guidance.) Research requiring full review means that it is read, discussed, and voted upon by the full IRB committee.

4. Requests for review from researchers sponsored by other institutions

All researchers who are not enrolled students, faculty or staff members of the College of Saint Benedict and Saint John's University are required to have permission from the appropriate authority at CSB/SJU. All researchers from other institutions who want to conduct human subject research at the College of Saint Benedict/Saint John's University must include in their applications the signature of the primary investigator from their own institution, the signature of the of the College of Saint Benedict/Saint John's University authority granting permission to access the population and complete the research and a letter of support and documentation showing approval by the IRB of the researcher's own institution. The researchers need to go through the exempt process.

5. Amended Protocols

During the course of a study, subjects may experience unexpected side effects or the researcher may gain knowledge from another research project that impacts research design. The researcher(s) are required to inform subjects of any important new information that might affect a subject's willingness to continue participating in the research. If researchers want to change a procedure in a study that has already received approval, they must prepare a written description of the change and the reasons for the change (<http://www.csbsju.edu/Institutional-Review-Board/Forms.htm>). Such changes include the entry or enrollment criteria of subjects, procedures for data collection, or some activity or procedure that must be changed because of an adverse event. The IRB will then reassess the balance of risks to benefits. In light of the reassessment, the IRB may require that the research be modified or halted altogether. Alternatively, the committee may relax special precautions or criteria for inclusion.

6. Adverse Events

An adverse event is defined as any undesirable and unintended, although not necessarily unexpected, impact on a subject, as a result of therapy or other intervention. Researchers must report in writing to the IRB all adverse events, including isolated incidents of unanticipated adverse reactions. The IRB must then decide whether the research should be modified. In addition, a report from one research activity may sometimes be relevant to the evaluation of another.

D. Review Procedures

Detailed review procedures are described in the IRB website. Information about general review procedures are included below. Researchers may not begin recruitment, enrollment of subjects, or data collection until they have received IRB approval.

1. General Procedures

- a. Researchers may find it helpful to consult with the IRB chair(s), or a committee member to determine the level at which to submit an application or procedures concerning the protection of human subjects. Members of the committee will provide assistance when asked. All student-initiated research and all research proposed by non-CSB/SJU community members must be overseen by a faculty or staff sponsor.
- b. Applications are submitted electronically to the IRB chair at irb@csbsju.edu.
- c. Exempt and expedited reviews may be turned in at any time. The IRB attempts to respond to exempt and expedited proposals within two weeks. Proposals requiring a full review can be submitted at any time; however, researchers are advised to allow a minimum of two weeks prior to the next scheduled IRB meeting to be included on the agenda. Review times may be longer during the summer, so researchers are advised to submit proposals at least two weeks prior to last scheduled IRB meeting of the Spring semester.
- d. The full IRB (all members) will conduct full reviews. The researcher and/or their faculty advisor should plan to attend this meeting if possible. In collaboration with the applicant(s), the IRB Chair(s) will schedule the project for full committee review during the scheduled IRB meetings. The researcher will be notified of the date. Researchers and faculty advisors will receive a response from the committee in writing. This may indicate approval as written, approval with stipulations, deferment/tabling the project, or disapproval/removal of ongoing approval. The IRB response will include details of any modifications requested and reasons for the committee's decision.

2. Research Conducted in a Class

When a faculty member is teaching a class in which students conduct research with human subjects, whether the research needs to be reviewed and approved by the IRB depends on the type of research and who the participants are. There are 3 possibilities:

- 1) Certain categories of research do not need to be reviewed or approved by the IRB if they are conducted in a class under close supervision of the instructor.
- 2) Other categories of research conducted in a class may be eligible to be reviewed under a Course Approval process that is designed to be faster and easier than the typical IRB review process.
- 3) Research conducted in a class that does not fit into categories 1 or 2 above needs to go through the typical IRB review process.

Each of these possibilities is explained in more detail on the IRB website here:
<https://www.csbsju.edu/institutional-review-board/research-conducted-in-a-class>

E. Roles and responsibilities

1. College of Saint Benedict

The College of Saint Benedict relies on the CSB-SJU IRB to carry out prior review and approval of human subjects research conducted by its faculty, staff and students. The college accepts the responsibility to meet the compositional requirements of IRB membership, and to provide both meeting space and sufficient staff and resources to insure the IRB's timely and appropriate review and record keeping duties. The College has assured the U.S. Department of Health and Human Services that it requires prior review and approval for all federally-funded research involving human participants. The College's Federalwide Assurance (FWA) number is FWA00019718.

2. Saint John's University

Saint John's University relies on the CSB-SJU IRB to carry out prior review and approval of human subjects research conducted by its faculty, staff and students. The university accepts the responsibility to meet the compositional requirements of IRB membership, and to provide both meeting space and sufficient staff and resources to insure the IRB's timely and appropriate review and record keeping duties. Saint John's University does not hold a Federalwide Assurance as of August 2013; however it may submit application to the federal Office of Human Research Protections for a FWA in the future.

3. College of Saint Benedict and Saint John's University Institutional Review Board

The main function of the CSB-SJU IRB is *to ensure that all research with human participants is conducted in accordance with the ethical principles outlined in the Belmont Report: respect for persons, beneficence and justice*. All research involving human subjects must be reviewed at one of three levels, described in more detail in Sections C and D. The purpose of these reviews is to determine if subjects will be placed at risk and if the benefits of the research warrant the risk. The review process will determine if:

- a. The potential risks to the subjects are clearly identified in the research protocol and in the consent form.
- b. The risks to the subjects are outweighed by the benefits to the subjects and the importance of the knowledge to be gained so that approval of the research project is warranted.
- c. The rights and welfare of all subjects will be adequately protected.

- d. A process is guaranteed to provide an adequate explanation of the potential risks and safeguards, as well as the benefits.
- e. The process and documentation conform to federal and the institutions' guidelines.

IRB decisions and requirements for modifications will be conveyed promptly to investigators in writing. Written notification of decisions to disapprove an application will be accompanied by reasons for the decision with provision of the opportunity to respond.

In accordance with 45 CFR 46.113, the IRB has the authority to suspend or terminate previously approved research when it determines that the research is not being conducted in accordance with the stipulations made by the IRB, or if the approved project experiences unexpected serious harm to subjects.

In observance of 45 CFR 46.112, neither the IRB Chair nor any office of either institution, including the presidents, may approve a research activity that has been disapproved by the IRB. The institutions may, however, prohibit research approved by the IRB.

Anyone who brings a complaint against the IRB shall present his/her concerns to the IRB Chair or Co-chair and, if unresolved, shall proceed to the following levels:

- a. Full IRB
- b. IRB Administrator
- c. Vice Provost
- d. President of the College

4. Researchers

Students, staff and faculty who propose to undertake research involving human subjects acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects. They also must comply with all applicable provisions outlined in this document. Research investigators involving human subjects also shall be responsible for complying with all IRB decisions, conditions, and requirements. Investigators will promptly report to the IRB anticipated changes they may propose or that may be imposed by an external IRB for previously approved human subject research activities. Researchers will not initiate any changes without IRB review and approval except where necessary to eliminate apparent immediate hazard to subjects. Researchers will report promptly to the IRB any injuries or unanticipated problems involving risk to research subjects or others. Students involved in human subjects research must complete ethics training through the CITI program, and submit proof of certification with their IRB application. Any faculty and staff conducting human subjects research are encouraged to complete the appropriate CITI training as well. Information on CITI training is available on the IRB website (<https://www.csbsju.edu/institutional-review-board/citi-training>).

5. Research Advisors

Academic advisors, faculty research advisors, or faculty members assigning research projects involving human subjects must take an active part in preparing students for the role of researcher, instructing them in the ethical conduct of research and assisting in the preparation of applications for IRB approval. Advisors shall take an active role in ensuring that the conduct of the research meets the highest ethical standards.

The signature of the faculty research advisor is required on the IRB application form, providing documentation that these aspects of research have been addressed, and that the advisor is ultimately responsible for the protection of human subjects in student research. If any research project also will be subject to review by an outside IRB, the application for that review may not be submitted until the research has been reviewed and approved by the outside IRB. Research advisors are responsible for assuring that applications to an outside IRB contain only the revised documents finally approved by the institution's IRB. If the outside IRB requires further changes in the project and/or the consent form, the amended documents must be filed with the Chair or Co-chair of the CSB-SJU IRB.

F. Structure and Process

1. Membership of the IRB

- a. **Composition:** The IRB shall be composed of a minimum of 7 faculty, staff and non-college community representatives with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The number and composition shall be in compliance with 45 CFR 46.107. Others with expertise in human subjects research may be consulted for specific topics/proposals. The IRB shall also include at least one member whose primary concerns are in scientific, at least one member whose primary concerns are nonscientific, and one member who is not otherwise directly affiliated with CSB/SJU and not part of the immediate family of a person who is affiliated with CSB/SJU.
- b. **Term of office:** Members of the IRB will serve staggered three-year terms, with no limit to the number of terms for any member. Members who wish to discontinue service after their term shall notify the IRB Chair or Co-chair by the end of semester.
- c. **Method of appointment:** Each college unit with representation on the IRB shall recommend to the IRB Chair or Co-chair prospective committee members when a vacancy occurs from that unit. The IRB will formally discuss the candidate, and if approved, will send a letter to the IRB administrator informing him/her of the new membership.
- d. **Quorum:** The IRB will observe the quorum requirements of Section 46.108(b). A quorum is met by the presence of a majority of the total number of members; the quorum must include at least one member whose primary concerns are in

- nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of the members present at the meeting. Informal discussion may occur in the event that a quorum is not present. No action can be taken without a quorum. The minutes will reflect discussion held when a quorum was not present.
- e. **Attendance:** The minutes will reflect committee member attendance at the IRB meetings.
 - f. **Conflict of interest:** Members who serve as advisers to an application under review or who have any other interest in an application or issue before the committee will declare this to the IRB. They may be called upon to answer questions on the topic but will refrain from voting.
 - g. **Chairperson:** The IRB shall elect its own chairperson in the last meeting of the academic year for the appointment to begin in July of the following academic year for a term of one or more years. The IRB may choose to elect two Co-chairpersons. No one may serve as a Chair or Co-chair who has served on the IRB for less than one academic year. It is preferred that the IRB Chair is tenured when possible.
 - h. **Agenda:** The Chairperson will distribute an agenda in advance of the meeting. Discretionary changes can be made in the agenda by the Chair or Co-chair and members may bring new issues to the group for addition to the initial agenda.
 - i. **Amendments to procedures or policy:** The IRB cannot make amendments to written policies and/or procedures at a meeting unless sufficient notice of the proposed change has been provided to all members in advance of the meeting. Amendments to policies and/or procedures can be discussed and implemented over email as long as the amendments do not require significant discussion, at the discretion of the Chair(s).
 - j. **Meetings:** IRB meetings, including those for Full review, can be held in-person or over video chat such as Zoom.
 - k. **Service to the College and University:** Serving on the IRB committee is recognized as service to the college and university as stated in the Faculty Handbook, section 4.5.1. Administrative committees have a designated purpose, such as the protection of human and animal subjects in research but are outside of the formal faculty governance structure. Members may be volunteers or appointed by the administrative committee. Participation on these committees is recognized as service to the college and university.

2. Maintenance of Records

- a. **Applications:** The IRB will maintain and arrange access for inspection of IRB records as provided for in Section 46.115. This includes applications, sample consent documents, correspondence between the IRB and the researchers, progress reports, statements of significant new findings provided to subjects, complaints and reports of

- injuries to subjects. All records will be retained for at least three years after completion of the research.
- b. **Meeting minutes:** The IRB will prepare and maintain adequate documentation of its activities in accordance with Section 46.115 and in conformance with any other requirements the committee may develop for itself. Meeting minutes will be distributed to IRB members and will be available upon request to the Vice Provost of Academic Affairs as well as authorized representatives of the Federal department or agency. The minutes will include:
- i. attendance of members including excused absences, researchers and advisers, and other visitors or observers
 - ii. actions taken by the IRB
 - iii. the vote on the actions, including the number of members voting for, against and abstaining
 - iv. the basis for requiring changes in or disapproving research
 - v. a written summary of the discussion of issues and recommendations for their resolution.
- c. **Membership records:** The Chair or Co-chairs will be responsible for maintaining a list of current IRB members as required by 46.108(a)(2). The membership records shall include the correspondence between the IRB and the Vice Provost regarding appointments of members. The list will identify members by name, earned degrees, representative capacity, indications of experience such as board certifications, licenses, etc. sufficient to describe each member's chief anticipated contributions to IRB deliberations, and any employment or other relationship between each member and the institution.
- d. **Written procedures:** Each member of the IRB will maintain a current link to the current OHRP Policy and Guidance Library (<http://www.hhs.gov/ohrp/policy/index.html>) and the Federal Policy (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>) and all additional subparts and revisions to the Federal Policy. In addition, the IRB will maintain and follow written procedures:
- i. for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution.
 - ii. for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.
 - iii. for ensuring prompt reporting to the IRB of proposed changes in a research activity.
 - iv. for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB

review and approval except when necessary to eliminate apparent immediate hazards to the subject.