Saint Mary's College of California
Policy on Human Subjects Research

Responsible Officer	Senior Vice President for Academic Affairs and Provost
Responsible Office	Academic Affairs
Issuance Date	March 9, 2015
Revision Date	Feburary 20, 2026
Effective Date	February 20, 2026
Applicability	This policy applies to Saint Mary's College administrators, faculty, staff, and students who are conducting research involving human subjects within the course and scope of their SMC duties.

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I. POLICY SUMMARY

This Policy describes the responsibilities of Saint Mary's College of California ("the College") in protecting the rights and welfare of human subjects who participate in research in which the College is engaged.

The College affirms its commitment to the ethical principles articulated in *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*—respect for persons, beneficence, and justice—and to compliance with applicable federal and state laws and regulations governing human subjects research, including the U.S. Department of Health and Human Services regulations at 45 CFR 46 ("the Common Rule").

This Policy applies to all research involving human subjects conducted by College administrators, faculty, staff, and students within the course and scope of their SMC duties or studies, regardless of funding source or research site, and establishes the framework for IRB review and related institutional procedures.

II. DEFINITIONS

A. Common Rule

The Federal Policy for the Protection of Human Subjects as adopted by (and codified in the regulations of) multiple federal agencies. For the purposes of this Policy and related policy guidance or procedure documents, the Common Rule refers to Subpart A of Department of Health and Human Services (HHS) regulations at Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46, Subpart A) (https://www.ecfr.gov/current/title-45/part-46/subpart-A).

B. Research

The systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge, consistent with the HHS definition of research (45 CFR 46.102(l)).

C. Human Subject

As defined in 45 CFR 46.102(e)(1) (https://www.ecfr.gov/current/title-45/part-46/subpart-A), a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

D. Intervention

Both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

E. Interaction

Includes communication or interpersonal contact between investigator and subject.

F. Private Information

Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

G. Minimal risk

The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

H. **Institutional Review Board (IRB)**

The generic name for any board, committee, or other group formally designated by an institution to review the conduct of Research involving human subjects and to protect the rights and welfare of those subjects.

I. Institutional Official (IO)

The individual who is legally authorized to act for the College and, on its behalf, obligate the institution to the terms of the Federalwide Assurance filed with the U.S. Department of Health and Human Services Office of Human Research Protection (OHRP) for the protection of Human Subjects.

J. **Reliance Agreement**: A formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an independent IRB

or an IRB of another institution. Institutions that are engaged in human subjects research, where one institution will rely on the other institution's IRB, must agree to the terms of the Reliance Agreement before research can begin.

III. POLICY TEXT

Definition of Respect for Persons

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information.

To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated. Some persons are in need of extensive protection. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

1. Application of respect for persons in research: Informed consent
   Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

   While the importance of informed consent is unquestioned, the nature and possibility of a subject's informed consent is not universal across all studies. There is widespread agreement that the consent process can be understood as containing three elements: information, comprehension and voluntariness.

   Information. Most codes of research establish specific items for disclosure intended to ensure that subjects are given sufficient information. These items generally include: the research procedures, their purposes, risks and anticipated benefits, alternative procedures (if any), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

   A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that:

   a. incomplete disclosure is truly necessary to accomplish the goals of the research,

b. there are no undisclosed risks to subjects that are more than minimal, and
c. there is an adequate plan for debriefing subjects, when appropriate, and for dissemination of research results to them.

2. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research.

   Comprehension. The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questions, all may adversely affect a subject's ability to make an informed choice.

   Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

   Voluntariness. An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

   Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins.

3. IRB review criteria

   The research plan must contain a clear and detailed description of the process by which participants' informed consent will be obtained. The informed consent process must be free of coercion and undue influence.

   Consent and/or assent forms, as well as written or oral scripts used in the consent process must be provided. When communicating research procedures and potential risks and benefits to prospective participants, information must be conveyed in a comprehensible manner.

IV. PROCEDURES

Implementing procedures and additional guidance related to this Policy are developed and maintained by the IRB, the Office of Research, and other responsible College units.

These procedures include, but are not limited to:

A. Determining whether proposed activities constitute human subjects research under this Policy and applicable regulations, and whether such activities qualify for exemption from IRB review.
B. Establishing and maintaining requirements and processes for IRB submission and review, including full, exempt, and expedited reviews, and communicating IRB decisions to investigators.
C. Maintaining standards and templates for obtaining and documenting informed consent.
D. Establishing requirements and processes for reporting unanticipated problems, noncompliance, and other events to the IRB and, when applicable, to external agencies or sponsors.
E. Establishing and documenting arrangements in which the College relies on an external IRB for review, or provides IRB review for external investigators, including reliance agreements.
F. Setting and communicating requirements for initial and ongoing human subjects protection training for investigators, key personnel, and IRB members.

Current procedures, forms, and investigator guidance are available through the College's IRB website at www.stmarys-ca.edu/offices-services/institutional-review-board.

V. COMPLIANCE / RESPONSIBILITIES

Saint Mary's College of California is responsible for compliance with this Policy. Implementing guidance specific to the College may supplement this Policy to ensure full compliance with all federal and state laws and regulations, as well as with all College policies governing the participation of Human Subjects in Research. Further responsibilities are provided below.

College Responsibilities: The Senior Vice President for Academic Affairs and Provost (hereafter referred to as "Provost") serves as the Institutional Official who oversees Human Subject protections at Saint Mary's College of California and serves as the signatory official on the Federalwide Assurance filed with OHRP. The Institutional Official ensures that the Institutional Review Board (IRB) remains free from undue influence in its decision-making and that adequate resources are provided to support the IRB's review. The Institutional Official, or their designee, also appoints members of the IRB.

Research conducted at the College that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by College officials, including the Institutional Official and other offices or committees described below. However, these officials may not approve Human Subjects Research that has not been approved by an IRB.

Institutional Review Board Responsibilities: Saint Mary's College of California maintains an IRB charged with the review and continuing oversight of Research involving Human Subjects, in accordance with College policies and federal regulations. The IRB has the authority to:

- Approve, disapprove, or require modifications to research protocols;
- Suspend or terminate approval of Human Subjects Research not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects; and
- Observe, or have a third party observe, the consent process and/or the conduct of Research.

The College may grant the IRB additional authorities as appropriate.
Other College Offices and Functions: The protection of Human Subjects participating in Research extends beyond the IRB and involves multiple groups, such as the Office of Research and functions such as risk management, research compliance, privacy, and legal counsel. These entities may work in concert with the IRB when carrying out their core functions supporting Research.

Investigator Responsibilities: All Saint Mary's College of California faculty and staff conducting Research involving Human Subjects within the course and scope of their college duties, as well as students conducting research involving Human Subjects within the course and scope of their college studies, regardless of whether the Research is funded or the source of funding, must submit Human Subjects Research protocols to the IRB for approval or follow college policies and procedures for obtaining an exempt determination before commencing Research. Investigators must maintain IRB approval for the lifespan of the project, submit continuing review documents to the IRB as necessary to maintain approval, and follow all IRB and college policies for the protection of Human Subjects in the conduct of the project.

VI. REVISION HISTORY

This policy is a revision of the *Saint Mary's College of California Human Subjects Policy*, effective March 9, 2015 through February 20, 2026.

- Presented to Saint Mary's Academic Senate, February 20, 2026
- Revised by the Institutional Review Board, January 26, 2026
- Policy Issued, March 9, 2015
- Approved by Saint Mary's President, February 23, 2015
- Drafted by the Institutional Review Board, 2014-2015