



SAN JUAN BAUTISTA SCHOOL OF MEDICINE

INSTITUTIONAL REVIEW BOARD (IRB)

APPLICATION TO CONDUCT RESEARCH INVOLVING HUMAN SUBJECTS

Form: SJBSM-IRB-01

Effective: January 2026

Supersedes: Revised May 2019

1. PURPOSE AND REGULATORY AUTHORITY

The purpose of this application is to ensure that all research involving human subjects conducted under the auspices of San Juan Bautista School of Medicine (SJBSM) complies with:

- **45 CFR 46 (Revised Common Rule)**
- Applicable **OHRP guidance and determinations**
- Relevant **FDA regulations**, when applicable
- Ethical principles of the **Belmont Report** (Respect for Persons, Beneficence, Justice)

No research involving human subjects may commence until **written IRB approval** has been issued.

2. APPLICABILITY

This application is required for **all research involving human subjects**, including:

- Faculty, student, and staff research
- Research using SJBSM facilities, data, or personnel
- Exempt, expedited, and full board research
- Secondary use of identifiable private information or biospecimens

Retroactive approval is prohibited.

3. TRAINING REQUIREMENTS (REQUIRED PRIOR TO SUBMISSION)

All investigators and study personnel must complete:

- Human Subjects Protection (CITI or equivalent)
- HIPAA for Researchers (if applicable)
- Responsible Conduct of Research
- Conflict of Interest disclosure

Certificates must be submitted with this application.

4. STUDY IDENTIFICATION

Check one:

New Study
 Resubmission / Modification
 Continuing Review

IRB Protocol Number (if applicable): _____
Previous Review Date (if applicable): ____ / ____ / ____

5. STUDY DURATION

- **Proposed Start Date:** ____ / ____ / ____
- **Proposed End Date:** ____ / ____ / ____

Note: Approval is granted for a maximum of **one year** unless the study qualifies for no continuing review under 45 CFR 46.109(f).

6. INVESTIGATOR INFORMATION

Principal Investigator (PI)

Name: _____

Department: _____

Phone: _____

Email (institutional): _____

Faculty Advisor (if student research)

Name: _____

Department: _____

Email: _____

Co-Investigators / Key Personnel

(List all individuals engaged in human subjects research)

7. MULTI-SITE / EXTERNAL INSTITUTIONS

No

Yes → Identify institution(s): _____

- Will another IRB rely on SJBSM IRB? Yes No
- Are IRB authorization agreements required? Yes No

8. RESEARCH LOCATION(S)

Describe where research activities will occur (physical and/or virtual):

9. PARTICIPANT POPULATION

Total number of participants: _____

Age Range: _____ to _____

Check all that apply:

- Adults (≥ 18 years)
- Children (< 18 years)
- Pregnant persons
- Prisoners
- Students
- Employees
- Patients
- Other vulnerable populations (specify): _____

10. STUDY ACTIVITIES (CHECK ALL THAT APPLY)

- Surveys / Questionnaires
- Interviews / Focus Groups
- Behavioral Observation
- Use of existing records/data
- Biospecimen collection
- Genetic analysis
- Audio / Video recording
- Deception
- Waiver or alteration of consent
- Investigational drug or device
- Clinical intervention
- Secondary research use of identifiable data
- Other (describe): _____

11. FUNDING AND CONFLICTS OF INTEREST

Is the study funded? No Yes

If yes, identify sponsor and attach abstract/protocol.

Does funding require IRB approval? Yes No N/A

Any financial interests related to this research? No Yes (disclose)

12. REQUESTED REVIEW CATEGORY (IRB DETERMINES FINAL STATUS)

Exempt (45 CFR 46.104 – specify category)
 Expedited (45 CFR 46.110 – specify category)
 Full Board Review

Investigators may **request**, but may not self-determine, exemption.

13. RESEARCH DESCRIPTION (REQUIRED)

Provide a clear, lay-language description including:

- Background and rationale
- Objectives / research questions
- Study design and procedures
- Data collection methods
- Data analysis plan
- Dissemination of results

14. RECRUITMENT METHODS

Describe:

- Source of participants
- Recruitment materials and procedures
- Avoidance of coercion or undue influence
- Special protections for vulnerable populations

Attach all recruitment materials.

15. INFORMED CONSENT PROCESS

Written consent
 Electronic consent
 Oral consent
 Waiver or alteration requested (justify under 45 CFR 46.116)

Consent documents must include **all required elements** under 45 CFR 46.116, including:

- Voluntary participation
- Risks and benefits
- Privacy and confidentiality
- Contact information
- Statement of IRB approval

16. CHILD ASSENT (IF APPLICABLE)

Describe assent procedures consistent with **45 CFR 46 Subpart D**.

17. RISKS AND BENEFITS

Describe all foreseeable risks (physical, psychological, social, legal, economic) and risk minimization strategies.

Describe anticipated benefits, if any.

18. PRIVACY, CONFIDENTIALITY, AND DATA SECURITY

Describe:

- Identifiability of data
- Coding / de-identification procedures
- Data storage (physical and electronic)
- Access controls
- Data retention and destruction timeline

19. DATA MANAGEMENT AND DISPOSITION

Explain how data and biospecimens will be stored, shared, retained, and destroyed.

20. UNUSUAL OR ETHICALLY SENSITIVE ASPECTS

Identify any issues requiring special IRB consideration.

21. INVESTIGATOR ASSURANCE

I certify that:

- The information provided is accurate
- I will comply with all IRB requirements
- I will not initiate research prior to IRB approval
- I will promptly report adverse events, protocol deviations, and modifications



PI Signature: _____ Date: _____

22. FACULTY ADVISOR / DEPARTMENT ASSURANCES (IF APPLICABLE)

Faculty Advisor Signature: _____ Date: _____
Department Chair / Dean Signature: _____ Date: _____

FOR IRB USE ONLY

Review Type: Exempt Expedited Full Board

Determination: Approved Modifications Required Disapproved

IRB Chair Signature: _____ Date: _____
