San Juan Bautista School of Medicine
Institutional Review Board

APPLICATION TO INVOLVE HUMAN SUBJECTS IN RESEARCH

(Form SJBSMIRB-1 revised May, 2019)

Note: Submit original signed documents and one electronically filed scanned copy of all application materials.

PROTECTING THE RIGHTS AND WELFARE OF HUMAN SUBJECTS IN RESEARCH AT SAN JUAN BAUTISTA SCHOOL OF MEDICINE(SJBSM)

The purpose of this application is to guarantee ethical principles based research protections of human subjects in research, ensure compliance with federal, state, and corporate regulations, and elicit from the Principal Investigator (PI), pertinent information which will facilitate a rapid and thorough review by the SJBSM Institutional Review Board (IRB).

SUMMARY GUIDELINES

SJBSM policy requires that all research involving human subjects* conducted by or under the direction of SJBSM personnel and students using any property or facility of SJBSM, regardless of location, must be submitted to the IRB for review and approval. Written notice of IRB approval must be issued before the Principal Investigator (PI) may initiate research. Only those documents (consent form, advertisement, questionnaires, etc.) that bear the IRB approval may be used in the conduct of research. Any change made to the protocol, consent form, or supporting documentation must be approved by the IRB before they can be implemented, as well. A review may be requested by submitting an addendum application to the IRB.

Note: The Clinical Research Unit (CRU) established under the San Juan Bautista School of Medicine Research Deanship is a separate entity with its own bylaws, policies, procedures, and IRB that oversees clinical research involving human subjects sponsored by industry.

The SJBSM IRB cannot approve a protocol for a period longer than one year and cannot, under any circumstances, grant retroactive approval. Continuing review is, therefore, required on a yearly basis. The IRB will issue a notification when an Application for Continuation is due. However, the Principal Investigator is responsible for ensuring that applications are submitted and approved before work is initiated and/or continued.

*Human Subjects are defined by the federal regulations as: “living individual(s) about whom an investigator conducting research obtains: 1) data through intervention or interaction with the individual, or 2) identifiable private information”

1. **PROJECT REVIEW**

The Faculty Advisor(s), Student Researcher(s), and any External Researcher(s) MUST complete the Online Training requirements in Human Subject Research, HIPAA for researchers, Responsible conduct of Research and Conflict of Interest before submitting IRB application. Submit copies of each certificate at the time of the IRB application submission. Training certificates can be obtained at SJBSM CITI Program.
https://about.citiprogram.org/en/homepage/

Check one:

☐ New IRB Project (ID # assigned by IRB):
☐ IRB Resubmission project (Enter IRB ID # assigned): (IRB#)
For resubmission include date of most recent previous review: (MM/DD/YYYY)

2. **DATA COLLECTION DATES**: From (MM/DD/YYYY) to (MM/DD/YYYY)

Required information; data collection dates. Please allow at least 30 days from the date you turn the application for IRB review decision.

3. **INVESTIGATOR(S)** (copy and paste additional investigator names as needed. If a student project the faculty advisor should be the Principal Investigator and as the approving faculty advisor).

Principal Investigator Name: (faculty)
Department: Phone:
SJB Email:

Faculty Advisor Name:
Department: Phone:
SJB Email:

Co-Investigator Name: Phone:
SJB email:

Co- Investigator Name: Phone:
SJB email:

Co-Investigator Name: Phone:
SJB email:

Co- Investigator Name: Phone:
SJB email:

Co-Investigator Name: Phone:
SJB email:

Co-Investigator Name: Phone:
SJB email:

Co-Investigator Name: Phone:
SJB email:

Co- Investigator Name: Phone:
SJB email:

Are there other participating Institutions requiring IRB review? Yes____No____

Where Will the Research Be Conducted? _____

4. **PROJECT TITLE**:

5. **PARTICIPANTS** (approximate number and all applicable categories):
Number of participants proposed: (list proposed population number here)

☐ Female ☐ Male ☐ Other:

☐ Children (17 or younger)
☐ Patients in institutions
☐ Prisoners
☐ Pregnant women
☐ Other: (describe population here)

☐ Adults (18 years of age or older)
☐ SJB students
☐ Faculty or external reviewers
☐ Child Development Center

Will the research involve any of the following?

_____Interviews
_____Use of private information
_____Use of private data/records
_____Survey/questionnaire
_____Behavior observation
_____Deception
_____Waiver of consent
_____Controlled substance
_____Study of diagnostic specimens
_____Study of pathological specimens
_____Venipuncture (<450cc)
_____Radiation
_____Personal identifying links to data
_____Clinical Studies
_____HIV/Aids
_____Hepatitis/TB/STD
_____Culturally or socially Sensitive Issues
_____Potential development of commercial products from human biological materials
_____Use of bodily materials from a living individual or fetus
_____Genetic research/analysis
_____Genetic notification
_____Data or tissues obtained specifically for this project
_____Investigational drugs
_____Investigational devices or materials
_____Study of existing documents
_____Minor change to previously approved research
_____Human in vitro fertilization
_____Micro-organisms or recombinant DNA
_____PI or alternate as attending physician or care giver
_____Environmental alternations (habitat/lighting, etc.)
_____Audio visual/tape recordings or photographs
_____Moderate exercise by volunteers
_____Individual observation or group behavior or characteristics
_____Tools developed specifically for this study

6. **FUNDING:** Project period from (MM/DD/YYYY) to (MM/DD/YYYY)

Are you seeking funding for this research? ☐ No ☐ Yes
If yes, submit one copy of the proposal summary or abstract with the application.

Does the funding agency require IRB approval? ☐ No ☐ Yes ☐ N/A
If yes, provide all relevant forms, instructions, etc. with this application.

7. **REVIEW CATEGORY**: Please mark all items that apply.

Note: Most research with children cannot be reviewed under exempt administrative review. The protocol would require either expedited or full board review. See HHS OHRP regulations.

☐ **Exempt Administrative Review** (based on the following categories):

☐ a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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.

☐ c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b) (2) of this section, if:(i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

☐ e. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

☐ f. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

☐ **Expedited Review** (See HHS OHRP Expedited Review Criteria List below):

A. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

B. The categories in this list apply regardless of the age of subjects, except as noted.

C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects= financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

D. The expedited review procedure may not be used for classified research involving human subjects.

E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Expedited Review Criteria List

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children [2], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b) (2) and (b) (3). This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
    b. where no subjects have been enrolled and no additional risks have been identified; or
    c. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

---

[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

[2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).

Source: 63 FR 60364-60367, November 9, 1998.

Content created by Office for Human Research Protections
Content last reviewed on March 21, 2016

Note: Submit original and one electronically filed copy of all application materials.

- ☐ Collection of data from voice, digital, or image recordings made for research purposes
- ☐ Moderate exercise, muscular strength testing, body composition and flexibility testing from healthy volunteers (excludes x-rays, or microwaves)
- ☐ Non-manipulative, non-stressful research on individual or group behavior
- ☐ Collection of biological specimens by noninvasive means (see full list at link above) Collection of blood samples by finger prick, heel stick, ear stick or venipuncture
- ☐ Study of existing data, documents, records, or pathological or diagnostic specimens
- Other: (see expedited link above and describe here)

☐ **Full Board Review**:

Unless otherwise determined to be either Expedited or Exempt research, all human subject research protocols are reviewed by a fully convened Institutional Review Board. Each Full Board protocol is assigned two reviewers based on those reviewers' background and expertise. Additional input may be sought, or required, if the research involves any Federally recognized vulnerable populations (see 45 CFR 46 subparts B, C, and D). During the meeting of the convened board, the primary reviewer is responsible for presenting general information about the study, including:

- Study goal
- Study design
- Study procedures
- Safety procedures and considerations
- Qualifications of the Investigators

8. **ATTACHMENTS**: All relevant project materials and documents, including

- ☐ Surveys, questionnaires, interviews, and measurement instruments
- ☐ Informed Consent Form
- ☐ Assent script (for children when applicable)
- ☐ Include letters of approval/permission on letterhead from cooperating agencies, schools, board of education, school districts, and other agencies
- ☐ Debriefing statement or explanation sheet if applicable
- ☐ Participant recruitment materials (e.g., fliers, advertisements)
- ☐ other: (describe other documents submitted here)

9. AFFIRMATION OF COMPLIANCE:

Note: Investigators or researchers are required to notify the IRB of substantive changes to protocol, unanticipated adverse, serious events experienced by participants, and project completion. Projects lasting longer than one year require an annual Request for Continuation (Protocol Renewal) or Notice of Project Ending by emailing the San Juan Bautista School of Medicine IRB Chairman at mperez@sanjuanbautista.edu.The consent forms and data must be kept at least three years after the study ends.

I agree to follow the procedures outlined herein and to ensure that the rights and welfare of human participants are properly protected. I will commence the study only after receiving approval from the IRB and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB by contacting the* IRB Chairman *at mperez@sanjuanbautista.edu. If the project continues for more than one year from the approval date, I will submit the required documentation.

I affirm that I have read and reviewed the accuracy of this application and accept responsibility for the ethical conduct of this research, supervision of human participants, and maintenance of data and informed consent documentation as required by the IRB. (Cut and Paste additional investigator signature lines as needed).

Signature of Investigator	SJB E-mail Address	Date (mm/day/year)
Signature of Co-investigator	SJB E-mail Address	Date

APPROVAL OF FACULTY ADVISOR OR SPONSOR:

I affirm that I have proofread and reviewed the accuracy of this application and accept responsibility for the ethical conduct of research, student supervision, and documentation maintenance. (Copy and paste additional faculty advisor approval signatures and contact information lines as needed below.)

I agree to follow the procedures outlined herein for my student(s) and to ensure that the rights and welfare of human participants are properly protected. I will ensure the study does not commence until the study has been approved by the SJB IRB and having complied with required modifications. I will promptly report additions, changes, or problems involving the rights or welfare of human participants to the IRB Chairman at mperez@sanjuanbautista.edu. If the project continues for more than one year from the approval date, I will submit the required documentation. (Cut and paste additional faculty advisor signature lines as needed).

Printed Name of Faculty Advisor	SJB Department	Phone
Signature of Faculty Advisor	SJB E-mail Address	Date (mm/day/year)

Department Chairperson's Assurance Statement

This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study and the competency of the investigator(s) to conduct the project. *(If the principal investigator is also the chairperson of the department, the Dean should sign the Signature Assurance Sheet)

Chairperson's Name (Typed/printed)	Signature	Date (mm/day/year)

Department Affiliation_____

10. RECRUITMENT OF PARTICIPANTS:

Include your recruitment of participants section below

Describe sources of potential participants, how they will be selected and recruited, and how and where you will contact them. Include all relevant characteristics with regard to age, ethnicity, sex, institutional status (i.e., patients or prisoners), and general state of physical and mental health.

Note: Recruitment issues can be especially critical when any federally defined "vulnerable population" is involved. This includes children, pregnant women, prisoners, others who are institutionalized, and anyone who might be at particular risk or whose cooperation might be dependent on coercions, no matter how slight.

11. DESCRIPTION OF THE PROJECT:

Include the description of the project section below.

Briefly describe the objectives and methodology of your research (including hypothesis and/or research questions), data collection procedures, and features of the research design that involve specific procedures or special conditions for participants (including frequency, duration, and location of participation.

It would be most helpful to organize this section with the following sub-headings:

a. Background of Theory and/or Literature Review
b. Objectives of the Study
c. Hypothesis or Research Questions
d. Methodology (the design of the study)
e. Data Collection
f. Data Analysis
g. Dissemination

12. CONFIDENTIALITY OF DATA:

Include the confidentiality of data section below. Please delete the instructions below when complete.

Clearly indicate specific procedures (e.g., coding of responses, aggregate reporting, etc.) to protect the confidentiality of participants and safeguard identifiable records and data. This includes safe and secure storage of the collected information and when the data will be destroyed after the data collection process has been completed. If not possible, state why.

13. RISKS AND BENEFITS:

Include the risk and benefits section below. *Please delete the instructions below when complete*.

Describe in detail any immediate, short-term, or long-range risks that may arise for participants as a result of procedures associated with your study. Risks may be physical, psychological, social, legal, or economic; they would include side effects, risks of placebo, delay in customary treatment, etc. Indicate any precautions that will be taken to minimize risks. Also indicate any anticipated benefits to participants and/or society from the knowledge that may reasonably be expected to result from the study. Risks and benefits MUST BE included in the protocol and in the informed consent document.

14. INFORMED CONSENT:

Informed consent is usually written; however, in some circumstances it may be oral or electronic in nature. Waivers of informed consent may be granted under certain limited conditions, and any request for such should include explicit justification. Remember that the informed consent should be unique to each study being proposed and should also be written at the 6^{the} grade reading level or lower if needed.

The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like written consent, they should include:

a. Identification of the researcher(s)
b. The nature and purpose of the study
c. Expected duration of participant involvement
d. How confidentiality or anonymity will be maintained
e. The voluntary nature of participation
f. Participants' right to withdraw at any time without penalty
g. Information about foreseeable risks and benefits (or none)
h. Contact information for questions or additional information
i. First paragraph should have a statement that the research has been approved by the Institutional Review Board of the San Juan Bautista School of Medicine.

A copy of the Informed Consent or text for oral consent must be provided to the IRB for approval. For non-Spanish speaking participants, be sure to include an accurate translation.

15. CHILD ASSENT:

"Assent" is defined by the regulations as follows: "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. (See federal regulation at 45 CFR 46.402 (b)) and OHRP frequently asked questions and answers at http://answers.hhs.gov/ohrp/questions/7202)

This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. When judging whether children are capable of assent, the Institutional Review Board (IRB) is charged with taking into account the ages, maturity, and psychological state of the children involved. The IRB has the discretion to judge children's capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis

16. INVOLVEMENT OF OTHER INSTITUTIONS

1. Describe any arrangements or agreements with other institutions which will directly affect the involvement of human subjects in this research. If applicable, provide letters of cooperation and or authorization.

2. Will human subjects review be required by any other institutions?

Yes_____Name of Institution: _____

No_____

3. Will research results be available to the institution in such a manner that participants can be easily identified? (Please elaborate).

17. UNUSUAL ASPECTS OF THIS RESEARCH

Please note any unusual aspects of this research, which should be called to the attention of the Institutional Review Board for Human Subjects Research and may affect the rights of the Human Subjects.

18. DATA MANAGEMENT AND DISPOSAL

Please explain how data will be managed during the research process and how it will be stored or destroyed. If video or recordings were obtained, explain how they were obtained and the method of disposal.

19. FINANCIAL CONSIDERATIONS

A. Cost: Will there be a compensation given for participation? Which cost will be reimbursed for travel and other expenses, if any? Will they receive services or other benefits instead of cash? What conditions must be fulfilled to receive full or partial payment?

FOR IRB USE ONLY

Status: New____Addendum _____
IRB Number: _____
Date Received: _____
Type of Review: Full:_____Expedited:_____Exempt: _____

Information Requested for Clarification:

Actions:

Date: _____
Contact
Manuel J. Pérez-Pabón M.D.
IRB Chairperson
mperez@sanjuanbautista.edu

Revised May 2019