



# ESCUELA DE MEDICINA San Juan Bautista

## **SJBSOM HUMAN RESEARCH PROGRAM POLICIES AND PROCEDURES**

The SJBSOM (SJBSOM) Human Research program (SJBHRP) and its Institutional Review Board (SJBIRB) function according to the ethical principles in the Belmont Report about human subjects' research. All institutional and non-institutional Human Subjects Research affiliated directly or indirectly with the SJBHRP must abide by the ethical principles delineated in the Belmont Report or as may be determined by the Secretary of Health & Human Services from now on the "HHS Secretary."

### **I. Principles of the SJBIRB in Reviewing Research:**

The SJBIRB must review all protocols for all Human Subjects Research. The primary responsibility of the SJBIRB is to protect human subjects from significant risks and protect their personal rights, dignity, and safety. These protections are based on the three principles of the Belmont Report:

Respect for Persons: Voluntary participation by Human Subjects, after free and informed consent, assured.

Beneficence: An appropriate balance exists between the actual or potential benefits of the Research to the Human Subject or to society and the risks accepted by the Human Subject.

Justice: There are fair procedures for the selection of Research subjects.

Belmont Report Principles followed by the SJBIRB in its Review of Research

#### **Respect for Persons:**

The SJBIRB will apply this principle by striving to ensure voluntary informed consent of human subjects through careful review of the recruitment and consent process and the consent forms or information sheets to be used with them. The guarantee of voluntary informed consent is one of the most essential elements in Research involving Human Subjects. Any person who is to be a Human Subject in a study, whether the study is designed for his/her own direct benefit or for the generation of scientific knowledge, must understand as completely as possible what is to be done and what are all the potential risks and benefits. The Human Subject must give his/her consent freely without coercion, pressure, or inappropriate inducement.

The SJBIRB will apply the informed consent concept to those studies in which the subjects are not able to give personal consent for themselves. In these instances, the consent document is

completed and signed by those who have been designated responsible for the Human Subject 'well-being' (e.g., parents of Children). The SJBIRB's concern is to verify that the consent process and document are likely to help these people make an informed decision that is in the best interest of the Human Subject.

The SJBIRB will consider the nature of the study population in determining its capacity for truly informed and voluntary participation in Research. The SJBIRB will take special care when considering study subjects whose ability to give free and informed consent may be compromised in any way and ensure that additional safeguards are completed as appropriate.

### **Beneficence:**

The SJBIRB will apply this principle by examining the risk-benefit ratio of the Research protocol it is reviewing. The SJBIRB approval is needed for any proposed Human Research activity that falls under its jurisdiction, whether "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result." [45 CFR Section 46.111(a) (2)].

In assessing the risk-benefit relation, the SJBIRB may include consideration of the following factors: (a) risks of injury or discomfort to the individual that can be physical, psychological, and social, and (b) potential benefits to the individual, a group to which the individual belongs and to society. In reviewing Research protocols, the SJBIRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and form.

While the SJBIRB is not responsible for reviewing the scientific design of Research per se, it must sometimes do so in order to assess the risk/benefit ratio. If a study's design does not seem adequate to achieve the stated aim of the study, then no benefit can be anticipated from conducting the study, and there is no justification for placing any Human Subject at risk, however minimal. Thus, the design of the study must be justified, and the nature and likelihood of all risks and benefits must be made clear in the application to the SJBIRB.

### **Justice:**

The SJBIRB will apply this principle by ensuring that the Research involves the fair selection of Human Subjects through (a) the sharing of Research risks and (b) the sharing of Research benefits. Both the risks and potential benefits of Research should be distributed fairly among potential individual Research subjects and groups. Study design and selection of subjects should avoid bias for social, racial, sexual, or ethnic groups.

**Sharing Research Risks:** The guiding principle in the ethical selection of research subject groups is that any risks of the research should fall upon those who might benefit from it. For example, If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (e.g., institutionalized people or Prisoners or patients at free clinics) simply because they are easily accessible or can be persuaded to participate. Instead, attempts should be made to include a fair sampling of the populations who might benefit from the study. When Research involves persons,

whose autonomy is/or could be considered compromised, it is expected that the Research has some direct relationship to the conditions or circumstances of the Research subjects. In addition, groups fully able to consider Research risks and informed consent should be asked to face Research risks before considering more Vulnerable Populations. For example, Investigational Drugs are usually tested in adults before they are tested in Children. Certain investigational drugs and procedures may be tested on healthy volunteers before being tested on patients.

**Sharing Research Benefits:** The SJBIRB should consider the desires of various groups to be included in Research. As individuals and through advocacy groups, many patients have demanded access to experimental treatments since these experimental treatments may provide the best medical care option available. In addition, researchers, ethicists, and public officials have recognized that because many clinical trials focused primarily on non-diverse subject groups, the results of some trials were of questionable value to members of other social, racial, sexual, and ethnic groups. As a result, both the National Institutes of Health (NIH) and FDA now require that study design include as broad a range of Research subjects as feasible and that the data be analyzed to reveal results that differ between groups. Applicable Regulations: 45 CFR § 46.111(a) (2) 45 CFR § 56.111

#### **Reference Sources:**

Nuremberg Code: <http://www.hhs.gov/ohrp/archive/nurcode.html>

Federal Register Notices: <http://www.hhs.gov/ohrp/archive/related.html#fed>

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research: <http://www.hhs.gov/ohrp/archive/nationalcommission.html>

Belmont Report: <http://www.hhs.gov/ohrp/archive/belmontArchive.html#anniversary>

## **II. Human Research Activities Approved and Monitored by the SJBIRB:**

The SJBIRB reviews all research that involves human subjects performed by SJBSOM's faculty, staff, students, and affiliated researchers. The site of the study and the funding source (or no funding) do not matter. When evaluating Human Research studies, the SJBIRB applies the OHRP regulations and the FDA regulations, as well as any other local or federal statutes or directives in effect.

The principal investigator listed on any SJBIRB application must be an SJBSOM faculty member with principal investigator status or an individual who has been granted special principal investigator status.

## **III. The San Juan Bautista School of Medicine Institutional Review Board (SJBIRB)**

### **Institutional Authority:**

The President of SJBSOM designates the Director as the person who serves as the Institutional Official (IO) responsible for conducting the SJBSOM's Human Research Protections Program.

The SJBIRB has jurisdiction over all Human Subjects Research conducted under the auspices of the SJBSOM.

### **Human Subjects Research Subject to SJBIRB Authority:**

The Human Subjects Research under the auspices of the SJBSOM that is subject to the authority of the SJBIRB includes:

Human Subjects Research conducted at SJBSOM.

Human Subjects Research conducted by or under the direction of any investigator/researcher or agent of SJBSOM in connection with his/her institutional responsibility.

Human Subjects Research conducted by students of SJBSOM in connection with their institutional responsibilities.

Human Subjects Research conducted by or under the direction of any researcher/investigator or agent of SJBSOM using any property or facility of SJBSOM.

Institutions in Addition to SJBSOM that have elected to rely on the SJBIRB per specific, written agreements with SJBSOM, other institutions may rely on the SJBIRB and are thereby subject to these Policies and Procedures.

### **Application to Submit Protocols for Western IRB Review**

The SJBIRB will rely on an external IRB, Western IRB (WIRB), for dual oversight of industry sponsored human clinical research and FDA-regulated human research. Under federal regulations, WIRB and SJBIRB agree to share oversight of the research study. Both IRBs agree to the following conditions for shared oversight:

1. If either IRB makes a finding of serious or continuing non-compliance or suspends or terminates the research, it will notify the other IRB of these actions and provide a summary of the reasons.
2. If either IRB receives a subject complaint relevant to the oversight of the other IRB, the IRB will notify the other IRB and provide information regarding the subject complaint.
3. Both IRBs will approve the consent form, the protocol, and other aspects of the research, and both IRBs will provide continuing oversight of the research for the duration of the study.
4. Both IRBs will follow their own written procedures.

### **Applicable Regulations:**

45 CFR Part 46, including 45 CFR §§ 46.103(b) (1)-(2); 46.109; 46.111; & 46.112.

21 CFR Parts 50 and 56, including 21 CFR §§ 56.109; 56.111 & 56.112.

38 CFR Part 16, including 38 CFR §§ 16.103(b) (1) – (2); 16.109; 16.111; & 16.112.

## **FEDERALWIDE ASSURANCE (FWA)**

SJBSOM holds a Federal Wide Assurance (FWA), which was approved by the OHRP. The regulations of the FWA apply whenever SJBSOM becomes engaged in Human Subjects Research that is conducted or supported by any U.S. department or agency that has adopted the requirements set forth at 45 CFR Part 46 (the “Common Rule”), unless the Research is otherwise exempt from the Common Rule requirements or the federal department or agency conducting, or the San Juan Bautista IRB determines that the Research will be conducted under a separate assurance. All activities of the SJBIRB regarding any Human Subjects Research covered by the Common Rule, as set forth above, are governed by and subject to the terms and conditions of the FWA. The San Juan Bautista’s FWA and its terms are the policies of the SJBIRB. The terms of the San Juan Bautista FWA can be found on the OHRP website at:  
<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>.

### **Principal Investigator (PI) Responsibilities: In fulfilling San Juan Bautista’s School of Medicine’s Human Research responsibilities, each PI is responsible for:**

**Training and Knowledge:** Make sure that prior to initiating any Human Subjects Research, he/she and all study staff and key personnel involved in his/her Research protocol have obtained the appropriate knowledge and training regarding protections, ethical conduct of Research, and applicable federal regulations, as well as the specific knowledge needed to conduct his/her specific protocol(s) properly.

**Completion of Required Training Programs:** Make sure that prior to beginning any Human Subjects Research that he/she, and all study staff and key personnel involved in his/her Research protocol, have each completed any training programs mandated by the SJBIRB or by other SJBSOM departments or committees that have oversight of the Research in which the PI is participating (e.g., NIH Human Protections Training Course, HIPAA for researchers training, Responsible Conduct of Research training), bloodborne pathogens training or any other pertinent, individually and without any assistance from others, attaining a passing score on any required examinations or tests covering the training materials.

**Knowledge of Protocol and Related Documentation:** Prior to initiating work under any Research protocol, you should master the Research protocol and any informed consent documents and complete the SJBIRB Protocol Application (including all appropriate materials) submitted to the SJBIRB for review and approval. All PIs are also responsible for ensuring that all personnel involved in carrying out the Research protocol are familiar with these documents and abide by all of these rules and regulations.

**Regulatory Compliance:** Ensuring that he/she and all key personnel involved in the Research protocol comply with all of the SJBIRB Policies and Procedures, as well as all requirements imposed by the FDA Regulations, HHS Regulations, HIPAA Regulations, VA Regulations (for Human Subjects Research that involves the Veterans Administration, Department of Defense, (DOD) requirements, and any other applicable laws and regulations.

**SJBIRB Committee and IRB Director Responsibilities:** In fulfilling SJBSOM's responsibility, they are responsible for:

**Protocol Review:** Providing an initial and continuing review of all Human Subjects Research subject to its authority.

**Documenting Review Activities:** Documenting its review and decisions regarding its review of Human Subjects Research, including documentation of any findings/decisions regarding risk/benefit evaluation, ethical considerations, scientific merit, access to Individually Identifiable information regarding Human Subjects and other information, privacy considerations and compliance with the HHS, FDA and HIPAA Regulations and VA Regulations (when applicable).

**Monitoring:** Monitor ongoing Human Subjects Research for compliance with HHS, FDA, and HIPAA Regulations and, as applicable, VA Regulations and/or DOD Regulations, as well as compliance with the SJBIRB Policies and Procedures. The SJBIRB will undertake further monitoring when indicated to ensure that corrective and preventive action (CAPA) plans are fulfilled.

**Addressing Inquiries/Complaints:** Appropriately inquire into and address complaints, concerns, or questions received regarding Human Subjects Research under the SJBIRB.

**IRB Director Responsibilities:** In fulfilling SJBIRB's responsibilities under the SJBSOM FWA, the SJBIRB Director, will be responsible for:

**FWA:** Updating and renewal of the SJBSOM's FWA.

**Registration:** Updating and renewal of SJBIRB registration.

**Membership Rosters:** Updating SJBIRB Committee membership rosters and providing updates to OHRP.

**Policies and Procedures:** Participating in drafting, reviewing, and revising updated versions to ensure compliance with HHS, FDA, and HIPAA Regulations.

**Agreements for SJBIRB Review:** Ensuring that appropriate agreements are in place with non-SJBSOM persons and entities relying upon the SJBIRB for review of Human Subjects Research, as well as with non-SJBIRBs that are providing review for SJBSOM-related Human Subjects Research and further ensuring that any applicable OHRP notification/approval regarding such agreements are in effect.

Applicable Regulations:

45 CFR § 46.103; SJBSOM FWA.

38 CFR §46.103.

DOD Directive 3216.2, Para. 4.5, SECNAVINST 3900.39D, Para. 6a(2).

### **IRB Members:**

At least five members, with diverse backgrounds, undertake a complete and adequate review of human research activities.

At least one member whose primary background is in science and at least one member whose primary background is not related to science.

At least one member is not affiliated with SJBSOM and is not part of the immediate family of a person who is affiliated with the SJBSOM.

Designated persons as needed who have knowledge and experience working with vulnerable populations, such as children, prisoners, pregnant women, or persons with cognitive impairments.

### **CONFIDENTIALITY OBLIGATIONS FOR IRB OFFICIALS, MEMBERS, CONSULTANTS, STAFF, AND GUESTS**

SJBIRB officials, Members, Consultants, staff, and guests at SJBIRB Committee meetings are required to maintain full confidentiality and non-disclosure of the documents reviewed in order to protect sensitive, confidential and proprietary information that they may come into knowledge while carrying out their SJBIRB duties or attending a meeting.

Obligation to Maintain Confidentiality: SJBIRB administrators, members, consultants, and staff members often receive sensitive information during the conduct of their SJBIRB duties. This information may concern patients or Research subjects, trade secrets or proprietary information; confidential inquiries or investigations being conducted by the SJBIRB or other institutional or governmental authorities; or matters that SJBSOM is required by laws, regulations, contractual obligations, or its policies to protect against disclosure to unauthorized individuals.

In order to protect this information, SJBIRB administrators, members, and staff are required to sign the Confidentiality and Non-Disclosure Agreement and to abide by the requirements thereof. The execution of this Confidentiality and Non-Disclosure Agreement is a condition required to be an SJBIRB member, consultant, or staff member. Any guest observing an SJBIRB meeting must sign a Confidentiality and Non-Disclosure Agreement; however, this does not apply to investigators attending an SJBIRB meeting to answer questions about a Research protocol under review.

Protected Health Information: The SJBIRB is part of the SJBSOM Covered Entity for purposes of compliance with institutional HIPAA Privacy Policies. Accordingly, in addition to complying with the confidentiality and non-disclosure obligations set forth here, each SJBIRB Member and staff member, as well as any Consultant, is also obligated to comply with all HIPAA Regulations and HIPAA Privacy and Security Policies with regard to the use and disclosure of Protected Health Information (PHI).

Reporting Breaches of Confidentiality and Non-Disclosure Obligations: SJBIRB officials, SJBIRB members, and research staff are required to report to the SJBIRB Director any occurrences of which they are aware that involved use or disclosure of information in violation

of the confidentiality agreements set forth in the Confidentiality and Non-Disclosure Document, these Policies and Procedures, HIPAA Regulations, or HIPAA Privacy and Security Policies. The SJBIRB Director will report the violation(s) to the SJBsOM's Dean for Research. The SJBIRB will take the appropriate steps to mitigate any damage that may have been caused by the breach and take corrective action as necessary in order to ensure that a similar breach does not occur in the future.

### **Records Retention:**

The SJBIRB will maintain appropriate written and electronic documents that pertain to its initial and ongoing review of Human Subjects Research. Records will be kept for three years from the time of their creation or receipt by the SJBIRB or longer as required by any other agency if required. Records pertaining to Human Subjects Research that is performed will be kept for at least three (3) years (five years for Veterans Administration Research) after the completion of Human Subjects Research. Contractual provisions for contract-supported Human Subjects Research may specify more extended retention periods. The longer provision should apply in case applicable requirements conflict.

### **IRB Documentation:**

The SJBIRB will maintain documentation of all human subject research protocols and related materials received for review and of decisions made with regard to the oversight of human subject's research within its jurisdiction. Documentation of study reviews by expedited procedures will include records showing the basis for expediting (permissible category, minimal risk), any regulatory required findings, and a description of any action taken by the member-reviewer. For exempt research, the documentation of review will include the basis for exemption (specific category).

### Documents Received by the SJBIRB:

The IRB Director will implement processes governing the tracking of documents that are sent to the SJBIRB and the routing of documents received.

Document Security: The following requirements will be observed with regard to document security practices:

Access to Documents: Access to paper and electronic documents maintained by the SJBIRB will be limited to SJBIRB Committee members, officials, and staff who need such access in order to perform their job duties, for compliance with regulatory requirements, or to report any compliance issues. Access to SJBIRB documents by other people must be approved by the SJBIRB Director and will be documented.

Removal of Original Documents: No original SJBIRB File materials will be removed from the SJBIRB Offices except as approved by the SJBIRB Director.

Removal of Copies: Copies of File materials will only be removed from the SJBIRB Offices with the consent of the SJBIRB Director or upon request of SJBIRB and governmental regulatory officials.



Electronic Records: The SJBIRB Director will implement processes and procedures concerning access to electronic records kept on computer systems that comply with all HIPAA Security Policies and requirements, as well as with any FDA or OHRP-mandated regulations. These processes and procedures will comply with all requirements set forth by the HIPAA Security Rule Policies and require the reporting of and inquiry into any unauthorized access to electronic records or breach of security procedures.

Reporting of Security Breaches: Persons who discover any security breaches or damaged documents or electronic information will immediately report the event to the SJBIRB Director. The SJBIRB Director will inquire into any such events and implement appropriate corrective measures.

Records Retention: At a minimum, all records are required to be kept by the SJBIRB for at least three (3) years from the date of creation or receipt by SJBIRB, and records relating to Human Subjects Research that is performed will be kept for a minimum of three (3) years after completion of the Human Subjects Research at the site or sites over which the SJBIRB has jurisdiction of the Human Subjects Research. Records will be kept longer if required by applicable governmental laws or regulations or contractual obligations with Research sponsors.

Applicable Regulations:

45 CFR §46.115

21 CFR §56.115

38 CFR §16.115

45 CFR §§ 164.308, .310, .312 & .530

### **Human Research Requiring Review and Levels of Review**

New Studies (Initial Submissions): All Human Research new studies require SJBIRB review and approval before they can begin.

Modifications to a study: All changes to a study, even minor ones, must be approved by the SJBIRB before they are implemented. The only exception to the requirement for prior SJBIRB review and approval is when the changes are “necessary to eliminate apparent immediate hazards to the subject” (45 CFR 46.103.b.4, 21 CFR 56.108.a). Investigators must still notify the SJBIRB when such changes are made.

Continuing Review: Re-review of all projects involving human subjects research is required at least annually. Minimal risk studies that are not subject to federal oversight may be eligible for extended approval (up to 3 years). Continuing review is required even if no changes are made, or even if the only study activity is patient follow-up, and/or even if the only study activity is data analysis.

Post-Approval Events: Including Adverse Events, Protocol Violations and Incidents, or Safety Information. Federal regulations and the SJBIRB require investigators to report any post-approval research-related event or information as pertains to unanticipated problems involving risk to participants or others, or serious or continuous noncompliance.

### **Level of Review:**

SJBIRB protocol applications undergo various levels of review based on an assessment of the study risks. The levels of review are Full Committee, Expedited, and Exempt.

### **EXEMPT RESEARCH:**

The SJBIRB must approve all Human Subjects Research. Specific categories of human subjects' research are considered to be exempt under federal regulations and do not require SJBIRB review and approval. However, the research must be determined to be exempt by the SJBIRB director. Investigators are not permitted to make a determination that Research is Exempt.

Prior to initiation of research, all Exempt Research protocols must be reviewed and approved by the SJBIRB Director to ensure that the study meets the principles embodied in the Belmont Report and exempt criteria under the Common Rule. All Exempt Research protocols must be reviewed and approved by the SJBIRB via the Principal Investigator's department Director before the determination of Exempt Research.

### **Qualifications for Exempt Research:**

Categories of Research that may be determined to be Exempt Research:

These Exempt categories do not apply to Research involving prisoners/detainees as subjects or to Research that involves FDA-regulated products or is otherwise regulated under the FDA Regulations:

- (1) Research conducted in established or commonly accepted educational settings involving everyday 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.
- (2) 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 a manner that Human Subjects can be identified, directly or through identifiers linked to the Human Subjects; and (ii) any disclosure of the Human Subjects' responses outside the Research could reasonably place the Human Subjects at risk of criminal or civil liability or be damaging to the Human Subjects' financial standing, usability, or reputation.
- (3) 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 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.

(4) 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 Human Subjects cannot be identified, directly or through identifiers linked to the Human Subjects.

a) This policy does not affect any state or local laws or regulations that may otherwise be applicable or that provide additional protection for human subjects.

b) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protection for human subjects.

Right to Review Research that may qualify as Exempt Research:

Based on the nature of the Research and of the Human Subject populations to be involved, the SJBIRB may require initial and continuing review and oversight of Human Subjects Research that may otherwise qualify as Exempt Research, per the HHS and VA Regulations and protocols that may not otherwise require prior SJBIRB Full Committee or Expedited review per FDA Regulations.

Procedure for Evaluation of Research Protocols to determine if they qualify as Exempt Research:

For any protocol that a PI believes constitutes Exempt Research, he/she must submit to the SJBIRB an SJBIRB application, Research protocol, consent document, and all other documentation that the SJBIRB office requires relevant to the proper review of the project.

Upon initial receipt of this documentation, the SJBIRB will conduct a preliminary review to determine whether the research protocol may be exempt from research.

If a protocol is determined to be Exempt from Research, the SJBIRB will send a written notice of this decision to the PI; otherwise, the protocol will be reviewed per Expedited Review or Full Committee Review.

The effective period for Exempt Research Determination: A determination of Exempt Research made pursuant to these policies and procedures will be effective indefinitely, but the Principal Investigator is responsible for notifying the SJBIRB if the project changes in a way that might alter the exempt status. The SJBIRB will review such changes to assess whether the project is still Exempt from Research or requires a new review.

Change in Protocol that Received an Exempt Research Determination: If a PI initially receives an Exempt Research determination but then decides that he/she would like to modify the protocol, then the PI must submit a description of how the protocol has been modified and request a determination as to whether the Exempt Research determination still applies.

Additional Protections and Review by Department Director: Although Exempt Research is not required to have prior IRB Full Committee or Expedited review, this Research is not exempt from SJBIRB's policies or the ethical guidelines of the Belmont Report. The PI will have all

Exempt Research protocols reviewed and approved by his/her department Director to ensure acceptability under these policies and guidelines. In addition, the senior reviewer making the Exempt Research determination will also determine whether additional protections for subjects (including specific informed consent procedures) should be required in keeping with the Belmont Report guidelines.

### **EXPEDITED REVIEW**

The SJBIRB may use an Expedited Review process for the Initial or Continuing Review of Research that is no more than Minimal Risk and falls within a category approved for Expedited Review under the HHS Regulations or for minor changes in previously approved Research during the period for which approval is authorized.

Research Eligible for Expedited Review: The SJBIRB may use Expedited Review for Research protocols that satisfy either or both of the following criteria:

The Research protocol falls into one of the categories set forth in the provision entitled Categories of Research Eligible for Expedited Review and is found by the SJBIRB reviewer to involve no more than Minimal Risk (except as noted) and

The Research protocol involves Minor Changes to previously approved Research during the period of one year or less for which approval is authorized.

Categories of Research Eligible for Expedited Review: The activities listed below 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. The categories in this list apply regardless of the age of the subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, usability, 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.

The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of SJBIRB review (Expedited or Full Committee Review).

### **Research Categories one (1) through seven (7) pertain to both initial and continuing IRB review:**

Category 1: Clinical Studies of drugs and medical devices when: (a) the study involves only Research on drugs for which an Investigational New Drug application is not.

Required (provided, however, that Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risk associated with the use of the product is not eligible for Expedited Review) OR (b) the study involves only Research on Medical Devices for

which an Investigational Device Exemption application is not required, or the Medical Device is approved for marketing and the Medical Device is being used in accordance with its approved labeling. This category may be applied to protocols undergoing either Initial or Continuing Review.

Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture when: (a) the samples are taken from healthy, non-pregnant adults who weigh at least 110 pounds, and amounts drawn do not exceed 550 ml. in eight weeks and collection does not occur more frequently than two times per week OR (b) the samples are taken from other Adults and Children 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, and the amount drawn may not exceed the lesser of 50 ml., or 3 ml. per kg. in an eight-week period and collection may not occur more frequently than two times per week. This category may be applied to protocols undergoing either initial or continuing SJBIRB review.

Category 3: Prospective collection of biological specimens for Research purposes by noninvasive means such as collection of (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at the time of exfoliation, or if routine patient care indicates a need for extraction; (c) excreta or external secretions (including sweat); (d) un cannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum base or wax or by applying a citric solution to the tongue; (e) placenta removed at delivery; (f) amniotic fluid obtained at the time rupture of the membrane prior to or during labor; (g) 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 acceptable prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab or mouth washings; (k) sputum collected after saline mist nebulization. This category may be applied to protocols undergoing either initial or continuing SJBIRB review.

Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely used in clinical practice, excluding procedures involving x-rays or microwaves; provided, however, that when Medical Devices are used, they must be 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 approved Medical Devices for new indications. Examples of data collection falling into this category include collection carried out by the following methods: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of significant amounts of energy into the participant or an invasion of the participant'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. This category may be applied to protocols undergoing either Initial or Continuing Review.

Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for research purposes such as medical treatment or diagnosis. NOTE: Some research in this category may be exempt under the HHS Regulations, as discussed in Exempt Research. This category refers only to research that is not otherwise exempt. This category may be applied to protocols undergoing either Initial or Continuing Review.

Category 6: Collection of data from voice, video, digital, or image recordings made for Research purposes. This category may be applied to protocols undergoing either initial or continuing IRB review.

Category 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 using survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies. NOTE: Some Research in this category may be Exempt Research under the HHS Regulations. This category refers only to research that is not otherwise exempt. This category may be applied to protocols undergoing either Initial or Continuing Review.

Category 8: Continuing Review of Research previously approved by the convened SJBIRB 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

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 and satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.

Category 9: Continuing review of Research not conducted under an Investigational New Drug application or an Investigational Device Exemption when the second through the eighth categories above do not apply, but the SJBIRB has determined and documented at a convened meeting that the Research involves no more significant than Minimal Risk; and no additional risks have been identified (provided, however, that this determination regarding “no additional risks” does not need to be made by the convened SJBIRB.)

If the review of a protocol requires special expertise, the Director and another SJBIRB member or consultant with appropriate expertise will review the protocol.

If the study does not meet the criteria for approval, then the SJBIRB office will inform the PI in writing what modifications are required. The PI’s modifications will be sent back to the Director/

Designated Reviewer for review and approval. In the event that Expedited Review is carried out by more than one SJBIRB member and the reviewers disagree, the SJBIRB Director will make the final determination, or if one of the reviewers is the Director or the Director otherwise determines in his/her discretion, the protocol will be submitted for Full Committee Review.

Applicable Regulations:

45 CFR §§ 46.101(b)(2)-(b)(4); .110; & .402(a)

21 CFR §§ 312 & 812

21 CFR § 56.110

Categories of Research that may be Reviewed by the Institutional Review Board (IRB) through an Expedited Procedure, 63 FR 60364-60367, November 9, 1998, at [www.hhs.gov/ohrp/humansubjects/guidance/expeditetd98.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/expeditetd98.htm).

**FULL COMMITTEE REVIEW**

The SJBIRB will refer for Full Committee Review those protocols that (a) do not otherwise qualify for a designation of Does Not Constitute Human Subjects Research, Exempt Research, or Expedited Review and (b) are being referred for Full Committee Review at the discretion of the SJBIRB in accordance with applicable policies and regulations.

Primary and Secondary Reviewers:

Selection: SJBIRB will assign each protocol to a primary and secondary reviewer from the members of the SJBIRB Committee, with a copy to all SJBIRB Committee members.

Assignment to primary and secondary reviewers will be made for all protocols that require Full Committee Review, whether initial, continuing, or modifications.

Assignments to primary and secondary reviewers will be made based on the scientific and scholarly expertise of reviewers, any vulnerable populations involved in the research, and the reviewers' experience with those populations. At least one reviewer who has appropriate scientific or scholarly expertise and experience with any Vulnerable Population involved will be assigned to the review. If the SJBIRB Director cannot identify an SJBIRB Member who has the necessary experience, then the SJBIRB Director will solicit consultants from the community with the necessary expertise to assist. Each protocol must be reviewed by at least one SJBIRB member.

Written Review: The primary and secondary reviewers will provide written reviews of each protocol assigned to them. Each reviewer's written comments should be submitted to the SJBIRB office at least one business day prior to the scheduled meeting.

Presentation: During the full SJBIRB Committee meeting, the primary reviewer will be responsible for presenting the protocol to the SJBIRB, including an overview of the goals, design, study procedures, safety procedures, and qualifications of the Investigators and will lead the SJBIRB Committee through the completion of the regulatory criteria for approval, as set forth in the SJBIRB Protocol Review Checklist appropriate to the type of review (i.e., Initial

Review, Continuing Review, modification). The primary reviewer will also present any comments from secondary reviewers.

**Recommendations:** The primary reviewer will make a recommendation to the SJBIRB Director regarding the action to be taken with regard to the protocol (e.g., Approval, Approval Pending, Deferral, Tabled or Disapproval), as well as the designation of any particular review category (e.g., Prisoner, Pregnant Women, Minors, Ward of State); risk status (Minimal Risk or Greater than Minimal Risk) and corresponding time for the following continuing review to occur; risk of device (as applicable); and grant of a partial or complete Waiver of HIPAA Authorization (as applicable).

If the SJBIRB Committee is reviewing a Research protocol involving Children as Human Subjects, then the primary reviewer's review will include assigning a Pediatrics Designation, i.e., making a recommendation as to the appropriate risk/benefit category for the Research under HHS Regulations 45 CFR §§ 46.403 - .407 and FDA Regulations 21 CFR §§ 50.51 - .54 (see Section 49, entitled: Research Involving Children – Additional Protections).

**SJIRB Committee Action:** After hearing primary and secondary reviewers, the SJBIRB Committee will discuss the protocol and entertain a motion and vote on the action that should be taken regarding the protocol in accordance with the P&P entitled Possible SJBIRB Committee Actions on Research Protocols. The SJBIRB office will notify the PI in writing of the action of the full Committee regarding the PI's protocol.

**Applicable Regulations:**

45 CFR §§ 46.107; .108; .109; .111; .115; & .403 - .407.

21 CFR §§ 56.107; .108; .109; .111; & .115; & 21 CFR §§ 50.50 - .54.

38 CFR §§ 16.107; .108; .109; .111; & .115.

## **IRB MEETINGS**

The SJBIRB Committee will hold convened meetings to provide an initial and continuing review of research protocols and modifications that come before the SJBIRB. A Quorum must be present in order to conduct an official committee meeting.

**Convened IRB Meetings:** Except when an Exempt Research or Expedited Research review procedure is used, the SJBIRB must review proposed Research at convened meetings at which a Quorum is present.

**Meeting Schedule and Location for IRB Committees:** The SJBIRB Director will schedule any meeting of the SJBIRB Committee. The IRB Director will be responsible for providing written notice to all SJBIRB members regarding the date, starting time, and location of the SJBIRB Committee meeting, as well as any changes to or cancellations of meetings.

**Attendance at Meetings:** SJBIRB members in attendance will be recorded in the minutes for each SJBIRB Committee meeting. All people, whether regular attendees or guests, who attend the



SJBIRB Committee meeting must sign an appropriate Confidentiality and Non-Disclosure Agreement

Leadership of IRB Meetings: The SJBIRB Director will convene and be present during each SJBIRB Committee meeting. In case the presiding director recuses him/herself before leaving the meeting room, he or she will designate a voting member to preside over the pro tem.

Distribution of Materials for Meetings:

The SJBIRB office will distribute to each SJBIRB member the agenda and the following materials for review at least one week prior to each meeting:

Complete the SJBIRB application form for the protocol.

Proposed consent; parental permission/assent form(s) and revocation letters (if applicable)

Proposed HIPAA authorization materials Recruitment materials/subject information

Data collection instruments (including all surveys and questionnaires).

In addition, at least the primary and secondary reviewers also will receive and review the following materials:

Any relevant grant application(s); Any investigator's brochure; Any HHS approved sample informed consent document; and Any HHS approved protocol.

Any IRB member may request any of the material provided to the primary and secondary reviewers by contacting the IRB Office.

If any SJBIRB member requires additional information to complete his/her review, he/she may contact the PI directory or contact the SJBIRB office to request additional information.

Meeting Procedures: The following procedures will be followed with regard to the conduct of each SJBIRB Committee meeting:

**Quorum:** The SJBIRB Director will call the SJBIRB Committee meeting to order when a Quorum is in attendance. A current membership roster reflecting compositional requirements will be available for reference.

At least one member who represents the general perspective of subjects must be present at the meetings of the convened SJBIRB. This role will be fulfilled by an unaffiliated (also known as "community") non-scientist member. The attendance of an unaffiliated non-scientist will be recorded in the meeting minutes. Without such a member in attendance, the meeting may not proceed with business.

SJBIRB members who have conflicts of interest with regard to research protocols or other matters that are being reviewed by the SJBIRB Committee must recuse themselves and leave the room during discussion and voting on such matters, and they cannot be counted toward Quorum for such matters.

Discussion: After each reviewer's presentation is complete, the SJBIRB Committee will discuss any issues concerning the review of the Research protocol and then vote on the Research protocol. The primary reviewer will include within his/her review recommendations as to Committee action, risk level, etc. , as discussed in the P&P entitled Full Committee Review).

Voting: Each voting member receives one vote, and voting by proxy is not permitted.

Voting on Matters Other than Research Protocols: Other matters to be voted on by the SJBIRB Committee will be placed before the SJBIRB Committee in terms of a motion, and votes on the motion will be taken and recorded in the same manner as set forth above in the provision entitled Voting.

Presence of PIs at SJBIRB Committee Meetings: The SJBIRB Committee may request a PI to come to the SJBIRB Committee meeting to address questions concerning his/her Research protocol. Similarly, a PI may request to come to the SJBIRB Committee to make a presentation regarding his/her Research protocol. Any such request should be made with reasonable notice in advance of the SJBIRB Committee meeting at which the PI's protocol is to be discussed, and the SJBIRB Director will review and grant or deny the request, as determined in his/her reasonable discretion. The SJBIRB Director should notify the PI of his/her decision in writing.

Applicable Regulations:

45 CFR §§ 45.107, .108, .109, .115 & .403 - .407.

21 CFR §§ 56.107, .108, 109; .111 & .115; & 21 CFR §§ 50.51 - .54.

38 CFR §§16.107, .108, .109; .111; & .115.

## **MINUTES OF AN IRB MEETING**

Written minutes must be taken of all SJBIRB meetings and be available for IRB members to review by the next regularly scheduled meeting date. Minutes must meet all requirements set forth in HHS, FDA, and VA Regulations, as well as all institutional requirements. Contents of Minutes: Minutes of each SJBIRB Committee meeting will, at a minimum, contain the following elements:

Attendance: A record of attendance of voting members, noting the critical compositional requirements for Quorum, and guests at the SJBIRB Committee meeting

Quorum: A record of Quorum and loss of Quorum at each SJBIRB meeting, including the presence of one member whose primary concern is in a non-scientific area.

Actions: A record of actions taken by SJBIRB. The minutes will reflect the deliberations, actions, and votes for each protocol undergoing initial review, continuing review, or review of modifications by the convened SJBIRB.

The SJBIRB will use the minutes or an appendix thereto to notify SJBIRB members of actions taken through Expedited Review and those studies that have been determined to be exempt from SJBIRB review.

**Votes:** A record of votes taken by the SJBIRB Committee on all actions, including the total number of votes, the number of votes for, against, and abstaining. The vote on each action will reflect those members present for the vote on that item.

**Basis for Action:** A description of the SJBIRB Committee's rationale for requiring changes in or disapproving a protocol.

**The basis for Vote in Opposition:** A description of the reason underlying any member's decision to vote in opposition to the motion.

**Discussion of Controverted Issues:** A written summary of the SJBIRB Committee's discussion of issues, including those involving opposing views and their resolution.

**Justification for Changes to HHS-Approved Consent Documents:** A record of the justification for any deletion or substantive modification of information concerning risks or alternative procedures contained in HHS-approved sample consent documents.

**Conflict of Interest:** For any SJBIRB Committee meeting in which an SJBIRB Director or IRB member recuses himself/herself due to a conflicting interest with the research under review, a record that reflects that a conflicting interest has been disclosed and that the individual with the conflicting interest left the meeting and was not involved in any discussion of or voting on the protocol in question and was not counted towards Quorum for the discussion.

**Vulnerable Populations:** A record that reflects that the SJBIRB reviewed additional safeguards to protect Vulnerable Populations if entered as study subjects if this information is not otherwise documented in SJBIRB records.

**Review Period:** For Initial and Continuing Review, a record of the duration of the approval granted to each protocol, as determined by the SJBIRB.

**Risk Level:** The risk categories to be used are minimal risk or more significant than minimal risk. **HIPAA:** A record, as required by 45 CFR Section 164(i) (2), indicating the approval of a waiver or alteration of the HIPAA Authorization requirement, including a description of protocol-specific elements that satisfy each criterion for a waiver or alteration.

**Retention of Minutes:** SJBIRB minutes will be kept according to the document retention specifications set forth in: (Documentation and Records Retention).

**Applicable Regulations:**

45 CFR §§ 45.107, .108, .109, .115 & .403 - .407.

45 CFR §§ 164.308; .310; .312; .512; & .530.

21 CFR §§ 56.107, .108, .109 & .115; & 21 CFR §§ 50.51 - .54.

38 CFR §§ 16.107, .108, .109 & .115.

## **CONFLICTS OF INTEREST – INVESTIGATORS**

Academic or staff members' participation in external activities that enhance their professional skills or constitute public service can be beneficial to the SJBIRB as well as to the individual. However, such activities can lead to conflicts of interest regarding an Investigator's responsibility to the SJBIRB. Accordingly, the SJBIRB has adopted a policy regarding Financial Interests in Research, with which Investigators are expected to comply.

Please note that, for Conflict-of-Interest purposes, the term Investigator is defined as follows:

The Project Directors, Principal Investigators, members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report, and individuals identified by the Principal Investigator or Project Director who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, such as Collaborators or Consultants named on the grant.

### **General Conflict Management:**

With regard to Research protocols submitted for SJBIRB review, all Investigators who are PIs, Project Directors, Senior Key Research personnel, and individuals identified by the Principal Investigator or Project Director as having responsibility for and substantial independence in decision making with respect to the design, conduct or reporting of the research, must follow all applicable SJBIRB's Policy for Investigators Holding a Financial Interest in Research. Based on the significance of the Significant Financial Interest Requiring Disclosure and the potential for adverse effects on the protection of subjects, management plans may include:

- ☐ disclosure to subjects through the consent process,
- ☐ modifications in the Research plan,
- ☐ monitoring by independent reviewers,
- ☐ divestiture of financial interests,
- ☐ appointment of a non-interested PI,
- ☐ Alternatively, research could be prohibited at the SJBIRB.

### **Applicable Regulations:**

21 CFR Parts 54, 312, 314, 320, 330, 601, 807, 812, 814 & 860.

45 CFR 46.107 (e)

38 CFR 16.107(e)

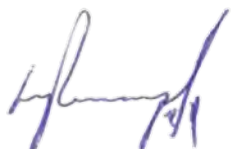
## **CONFLICTS OF INTEREST ON THE PART OF IRB MEMBERS**

Any SJBIRB member (or consultant), SJBIRB Director, SJBIRB staff, or SJBIRB Patient Subject Advocate must disclose a conflicting interest in a project to the SJBIRB Director. He/She may not review a project in which he/she has a conflict of interest, and he/she must leave the room during the discussion of and voting on a project, except if the SJBIRB member, SJBIRB Director, SJBIRB staff, or SJBIRB Patient Subject Advocate is providing information at the SJBIRB's request, in which case he/she will be present to provide the information, but will leave the room for the remainder of the discussion and voting.

A "conflicting interest" of an SJBIRB member (or consultant), SJBRB Director, SJBIRB staff, or SJBIRB Patient Subject Advocate includes the following:

- 1) Participation in a project (listed as an investigator on the project or is a member of the research team).
- 2) Supervisory relationship between the SJBIRB Member and the Principal Investigator.
- 3) Financial interest if it involves: (a) receiving more than \$10,000 annually as salary, consulting income, or other compensation from the sponsor of the project or from an entity whose products or services are being studied; (b) having an equity interest (including stock or stock options) that exceeds \$10,000 or that represents more than 1% of a public company sponsoring the research or whose products or services are being studied; (c) any equity interest in a privately held company sponsoring the research or whose products or services are being studied; (d) having an ownership interest (including patent, trademark, trade secret or copyright interest) in the drug/product/technology that is the subject of the research project; or (e) receiving or expecting to receive compensation with a value that may be affected by the outcome of the study. For purposes relating to financial interests, the financial interests of the SJBIRB member (or consultant), SJBIRB Director, or SJBIRB Patient Subject Advocate and his/her immediate family are considered.
- 4) Personal relationship with the investigator (has an immediate family relationship or other close personal relationship with the investigator).
- 5) Fiduciary relationship to sponsor or the product or service being studied (serves as an executive to a company sponsoring the research or the product or service being studied or serves on such a company's board of directors).
- 6) Other non-financial interests that may be conflicting interests, such as having an interest that he/she believes conflicts with the ability to review a project objectively.
- 7) Any other reason for which the individual believes he or she has a conflicting interest in the research.

These Policies and Procedures were approved on February 13, 2025 by

A handwritten signature in blue ink, appearing to read 'Yocasta Brugal'.

Yocasta Brugal MD

President San Juan Bautista School of Medicine

A handwritten signature in blue ink, appearing to read 'Estela S. Estapé'.

Estela S. Estapé PhD

Research Center Director