Institutional Review Board (IRB)
Standard Operating Policies and Procedures for the Protection of Human Research Subjects

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Responsible University Official: Vice President for Research

TABLE OF CONTENTS

1.0 INTRODUCTION – PRINCIPLES THAT GOVERN THE IRB

Saint Louis University (the University) is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report). The University is also is guided by the ethical principles of the Declaration of Helsinki, as well as the Nuremberg Code, and the Ethical Principles of the American Psychological Association. These principles will apply regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship). All institutional and non-institutional performance sites for the University, domestic or foreign, are and will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited above.

2.0 PURPOSE

The purpose of the Saint Louis University Institutional Review Board (SLU IRB) is to protect the rights and welfare of subjects in human subject research and through the IRB Office, to help facilitate the conduct of human subject research to ensure compliance with applicable federal regulations and University policy.

3.0 PERSONNEL AFFECTED

It is the expectation that any faculty member, employee, student, or other agent of the University who wishes to conduct human subject research, will adhere to the policies and procedures set by the SLU IRB in accordance with federal and state regulations and Saint Louis University's assurance with the Department of Health and Human Services to ensure the protection of human subjects.

4.0 RESEARCH POLICY AND AUTHORITY

It is the policy of Saint Louis University that all research involving human beings as subjects of research, or human material used in research, will be reviewed and approved by an Institutional Review Board prior to initiation of the research, whether conducted by, or under the direction of, any faculty member, employee, student, or other agent of the University, regardless of funding, funding source or the location of the activity. Investigators are expected to follow the ethical guidelines set forth by the Belmont Report, Declaration of Helsinki, the Nuremberg Code, or the Ethical Principles of the American Psychological Association for the research described. The investigator must have the requisite funding, credentials, training, and any necessary hospital privileges, if needed, to carry out all procedures and treatments involved in the protocol.

4.1 Institutional Authority: The Saint Louis University Vice President for Research is the authority under which the Institutional Review Board (IRB) at Saint Louis University (SLU) is established and empowered. The "Institutional Review Board" or "IRB" shall refer to any SLU IRB unless specified otherwise.

4.2 The Authority of the IRB:

4.2.1 Policy Jurisdiction/Applicability: This policy applies to all research involving human subjects at SLU and its affiliated institutions as outlined in its Federal Wide Assurance (FWA) including the review of records, use of tissues, or other derived materials regardless of the source of funding support when:

1. The research is sponsored by this institution, or
2. The research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities, or
3. The research is conducted by or under the direction of any employee or agent of this institution, or any external agent, using any property or facility of this institution, or
4. The research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

4.2.2 IRB of Record: SLU IRB will be the IRB of record for research under its authority unless a waiver of jurisdiction is granted or a reliance agreement designating another IRB of record is reached.

4.2.3 Collaborative Research Involving Non-SLU Institutions: In the conduct of collaborative research that involves non-SLU institutions, researchers should comply with the Guidance for Studies Involving Non-SLU Researchers or Non-SLU Sites. SLU IRB may enter into agreement with other registered IRBs to designate IRB oversight for a particular study or subset of studies. These agreements are on file in the IRB Office.

4.2.4 IRB Authority to Approve, Require Modification, or Disapprove: The IRB will review, and have the authority to approve, require modification in, or disapprove all human subject research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

4.2.5 Initial and Continuing IRB Reviews: Initial and Initial and continuing IRB reviews and approvals will occur in compliance with federal regulations. Continuing reviews will be preceded by IRB Receipt of Progress Reports from the investigator, including available study-wide findings, except for research that is exempt from continued IRB monitoring. The IRB Office has the authority to close out a previously approved protocol if the investigator fails to provide the progress report within the period of time specified by the Institutional Review Board for continuing review. The IRB Office will so inform the investigator. Studies may not continue after IRB approval has expired.

4.2.6 IRB Suspension or Termination of Previously Approved Research: The IRB will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects, in accordance with federal

regulations.

4.2.7 Additional Protections for Vulnerable Populations: Where appropriate, the IRB will determine that adequate additional protections are ensured for vulnerable populations such as fetuses, pregnant women, prisoners, and children, as required by Subparts B, C and D of 45 CFR 46. The IRB will notify the Office for Human Research Protections (OHRP) promptly when IRB membership is modified to satisfy requirements of 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).

4.2.8 IRB Responsibility to Report to Federal Agencies, Sponsors, and Institutional Officials: When appropriate, the IRB has the responsibility to forward to federal agencies, sponsors and institutional officials, significant or material findings or actions, to include at least the following:

1. Any unanticipated problems involving risks to subjects or others;
2. Any serious or continuing noncompliance with the regulations or requirements of the IRB; or
3. Any suspension or termination of IRB approval for research.

4.2.9 HIPAA Privacy Board: The IRB serves as the HIPAA Privacy Board which may consider, and act upon, requests for a partial or complete waiver or alteration of the Privacy Rule's Authorization requirement for uses and disclosures of PHI for research. When acting upon a request to waive or alter the Authorization requirement, the IRB must follow the procedural requirements of the HHS Protection of Human Subjects Regulations and/or, if applicable, FDA regulations, including using either the normal review procedures (review by the convened IRB) or the expedited review procedures. The FDA Protection of Human Subjects Regulations also require the IRB to follow its established written procedures whether a request for a waiver or an alteration of the Authorization requirement is considered by a convened IRB or by an IRB under the expedited review procedures.

4.3 Conflict of Interest: Investigators may not select IRB members to review their protocols. IRB members are responsible for disclosing conflicts of interest to the IRB staff and/or IRB Chair. No member shall review a project for which they have a conflict of interest. IRB members are required to be absent from the meeting room for deliberation and vote of the project for which they have a conflict of interest. They may, however, be permitted to address any questions or concerns of the IRB. The member with conflict of interest will not be considered part of quorum for the project's deliberation and vote. The conflict of interest will be recorded in the meeting minutes.

4.4 Confidentiality: IRB members, staff, consultants, ex-officio members and guests are expected to maintain the confidentiality of all discussions, deliberations, records, and other information related to the function of the IRB. Individuals attending convened IRB meetings sign confidentiality agreements, which are kept on file in the IRB Office.

5.0 RESPONSIBILITIES

5.1 General

5.1.1 IRB: The SLU IRB functions under the direction of the IRB Chairperson(s) and the IRB Director who report up to the SLU Associate Vice President for Research.

5.1.2 Departmental: Departmental Chairpersons (or their designees), Faculty Advisors (or their designees), or other appropriately authorized personnel authorize human research subject protocol submissions from their respective department's faculty, students, and staff.

5.1.3 Education and Guidance: The IRB provides education and guidance to investigators and ancillary research staff that are covered by its FWA in an effort to ensure that research subjects' rights and welfare are protected. Educational information is provided via the IRB instructions and guidelines for investigators, presentations, seminars, open forums, invited departmental sessions, mandatory individual training currently utilizing the Collaborative Institutional Review Board Training Initiative (CITI) Human Subjects Research Training Site, and one-on-one training with research faculty and staff. Educational information is also available via the SLU IRB website.

5.1.4 Regulatory Compliance: The SLU IRB complies and cooperates with federal and state regulatory agencies concerned with the protection of human subjects of research.

5.2 Membership of the IRB:

5.2.1 IRB Boards and Membership Rosters: The SLU IRB is currently comprised of three review boards. Membership rosters are on file with the Office for Human Research Protections (OHRP) and the SLU IRB Office.

5.2.2 Member Experience, Expertise and Other Qualifications: The SLU IRB is sufficiently qualified through experience and expertise, and the diversity of members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. Further consultation is sought whenever a reviewer or a Chairperson requests an additional expert opinion on any human subjects research submission.

5.2.3 Diversity of Membership: The SLU IRB membership is comprised of individuals with varying scientific and non-scientific backgrounds to promote complete and adequate review of research activities commonly conducted at SLU. The membership includes men and women, minority, and non-affiliated community representation.

5.2.4 Alternate IRB Members: Alternate IRB members may attend meetings in place of an absent full board member. Alternate members will be called upon if the full board member is unable to attend the scheduled IRB meeting. Alternate members are designated for full board members with similar expertise and background experience. Alternate members can be designated for more than one full board

member. The meeting minutes will reflect which full board member the alternate member is replacing. If an alternate member chooses to attend a meeting at which the full board representative is present, only the full board member's vote will be counted and only the full member would be counted toward quorum. Alternate member's names and qualifications are on file with OHRP.

5.2.5 Prisoner Representative or Advocate: A prisoner representative or prisoner advocate will attend IRB meetings where a prisoner study is being initially reviewed or will be assigned as a reviewer if the study qualifies for expedited review. The prisoner representative or advocate will be called upon when prisoner studies are submitted for review by the IRB and shall have no association with the prison(s) involved, apart from his/her membership on the IRB. The prisoner representative or prisoner advocate is only responsible for voting on prisoner-related studies and will only be included as part of quorum for prisoner-related studies. The prisoner representative or prisoner advocate's attendance will be recorded in the meeting minutes. The prisoner representative or prisoner advocate is considered an alternate member, and such members' names and qualifications are on file with OHRP and the SLU IRB Office.

5.3 Management of the IRB:

5.3.1 Selection and Appointment of the IRB Chairperson: The Institutional Official selects and appoints the IRB Chairperson(s). The appointment is for a renewable three-year term. The Chairperson shall ensure that investigators are promptly notified of IRB actions. The Chairperson conducts convened meetings in accordance with applicable federal regulations and institutional policies. Any IRB Member can Chair the meeting in the Chairperson's absence. The Institutional Official can remove the Chairperson for cause.

5.3.2 Appointment of Experienced Members for Expedited Reviews: On behalf of the Institutional Official, the IRB Chairperson shall appoint experienced members of the IRB (Designees) to conduct expedited reviews. An experienced IRB member is a member determined by the IRB Chair to be qualified to perform reviews using expedited procedures. The following criteria are considered when determining whether an IRB member is experienced: length of IRB service, research experience/expertise, experience with the research participants being studied, and/or training in expedited review.

5.3.3 Selection and Appointment of New Members: New IRB members are sought through the recommendation of other IRB members and departmental chairpersons or may volunteer to participate on the IRB. On behalf of the Institutional Official, the IRB Chairperson appoints IRB members for renewable three-year terms. Upon consultation with the Chairperson of the IRB and others as appropriate, the Institutional Official may remove a member for cause. IRB membership will be terminated if an individual does not support the IRB's mission to protect the rights and welfare of human research subjects or fails to regularly attend meetings.

5.3.4 Training of IRB Chair and Members:

1. Board members participate in an orientation session with IRB staff before or

following their attendance at an IRB meeting. Extensive educational materials are discussed and provided to new members. A new member generally observes at least one meeting before participating as a reviewer. Members are encouraged to consult with the Chairperson or IRB staff whenever they have questions or concerns.

2. Continuing education of IRB members includes: information enclosed in Board member's meeting materials, information disseminated electronically, individual consultations with the Chairperson or IRB staff, encouraged attendance at regional or national human research subjects conferences, and lectures throughout the academic year.

3. The IRB Office maintains a library of books, videotapes, audiotapes, and newsletters for members to check out.

5.3.5 Community Members: Unaffiliated members from the community serve as volunteers and receive and honorarium and/or paid parking for their participation.

5.3.6 Indemnification of Members: Members are covered under the university's self-insurance liability program.

5.3.7 Consultants: The IRB will use expert consultants for review of any human research protocol submission when requested by a reviewer, IRB Chairperson, or IRB staff.

5.3.8 Support Services to the IRB:

1. The IRB professional and administrative staffs are responsible for providing support to the IRB Chairperson(s) and the IRB to include clerical assistance and guidance. The current organizational structure is further detailed in organizational charts available on the IRB website or by contacting the IRB Office.

2. SLU provides meeting space for the IRB and sufficient staff, office space, filing space, reproduction equipment, computers, and software to support the IRB's review and record keeping duties.

6.0 PROCEDURES

6.1 Functions of the IRB:

6.1.1 Conducting Initial and Continuing Reviews

1. The IRB reviews and has the authority to approve, require modifications, or disapprove all research activities under its jurisdiction. All IRB determinations are based upon consideration of the criteria for IRB approval outlined in 21 CFR56.111 and 45 CFR 46.111.

2. The IRB requires that information given to research subjects as part of informed consent is in accordance with applicable federal regulations.

3. The IRB requires documentation of informed consent in accordance with applicable federal regulations. Under 45 CFR 46.117(c), the IRB may waive written consent if (a) the consent form is the only record linking the subject

and the research, and the principal risk would be potential harm resulting from a breach of confidentiality; or (b) the research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside of the research context.

4. In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5. The IRB conducts continuing review of all non-exempt research at intervals appropriate to the degree of risk, but not less than once per year. It also has the authority to observe or have a third party observe the consent process and the research. At the time of continuing review, an assigned qualified reviewer will review the study file including changes that have occurred since the beginning of the study. Particular attention will be paid to numbers and types of serious adverse events, numbers of subjects recruited, and new knowledge gained since the prior review. Each protocol subject to continuing review at a convened meeting will be individually presented to the Board and will be voted upon separately, with the vote recorded in the minutes.

6. The decision regarding the time interval for subsequent continuing review is made during IRB review. This decision is based in part upon the recommendation of the reviewers and the judgment of the Board members regarding various characteristics of the research, particularly including its novelty, potential or actual risks of harm or discomfort to human subjects, potential costs to subjects, predicted difficulties with recruitment or accrual of subjects, vulnerability of the subject population, perceived appropriateness of the research in this scientific and cultural community, etc. Generally, protocols are re-reviewed no less frequently than once per year; however, if the risks to subjects are regarded as extraordinary (high risk), re-review at more frequent intervals may be required. On occasion, the Board may request re-review after a study enrolls a stipulated number (usually very small) of subjects. The decision regarding frequency of continuing review becomes a part of the minutes and IRB protocol file.

6.1.2 Notification of Investigators: The IRB will notify investigators in writing and/or by email of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity (contingent approval). If the IRB decides to disapprove or defer approval of a research activity, it will include in its notification a statement of the reasons for its decision and give the investigator an opportunity to respond.

6.1.3 Research Audit: The Chairperson or a board member may request verification that no material changes have occurred since previous IRB review. Any information that may prompt the IRB to question the accuracy or completeness of data may result in a discussion of the situation with the principal investigator and/or his or her departmental chairperson and/or division director. The IRB, alone or in collaboration with other University offices, such as the SLU Office of University Compliance, will conduct for-cause and random audits to ensure compliance of the

human subjects research and to protect the integrity of the data.

6.1.4 Protocol Amendments

1. Except where necessary to eliminate immediate hazards to research subjects, all amendments and revisions to a research protocol require review and approval by the IRB before the investigator can implement the proposed changes.
2. All amendments and revisions must be reported to the IRB.
3. Unless a proposed change in research protocol can be approved on an expedited basis, the proposed change will be reviewed and voted upon by the IRB at a regularly scheduled meeting.

6.1.5 Adverse Events, Unanticipated Problems and Injuries: Principal investigators are responsible for reporting promptly to the IRB any serious adverse events or unanticipated problems that may involve risks to human research subjects or others, or any injuries or untoward events, such as deaths or legal actions, that are the result of their participation in the research. Investigators should submit reports in accordance with the SLU IRB Requirements for Reporting Events Related to Subjects/Subject Safety. An educational letter will be sent to an investigator if his or her reports are not submitted in a timely manner and when, upon review, such a letter is deemed appropriate. Educational programs previously described are a key mechanism for providing investigators and support staff with SLU IRB's requirements for reporting such problems.

6.1.6 Noncompliance

1. Reports by investigators, research subjects, or other individuals concerning noncompliance with IRB regulations or requirements are requested to be put in writing. *Noncompliance* is defined as conducting research in a manner that disregards or violates federal regulations or institutional policies and procedures applicable to human subjects research. The appropriate IRB staff and/or the IRB Chairperson will review the report or allegation and conduct a preliminary investigation of the matter, which may include interviewing the individual making the report.
2. Reports of noncompliance that are deemed minor in nature will be handled by the IRB Director or designee, generally by acknowledging the report of noncompliance or responding with a letter to the PI, copied to the appropriate institutional officials, which details the violation, reiterates the policy or regulation that was violated, and includes any corrective action plans for the investigators and/or departments involved.
3. If there is probable cause to believe that there may be serious or continuing noncompliance with IRB regulations or requirements, the IRB Chairperson may request that one or more Board members and appropriate IRB staff conduct a further investigation that will include interviewing the individual(s) alleged to have acted out of compliance. Upon the initiation of such an investigation, when appropriate, the IRB Chairperson or IRB staff may notify University Counsel, the SLU Office of University Compliance, the Vice

President for Research, and the Department Chairperson. OHRP and/or the FDA or other federal agencies will be notified of the conduct of such an investigation for research falling under their oversight jurisdiction.

4. A report of the noncompliance and recommendations for further action, if necessary, will be presented to the Board for its review. If the review results in a conclusion that serious or continuing noncompliance has occurred, the investigator will be provided with a written summary of the determination and be given an opportunity to respond within a specified timeframe, in writing or in person before the Board, or both. If there is no response, or if after consideration of the investigator response the previous conclusion stands, notice will be sent to institutional officials, the head of the supporting federal agency, OHRP, and/or the FDA as appropriate. The IRB may also determine that a more comprehensive audit of the investigator's or department's research activities is necessary. The investigator and the individual's chairperson or supervisor will be notified of any such determinations.
5. IRB approval of research will be suspended or terminated when an investigator is found to be in serious or continuing noncompliance with IRB requirements or federal regulations in those instances where the IRB deems such suspension or termination to be appropriate. Except in extraordinary circumstances, any such action will be taken only after a vote to such an effect by the Board. In circumstances involving serious and/or immediate risks to subjects, in which a decision should not wait for the next convened IRB meeting, an order to suspend the research may be made by the Chairperson and at least one additional Board member, pending review by the full Board.
6. In accordance with the University's Assurances, when appropriate, the following will be reported to institutional officials, sponsors, OHRP, the FDA, and/or other governmental agencies: any unanticipated problems involving risks to subjects or others; serious or continuing noncompliance with pertinent federal regulations or the requirements of the IRB; and suspension or termination of IRB approval of research protocols.
7. The IRB may determine that corrective actions should be taken upon finding issues of noncompliance with federal regulations and/or IRB policies. Corrective actions may include, but are not limited to: decrease in duration of IRB approval periods; additional training for the PI and/or research team; modifications to the protocol; notification to participants; increased monitoring of the research; and/or suspension or termination of the research. Additionally, the IRB may recommend to the Institutional Official that sanctions be placed on the investigator or department acting in noncompliance, including placing a limitation on the number of active studies an investigator can conduct or prohibiting conduct of research.
8. If an IRB investigation determines that there is just cause to suspect scientific misconduct has occurred, the matter will be reported to the University's Research Integrity Officer.

6.1.7 Device Risk: The IRB is responsible for determining which device studies pose

significant or non-significant risks to research subjects. The Board discusses whether the risk is significant or not and then the determination is recorded in the minutes. Guidance will be sought from regulatory documents and consultation obtained from the Device Division of the FDA whenever necessary to determine the appropriate risk category.

6.1.8 Humanitarian Use Device: According to 21 CFR 814.124, the IRB is responsible for the review of Humanitarian Use Devices (HUD) that have been approved for use through a Humanitarian Device Exemption (HDE). Reviewers will be assigned to review HUD submission(s). HUD submission will be processed similarly to other IRB submissions. Federal regulations and guidance do not require the use of a consent form with HUDs; however, the SLU IRB requires the use of a consent form for all non-emergency HUDs. Assent forms are not generally required. HUD submissions will undergo annual continuing review by the IRB unless a shorter approval period is otherwise determined. A HUD submission may receive an expedited continuing review if criteria are met. In the event a physician determines that approval from the IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered. In this event, the physician is to notify the IRB within 5 days after the use of the device, by submitting an Emergency Use form, available on the IRB website.

6.2 Operations of the IRB:

6.2.1 Scheduling of Meetings: IRB meetings are regularly scheduled every month except for holidays. Meetings are canceled if quorum is not met. Canceled meetings are rescheduled on an ad hoc basis to provide review of submitted research proposals. The University community is notified of meeting dates as well as deadline dates for submission of materials to be reviewed at IRB meetings. In regard to conducting IRB meetings via telephone conference call, the SLU IRB recognizes the DHHS letter dated March 28, 2000 which states "…circumstances sometimes warrant conducting IRB meetings via telephone conference call."

6.2.2 Pre-Meeting Distribution of Materials to Members: Meeting materials are provided approximately a week before the scheduled meeting date to reviewers and members who have indicated an intention to attend the meeting. Attending members have access to all protocols to be discussed at the meeting, including consent forms and other items relating to protocols. A meeting agenda, the previous meeting's minutes, a listing of protocol submissions approved through the expedited review procedure and appropriate educational materials are also distributed. Meetings are held in the conference room near the IRB Office at scheduled times.

6.2.3 The Review Process

1. IRB staff assign two reviewers who receive study related material including (when applicable): SLU protocol, informed consent documents, sponsor's protocol, and other supplemental materials such as an investigator's brochure prior to the meeting. Reviewers complete a checklist that indicates various issues that need to be addressed in the protocol and consent documents and provide comments regarding items that need revision. Reviewers submit the checklist and comments to the IRB office for assistance in preparing

correspondence. All other attending Board members have access to documents, but do not complete the checklist or submit comments. The designated reviewers lead the discussion of the research protocol at the IRB meeting.

2. The SLU IRB Chairperson, member designee, and/or qualified IRB staff have the authority to make determinations of exemption from OHRP and/or FDA regulations. Research protocols not eligible for exemption are processed under expedited or full board review.

3. Investigators are encouraged to consult with the IRB Office prior to conducting emergency treatment with an investigational drug or device (test article) if time permits. Irrespective of the investigator's ability to obtain guidance from the IRB Office, the investigator is required to report the conduct of the emergency research activity to the IRB within five days. The emergency treatment and consent documents are presented at the next scheduled IRB meeting for review. The IRB may request that the subject be given a revised or an amended consent form if additional information is deemed necessary. Investigators anticipating subsequent use of the investigational drug or device (test article) are directed to submit a research protocol subject to IRB review.

4. Research protocols deemed eligible are reviewed in accordance with the expedited review procedures authorized in 45 CFR 46.110 and 21 CFR 56.110. The IRB Chairperson or IRB member designee conducts the review. Non-exempt research deemed not to meet an expedited category is submitted for full board review. Notification of research protocols approved using expedited review procedures is provided to the full board at a convened meeting.

5. Minor changes that do not increase risks to subjects in previously expedited or full board approved research during the period for which approval is authorized are routinely reviewed and approved by the IRB Chairperson or IRB member designee utilizing the expedited review procedure. Changes to research previously determined to meet exempt criteria under 45 CFR 46.101(b) are routinely reviewed and approved by the IRB Chairperson, IRB member designees, or qualified IRB staff.

6.2.4 Criteria for IRB Approval: The criteria for IRB approval are those outlined in 21 CFR 56.111 and 45 CFR 46.111.

1. To approve research on human subjects at Saint Louis University, the IRB must determine that all of the following requirements are satisfied:

   (a) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;

   (b) Risks to subjects are reasonable in relation to anticipated benefits, if any,

to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;

(c) Selection of subjects is equitable. In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted and be cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons;

(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by federal and state regulations;

(e) Informed consent will be documented in accordance with and to the extent required by federal and state regulations.

(f) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;

(g) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards must be included in the study to protect the rights and welfare of these subjects.

6.2.5 Voting Requirements

1. Quorum required to transact business. The SLU IRB requires a quorum to convene a full board meeting. A quorum is comprised of a majority of the members of the IRB, including at least one member whose primary concerns are in nonscientific areas. The Chairperson is included in determining the presence of a quorum.

2. Diversity requirements of quorum. Review of studies involving FDA-regulated articles will only occur in the presence of at least one physician member. Review of studies involving vulnerable populations will only occur in the presence of at least one Board member with familiarity with that population.

3. Percent needed to approve or disapprove a study. Approval of a protocol is granted by a majority vote of members present.

4. Full voting rights of all members. All full members present at the meeting are permitted to vote. Alternate members are permitted to vote in the absence of the members they are replacing. Prisoner representative members will vote for prisoner studies only. The Chairperson only votes in case of a tie and otherwise abstains and is not included in the vote count.

5. Proxy Votes. No proxy votes are authorized, but comments received from a reviewer member that is unable to attend a meeting will be read to the full board for consideration.

6. Prohibition against conflict of interest voting. A member who is also an investigator on a protocol being reviewed at a meeting will not participate in determining whether his or her research is approved. The investigator member must leave the meeting during the discussion and vote, although the member may be present to answer questions.

6.2.6 Further Review/Approval of IRB Actions by Others Within SLU: Research that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by University officials or officials of sites at which an investigation is to be conducted. However, those officials may not approve the research if it has not been approved by an IRB.

6.2.7 Communications from the IRB:

1. To the Investigator Conveying the IRB Decision: Following a convened IRB meeting, investigators receive notification informing them of: protocol approved as submitted, protocol approved contingent upon receipt of further information or modifications, protocol tabled, protocol deferred pending receipt and review of additional information or protocol disapproved. When a study receives full approval, an approval letter is made available to the investigator along with a consent form, if required, stamped with the approval date for which the consent form is valid to avoid the inadvertent use of an unapproved or outdated consent document. Certifications of IRB review and approval will be issued by the Office of the IRB and forwarded by the Investigator to the appropriate funding agency when appropriate.

2. To the Investigator for Requesting Additional Information: Investigators are frequently contacted following an IRB meeting regarding the need for additional information or to request that modifications be made to the submitted materials. Generally, these communications are made via documented correspondence (letter, e-mail or electronic IRB system); however, other communication methods (e.g., telephone) may be used when the information needed is minimal and does not warrant a formal letter, e.g., insertion of a word in a consent form to clarify the text. The IRB may request an investigator to appear at a subsequent IRB meeting to provide further information. For new studies, if a response is not received within 30 days, the study may be administratively withdrawn.

3. To the Research Sponsor Conveying the IRB Decision: The IRB conveys its decisions to the research investigator who is responsible for communicating

with any external research sponsor.

6.2.8 Appeal of IRB Decisions: Any investigator dissatisfied with the IRB's decisions, conditions, or requirements is entitled to a rehearing at a subsequent IRB meeting at which time the investigator should be present for purposes of questioning and further discussion. Any such request for a rehearing must be in writing and may be addressed to the Chairperson of the IRB or the IRB as a whole. Any such request that is not deemed to be trivial by the IRB Chairperson will be brought to a full board meeting for review. If the IRB does not approve the protocol, University officials may not approve the research.

6.3 IRB Record Requirements

6.3.1 Membership Roster: The IRB maintains a membership roster with qualifications listed as stated in 21 CFR 56.115 (a)(5) and 45 CFR 103 (6)(3). The list identifies members by name; earned degrees; representative category; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution (e.g., full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant).

6.3.2 IRB Guidelines: The IRB maintains written guidelines and reviews such guidelines, as necessary. IRB guidelines are referenced in this document and the FWA. IRB guidelines are accessible on the Saint Louis University IRB website.

6.3.3 Minutes of IRB Meetings: Minutes of the IRB meetings are kept in sufficient detail to show attendance at the meetings; listing of educational materials distributed to Board members; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution, including unique questions or concerns that may be deemed valuable. When appropriate, regulatory subpart determinations are recorded as well as the level of risk determined for University indemnification purposes (high, not high) and studies involving an investigational device (significant risk versus non-significant risk). The period of approval (e.g., for one year or other time period) for the study is also reflected in the minutes, as is the presence of any consultants, guests, or other non-member in attendance. These individuals are required to sign an agreement assuring that they will keep information discussed at the meeting confidential.

6.3.4 Retention of Protocols Reviewed and Approved Consent Documents: Copies of all research protocols reviewed and their related consent documents, as well as reviewer's comments, progress reports submitted by investigators and reports of injuries to subjects are on file with the IRB. Records shall be maintained for at least 3 years after completion of the research. Some records relating to specific research activity may be maintained indefinitely. Studies that meet criteria for exemption will be destroyed after study completion or according to determination of the IRB Chair and/or IRB Director.

6.3.5 Communications to and from the IRB: Communications to and from the IRB are maintained in the IRB protocol file. Any complaints are maintained in an investigator file and/or the IRB protocol file.

6.3.6 Serious Adverse Events Reports: Serious Adverse Events (SAEs) are submitted to the IRB on a Serious Adverse Event report form. This paper form is available via the IRB website and an electronic version in the electronic IRB system. The reports are maintained in the IRB protocol file.

6.3.7 Unanticipated Problem Reports: Investigators are responsible for promptly reporting to the IRB and the research sponsor any unanticipated problems which may involve risk to human subjects, or any injuries or untoward events, such as deaths or suits, which are the result of participation in the research. All reports are reviewed by the IRB Chairperson or IRB member designee. If any reports have obvious omissions, they are returned to the investigator with an explanation of what is needed or requesting the need to amend the consent document(s). Following the review, the forms will be acknowledged to indicate they have been reviewed and the research may continue uninterrupted if warranted. Correspondence is kept in the IRB protocol file and any discussion is referenced in the IRB minutes.

6.3.8 Record of Continuing Review: Continuing reviews are filed in the IRB protocol file.

6.3.9 Budget and Accounting Records: Budget and accounting records are retained within the Office of the IRB for the current fiscal year and the Office of the Vice President for Research for the past three fiscal years.

6.3.10 Emergency Use Reports: Emergency use reports are retained in the IRB protocol file.

6.3.11 Statements of Significant New Findings Provided to Subjects: Significant new findings may be included in a revised informed consent document, in an addendum document, or in a letter to the subject. The method used for informing subjects of significant new findings will be appropriate to the status of the research and whether subjects are actively receiving treatment. Such statements are included in the relevant protocol files.

6.4 Information the Investigator Provides to the IRB: As part of each application for review, the principal investigator will provide to the IRB a research protocol, in a form available via the IRB website or in the electronic IRB system, which includes:

6.4.1 Qualifications of Investigator(s): The professional qualification of each investigator to do the research (including a description of necessary support services and facilities) is described in the protocol.

6.4.2 Protocol Elements: The submission will include or address the following information as deemed appropriate to the research submission: protocol title; purpose; sponsor; results of previous related research; subject selection and exclusion criteria; justification for use of any special/vulnerable subject populations; study design; description of procedures to be performed; provisions for managing serious adverse reactions; circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, vulnerable population and other details; procedures for documentation of informed consent, including any procedures for obtaining assent from minors, using witnesses, translators, document storage, compensation to subjects, compensation for injuries; provision of protection of

subjects' privacy, extra costs to subjects for their participation, and extra costs to third party payers.

6.4.3 Investigator's Brochure: The research sponsor's investigator brochure (when one exists) is to be submitted to the IRB for review with the research proposal.

6.4.4 Informed Consent Document: The proposed informed consent document is to contain the basic elements of informed consent as required by federal regulations. These include:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the IRB, the Food and Drug Administration, and study sponsors may inspect the records;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;
9. When appropriate, one or more of the following elements of information should also be provided to each subject:
    (a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
    (b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
    (c) Any additional costs to the subject that may result from participation in the research;

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(f) The approximate number of subjects involved in the study.

10. The investigator must also provide translated consent documents, as necessary, considering likely subject population(s). The informed consents and translated informed consents will be reviewed by appropriate language specialists prior to approval by the IRB.

6.4.5 Requests for Changes in the Protocol after Initiation of the Study: Investigators are required to submit proposed changes to the protocol as outlined on the Change-in-Protocol paper form or Amendment form in the electronic IRB system. Proposed changes to research protocols must be approved by the IRB prior to implementation. The forms are available via the IRB website.

6.4.6 Reports of Unanticipated Problem: Investigators are required to submit Unanticipated Problems (UPs) in accordance with and as described in the SLU IRB Requirements for Reporting Events Relating to Subjects/Subject Safety. The requirements and relevant forms are available via the IRB website.

6.4.7 Progress Reports: Investigators are required to submit a progress report as designated by the IRB (but not less than once a year). The information required is outlined on the SLU IRB Request for IRB Continuing Review/Notice of Study Completion paper form or continuing review form in the electronic IRB system. The forms are available via the IRB website. Investigators who do not comply will be notified that approval to conduct the research has expired.

6.4.8 Final Report: Investigators are required to submit a Notice of Study Completion paper form or Final Report form in the electronic IRB system when research has been completed. Investigators who do not comply will be notified that approval to conduct the research has expired.

6.4.9 IRB Forms and Reports: All IRB paper and electronic forms are available via the IRB website.

6.5 Exemption from Prospective IRB Review for One-Time Emergency Use: SLU IRB policy allows for an exemption from prospective IRB review for a one-time emergency use of a test article. Written documentation by the investigator of such an emergency use must be provided to the IRB within five working days. Included should be the patient's condition, therapies already tried and justification for the use of the test article, and the expected outcome in the situation described. The investigator must also provide a copy of the informed consent document for the IRB file. Any subsequent use of the test article must be preceded by the submission and approval of a protocol and informed consent document. If consent cannot be obtained, the investigator must certify in writing that the criteria for the exception to informed consent are met. This must be documented on the emergency treatment form which is available via the IRB website. Please see the Guidance for Emergency Use of Test Articles for additional information regarding this policy.

7.0 SANCTIONS

It is the expectation that any faculty member, employee, student, or other agent of the University who wishes to conduct human subject research adhere to the policies and procedures set by the Saint Louis University IRB in accordance with federal and state regulations and Saint Louis University's assurance with the Department of Health and Human Services to ensure the protection of human subjects. Failure to comply with these policies and procedures may result in University disciplinary action pursuant to the applicable policies governing faculty, staff, students, or other agents of Saint Louis University. Additionally, violations may result in additional sanctions including suspension of research and limitation of research activities.

8.0 REFERENCES

8.1 ***Department of Health and Human Services 45 CFR 46.*** Available at the following link: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html

8.2 ***U.S. Food and Drug Administration (FDA) Clinical Trials and Human Subject Protection.*** Available at the following link: https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

8.3 ***U.S. Food and Drug Regulations,*** *specific topics available at the links specified below.*

21 CFR Part 50 – Protection of Human Subjects. https://www.ecfr.gov/cgi-bin/text-idx?SID=ed5d86dda1fbd22cdf7acc276206c199&mc=true&node=pt21.1.50&rgn=div5

21 CFR Part 56 – Institutional Review Boards. https://www.ecfr.gov/cgi-bin/text-idx?SID=ed5d86dda1fbd22cdf7acc276206c199&mc=true&node=pt21.1.56&rgn=div5

21 CFR Part 54 – Financial Disclosure by Clinical Investigators. https://www.ecfr.gov/cgi-bin/text-idx?SID=ed5d86dda1fbd22cdf7acc276206c199&mc=true&node=pt21.1.54&rgn=div5

21 CFR Part 312: Investigational New Drug Application. https://www.ecfr.gov/cgi-bin/text-idx?SID=576cdc22b2547f52b1da250d4408bce9&mc=true&node=pt21.5.312&rgn=div5

21 CFR Part 600 – Biological Product: General. https://www.ecfr.gov/cgi-bin/text-idx?SID=ed5d86dda1fbd22cdf7acc276206c199&mc=true&node=pt21.7.600&rgn=div5

21 CFR Part 812 – Investigational Device Exemptions. https://www.ecfr.gov/cgi-bin/text-idx?SID=78e24c9cae2164f8f5d5ec93b2ab07bc&mc=true&node=pt21.8.812&rgn=div5

8.5 ***The Nuremberg Code.*** Available at the following link: https://history.nih.gov/display/history/Nuremberg+Code

8.6 ***World Medical Association Declaration of Helsinki:*** Available at the following link: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

8.7 ***The Belmont Report.*** Available at the following link: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

8.8 ***American Psychological Association Ethical Principals of Psychologists and Code of***

Conduct. Available at the following link: http://www.apa.org/ethics/code/

8.9 ***Saint Louis University Research Policies.*** Available at the following link: http://www.slu.edu/research/faculty-resources/research-policies.php

9.0 RECISION

The Institutional Review Board Standard Operating Policies and Procedures for the Protection of Human Research Subjects, Version 8.0, dated July 21, 2018.

10.0 REVIEW DATE

This policy will be reviewed regularly as needed to assure that it remains current with applicable federal, state, and other requirements.

APPROVAL SIGNATURES

This policy has been approved by:

Kenneth A. Olliff
Vice President for Research and Partnerships
Saint Louis University

March 11, 2022
Date

REVISION HISTORY		
Effective Date	**Revision Number**	**Modifications**
1994	1.0	New Document
January 21, 2001	2.0	Policy Revision
November 7, 2001	3.0	Policy Revision
February 17, 2007	4.0	Addition of sections/subsections: A. 5.0 Responsibilities, 5.2.5 (Prisoner Representation at IRB Meetings) B. 6.0 Procedures, 6.1.8 (Humanitarian Use Device), 6.3 (IRB Record Requirements), 6.4.6 (Reports of Unanticipated Problem) C. 8.0 Sanctions Format Change Document Controlled
August 1, 2010	5.0	Administrative Updates
Augusts 12, 2013	6.0	Addition of sections/subsections: A. 4.0 Research Policy and Authority, 4.2.2 (IRB of Record) B. 4.0 Research Policy and Authority, 4.4 Confidentiality Policy Revision Administrative Updates
November 18, 2014	7.0	Removal of section/subsection: A. 6.2.7 (3), Reporting of IRB Meeting Minutes to Associate Vice President for Research (AVPR) Removal of references to AVPR Administrative Updates
July 1, 2018	8.0	SLU IRB Program Organizational updates: A. Elimination of Deputy Chair (Vice Chair) positions. Reformatting of document. Added subtitles/headings to some subsections. Correction of minor typos and minor clarifications of terminology. Addition of sections/subsections: A. 5.3 Management of the IRB, subdivided Section 5.3.1 into two sections, now titled: 5.3.1 Selection and Appointment of the IRB Chairperson and 5.3.2 Appointment of Experienced Members for Expedited Reviews. B. 8.0 References (added numbering to this existing section) C. 9.0 Rescission (new) D. 10.0 Review Date (new) Expansion of references in newly numbered Section 8.0 to include webpage links. Reformatted Revision History Table.
June 30, 2021	9.0	Addition of section: 4.0 Research Policy and Authority, 4.2.9 (HIPAA Privacy Board)