the Protection of Human Research Subjects

Policy Number: RC-002 **Version Number:** 9.0

Classification: Research Compliance **Effective Date:** June 30, 2021

Responsible University Official: Vice President for Research

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4.2 The Authority of the IRB:

4.2.1

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

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 cally, 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 - 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 ord 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

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

   activities is necessary.
   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 U , 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

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.
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 iERSITY

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

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

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

xtra costs to third party payers.

6.4.3 _____:
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 2 re5 b3h(nt t1 12 Tf0)G[ )]TJx4rmele;

(a)

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