



the Protection of Human Research Subjects

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Responsible University Official: Vice President for Research

TABLE OF CONTENTS

| Section | Page |
|--|-------------|
| 1.0 Introduction Principles That Govern the IRB | 2 |
| 2.0 Purpose | 2 |
| 3.0 Personnel Affected | 2 |
| 4.0 Research Policy and Authority | 2 |
| 4.1 Institutional Authority | 2 |
| 4.2 The Authority of the IRB | 3 |
| 4.3 Conflict of Interest | 4 |
| 4.4 Confidentiality | 4 |
| 5.0 Responsibilities | .. 4 |
| 5.1 General | 4 |
| 5.2 Membership of the IRB | 5 |
| 5.3 Management of the IRB | 6 |
| 6.0 Procedures | 7 |
| 6.1 Functions of the IRB | 7 |
| 6.2 Operations of the IRB | 11 |
| 6.3 IRB Record Requirements | 15 |
| 6.4 Information the Investigator Provides to the IRB | 16 |
| 6.5 Exemption from Prospective IRB Review for One-Time Emergency | 18 |
| 7.0 Sanctions | ... 19 |
| 8.0 References | 19 |
| 9.0 Rescission | 20 |
| 10.0 Review Date | 20 |

4.2 The Authority of the IRB:

4.2.1

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



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

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{)JTJx4rmele;

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

