Policy & Procedures

Introduction

This document sets forth the standard operating policies and procedures for JISRF’s Institutional Review Board (IRB)

All members of the IRB, and research personnel are expected to be familiar with these policies.

The primary purpose of this document is to enforce the regulations, which govern the protection of research participants, enrolled in JISF’s studies through oversight by the IRB and IRB staff.

A key goal of IRBs is to protect human subjects from physical or psychological harm, which they attempt to do by reviewing research protocols and related materials. The protocol review assesses the ethics of the research and its methods, promotes fully informed and voluntary participation by prospective subjects capable of making such choices (or, if that is not possible, informed permission given by a suitable proxy), and seeks to maximize the safety of subjects.

In the United States, the Food and Drug Administration (FDA) and Department of Health and Human Services (specifically Office for Human Research Protections) regulations (see Human subject research legislation in the United States) have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research. IRBs are responsible for critical oversight functions for research conducted on human subjects that are “scientific”, “ethical”, and “regulatory”. IRBs are most commonly used for studies in the fields of health and the social sciences, including anthropology, sociology, and psychology. Such studies may be clinical trials of new drugs or devices, studies of personal or social behavior, opinions or attitudes, or studies of how health care is delivered and might be improved.

International ethics review committees

Numerous other countries have equivalent regulations or guidelines governing human subject studies and the ethics committees that oversee them. However, the organizational responsibilities and the scope of the oversight purview can differ substantially from one nation to another, especially in the domain of non-medical research. The United States Department of Health and Human Services maintains a comprehensive compilation of regulations and guidelines in other countries, as well as related standards from a number of international and regional organizations.
Organization and Personnel

JISRF’s IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, 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.

Every nondiscriminatory effort will be made to ensure that our IRB does not consist entirely of men or entirely of women, including the institution’s consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. JISRF’s IRB may not consist entirely of members of one profession.

JISRF’s IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

JISRF’s IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

JISRF’s IRB may not have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

JISRF’s IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues, which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Informed Consent

The fundamental purpose of IRB review of informed consent is to assure that the rights and welfare of subjects are protected. A signed informed consent document is evidence that the document has been provided to a prospective subject (and presumably, explained) and that the subject has agreed to participate in the research. IRB review of informed consent documents also ensures that the institution has complied with applicable regulations.

The sponsor may provide a service to the clinical investigator and the IRB when it prepares suggested study-specific wording for the scientific and technical content of the consent document. However, the IRB has the responsibility and authority to determine the adequacy and appropriateness of the entire wording in the consent. If an IRB insists on wording the sponsor cannot accept, the sponsor may decide not to conduct the study at that site. For medical device studies that are conducted under an IDE, copies of all forms and informational materials to be provided to subjects to obtain informed consent must be submitted to FDA as part of the IDE.

For investigational devices, the informed consent is a required part of the IDE submission. FDA as part of the IDE application therefore, approves it. When an IRB makes substantive changes in the document, FDA re-approval is required and the sponsor is necessarily involved in this process.
FDA regulations for other products do not specifically require the sponsor to review IRB approved consent documents. However, most sponsors do conduct such reviews to assure the wording is acceptable to the sponsor.

The FDA requirements for informed consent are the minimum basic elements of informed consent that must be presented to a research subject. An IRB may require inclusion of any additional information, which it considers important to a subject’s decision to participate in a research study.

The signed informed consent document is the written record of the consent interview. Study subjects are given a copy of the consent to be used as a reference document to reinforce their understanding of the study and, if desired, to consult with their physician or family members about the study.

**IRB Process and Policy (minutes and members)**

The FDA regulations do not require public or sponsor access to IRB records, as such JISRF’s records are considered confidential.

**IRB’s Audit Responsibility**

FDA does not expect IRBs to routinely observe consent interviews; observe the conduct of the study or review study records. However, 21 CFR 56.109(f) gives the IRB the authority to observe, or have a third party observe, the consent process and the research. When and if the IRB is concerned about the conduct of the study or the process for obtaining consent, the IRB may consider whether, as part of providing adequate oversight of the study, an active audit is warranted.

**Relationship between Investigators, Sponsors and IRB**

It is important that a formal line of communication be established between the clinical investigator and the IRB. Clinical investigators should report adverse events directly to the responsible IRB, and should send progress reports directly to that IRB. However, FDA does not prohibit direct communication between the sponsor and the IRB, and recognizes that doing so could result in more efficient resolution of some problems.

**IRB Review Process**

JISRF’s IRB does not require an annual approval process but does require an annual review and in some cases a quarterly review may be required.

**Changes to Study Protocol**

Protocol amendments must receive IRB review and approval before they are implemented, unless an
immediate change is necessary to eliminate an apparent hazard to the subjects. Those subjects who are presently enrolled and actively participating in the study should be informed of the change if it might relate to the subjects’ willingness to continue their participation in the study. FDA does not require re-consenting of subjects that have completed their active participation in the study, or of subjects who are still actively participating when the change will not affect their participation, for example when the change will be implemented only for subsequently enrolled subjects.

**Clinical Investigations**

Private physicians conducting research with an FDA regulated product should obtain IRB approval. The FDA regulations require IRB review and approval of regulated clinical investigations, whether or not the study involves institutionalized subjects. FDA has included non-institutionalized subjects because it is inappropriate to apply a double standard for the protection of research subjects based on whether or not they are institutionalized. FDA approved product should also obtain IRB approval.