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Subject: Statement of Authority and Purpose
Division: IRB
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IRB Policy 100.1: STATEMENT OF AUTHORITY AND PURPOSE

Governing Principals

Institutional Review Boards (IRBs) are guided by the ethical principles applied to all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the "Belmont Report"). These principles are defined in the Belmont Report as follows:

- **Respect for Persons** – Legally effective informed consent is obtained, unless the requirements for waiver of informed consent are met by adequate and appropriate methods in accordance with the provisions of applicable regulations.

- **Beneficence** – The sum of the benefits to the subject and the importance of the knowledge to be gained so outweigh the risks to the subjects as to warrant a decision to allow the subject to accept these risks.

- **Justice** – The selection of subjects is equitable and is representative of the group that will benefit from the research.

Authority

1. An Institution's IRB is established and empowered by that Institution's executive authorities, and by the Institution's Assurance with OHRP. An institution may have more than one IRB, but all must subscribe to the same underlying principles and authorities. This Institution, Friends Research Institute (FRI), requires that all FRI research projects involving human subjects or living human material (tissues, cells, serum, etc.), in which FRI is the sponsor, the applicant organization or otherwise engaged in research, be reviewed and approved by the IRB prior to initiation of any research-related activities, including recruitment and screening activities.

2. Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46.101(b)(1-6) or 101(i), all research involving human subjects, and all other activities which even in part involve such research, are subject to these policies and procedures if one or more of the following apply:

   a) The research is sponsored (funded) in whole or in part by FRI, or the federal government;
   b) FRI is the applicant organization (or the contract organization has requested that a project be reviewed by FRI's IRB as a service to them);
   c) The research is conducted by or under the direction of any employee of FRI, in connection with

his or her official responsibilities, or using any property or facility of FRI;
d) The research involves the use of nonpublic information to identify or contact subjects;
e) Or if FRI is otherwise considered to be engaged in research.

3. The IRB has the authority to ensure that such research is designed and conducted in a manner that protects the rights and welfare of participating subjects. Specifically:

   a) The IRB may disapprove, modify or approve studies based upon consideration of human subject protection aspects;
   b) The IRB reviews, and has the authority to approve, require modification in, or disapprove, all research activities that fall within its jurisdiction;
   c) The IRB has the authority to conduct continuing review as it deems necessary to protect the rights and welfare of research subjects, including requiring progress reports from the Investigators and auditing the conduct of the study, observing the informed consent process and/or auditing the progress of any study under its jurisdiction as it deems necessary to protect the rights and welfare of human subjects;
   d) The IRB may suspend or terminate approval of a study; and
   e) The IRB may place restrictions on a study.

4. Regarding federally funded research, if the study is part of an application to a federal sponsoring agency, the human protocol must be reviewed by the IRB when the application is processed, and prior to expenditure of any grant funds.

5. Research that has been reviewed and approved by the IRB may be subject to review and disapproval by institutional officials or other committees. However, those officials or committees may not approve research if it has been disapproved by the IRB.

Responsibility

1. IRB Review of Research

   a) All applicable research involving human subjects (see above), and all other activities must be reviewed and approved by the IRB prior to implementation. No intervention or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations as to the definition of "research" or "human subjects," and their implications for the jurisdiction of the IRB under Institutional policy will be determined by the Institution and the IRB.

   b) The purpose and responsibility of the IRB is to protect the rights and welfare of human subjects. The IRB reviews and oversees such research to ensure that it meets well-established ethical principles and that it complies with federal regulations at 45 CFR 46 and 21 CFR 50 and 56, that pertain to human subject protection, as well as any other pertinent regulations and guidelines, such as the Good Clinical Practice (GCP) Guideline (E6) of the International Conference on Harmonization (ICH).

   c) According to federal regulations, activities that require IRB review include any activities involving the collection of data through intervention or interaction with a living individual, or involving identifiable private information regarding a living individual. Specific activities that require IRB review include, but are not necessarily limited to the following:

      (i) Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration (FDA) under relevant investigational drug or medical device provisions of the Food, Drug, and

Cosmetic Act, or experiments that do not meet the requirements for prior submission to the FDA, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

(ii) Collection of data about a series of standard procedures or treatments for dissemination or generalization.

(iii) A patient's care or assignment to intervention is altered for research purposes in any way.

(iv) A diagnostic procedure for research purposes that is added to a standard treatment.

(v) Systematic investigation involving innovative procedures of treatments, for example, if a physician plans to collect information about the innovation for scientific purposes or will repeat the innovation in other patients in order to compare it to standard treatment.

(vi) Emergency use of an investigational drug or medical device. Note that when emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject, and data generated from such care *cannot be included in any report of a research activity*. (Except for 21 CFR 50.23)

(vii) Human cell or tissue (genetic tissue) research that typically involves repositories that collect, store, and distribute human tissue materials for research purposes. However, human cell or tissue repositories activities *do not require* IRB review if material submitted to the repository satisfies *both* of the following conditions: (i)The material, in its entirety, was collected for purposes other than submission to the repository (*e.g.*, the material was collected solely for clinical purposes, or for legitimate but unrelated research purposes, with no "extra" material collected for submission to the repository); **and** (ii) The material is submitted to the repository without any identifiable private data or information, *i.e.*, no codes or links of any sort may be maintained, either by the submitter or by the repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained.

(viii) Investigator-initiated research, where an Investigator both initiates and conducts, alone or with others, a clinical trial. In the case of Investigator-initiated studies, it is the Investigator's responsibility to keep the IRB informed of unanticipated non-serious research related events and unanticipated serious adverse events and other unexpected findings that affect the risk/benefit assessment of the research, even if the event occurred at a location for which the IRB is not the IRB of record. The IRB further recommends that an independent data safety monitoring board (DSMB) review all reportable adverse events, and that the DSMB reports are forwarded to the IRB in addition to individual reports.

(ix) Case studies, such as when a series of subject observations are compiled in such a way as to allow possible extrapolation or generalization of the results from the reported cases. Such activity constitutes research that must be reviewed by the IRB. Additionally, this type of activity must always be reviewed by the IRB when there is intent to publish or disseminate the data or findings.

2. Failure to Submit a Project for IRB Review

The consequences of engaging in activities that qualify as research subject to IRB review, without obtaining such review, are significant. To do so is in violation of Institutional policy. Results from such studies may not be eligible for publishing unless IRB and other applicable institutional approval has been obtained prior to collecting the data. If an Investigator begins a project and later finds that

the data gathered could contribute to the existing knowledge base, or that he or she may wish to publish the results, the Investigator should submit a proposal to the IRB for review as soon as possible. If the IRB does not subsequently approve the research, data collected cannot be used as part of a thesis or dissertation, and/or the results of the research cannot be published. Furthermore, FDA may reject such data if it is submitted in support of a marketing application.