



# KESSLER FOUNDATION

## *Policies and Procedures Manual* *IRB*

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| <b>SUBJECT: Initial Review of Research Projects</b>   | <b>POLICY # 5004</b>   |
| <b>APPROVED:</b><br><br>Richard J. Greene, M.D., Ph.D.<br>IRB Chair<br><br><br>John DeLuca, Ph.D.<br>Senior Vice President for Research<br> | <b>EFFECTIVE DATE:</b><br><br>January 1, 1998<br><br><b>REVISED DATE:</b><br><br><u>April 10, 2014</u><br>Incorporates former Policies 5002 and 5003 |

### **PURPOSE**

The Kessler Foundation has adopted as policy the terms of Federal regulations 45 CFR 46.109 and 45 CFR 46.110 for initial review of research projects by its IRB.

### **POLICY**

The Kessler Foundation conducts the initial review of research projects according to Federal regulations.

### **PROCEDURE**

#### **A. Submission and Categorization of Research Applications**

1. All initial research applications are received by the IRB Coordinator, are assigned an IRB tracking number, and are entered into the IRB database. The IRB Coordinator reviews the research protocol to confirm the investigator has designated the appropriate review category.
2. With the exception of externally funded research studies, all protocols are sent first to the Research Review Committee for consideration regarding soundness of the research design and the scientific methodology. Upon approval by the Research Review Committee, the research proposal is scheduled for an IRB review.
3. In rare cases, a protocol may be **exempt** from IRB review, if the research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

4. For certain research studies that involve no more than minimal risk, the IRB may use the **expedited review** process. Under this process, the review will be carried out by the IRB Chair or by one or more experienced reviewers designated by the IRB Coordinator in consultation with the Chair.

The research activities that qualify for **expedited** review are described in detail in the Federal Register 63: 60364-60367, November 9, 1998 (attached). They are minimal risk studies that can include the collection of biological samples (e.g. blood, hair, nails, saliva, sputum); the non invasive collection of data from subjects (e.g. EKG, EEG, ultrasound); the study of data, records, or specimens collected for non research purposes; collection of data from voice or video; studies using surveys, interviews or focus groups; and drug or device studies when an investigational new drug or device application is not required.

The IRB will keep all IRB members apprised of the research proposals approved under expedited review by including a list of these projects on the agenda of the next IRB meeting.

#### **B. Review Process by the Full IRB:**

**The IRB will meet once a month provided that initial research applications requiring Full Committee review, and/or applications for continuation of approval or other business items requiring Full Committee action are on the agenda.**

**Special meetings of the IRB may be called by the Chair when necessary. The special meeting can be in person or via teleconference. The rules governing Full Committee review of protocols, described below, apply to special IRB meetings.**

At least one week prior to regularly scheduled IRB meeting copies of all protocols scheduled for initial review will be sent to all IRB members.

The Principal Investigators of protocols scheduled for initial review will be informed of the time and date of the initial reviews and are required to attend the review (or send another member of the research team) to provide a brief summary of the study and to answer questions from IRB members.

A majority of the membership of the IRB, including at least one member whose expertise is in a non-scientific area, will constitute a quorum for official IRB action on the protocol.

For a research protocol to be approved, it must receive the approval of a majority of the voting members.

IRB members participating in a study under review or who may have a conflict of interest may not vote on the study.

Depending on the potential risks involved in the study, the IRB will determine whether more than annual continuing review of the project is required.

#### **C. Criteria for IRB Approval of Research:**

The IRB will approve research protocols based on its determination that the following requirements are satisfied:

Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not expose subjects to unnecessary risk.

Risks to subjects are reasonable in relation to 1) anticipated benefits, if any, to subjects and 2) the importance of knowledge that may reasonably be expected to result from the study.

Selection of subjects is equitable. The IRB will be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons and economically or educationally disadvantaged persons.

Informed consent will be obtained from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by 45 CFR 46.116. An informed consent document, written in lay language at the 8<sup>th</sup> grade English level, will explain the details of study participation to potential participants. The subject (or his/her legally authorized representative) must sign the informed consent document and the signature must be witnessed. The informed consent documents must be securely stored, in accordance with and to the extent required by 45 CFR 46 117.

There must be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

#### **D. Action on Proposed Research:**

Following the presentation and discussion of a research protocol, the IRB shall vote one of four courses of action:

1. Approval
2. Approval pending changes specified by the IRB. The changes may be approved by the Chair, or in some cases, may be referred back to the Full IRB for review and approval.
3. Tabled for major revisions, to be re-reviewed by the Full IRB following receipt of the revised protocol.
4. Disapproval

The minutes of the IRB meeting will reflect the actions of the IRB on the research project.

The applicant will be notified in writing of the action of the IRB and the date for Continuing Review, if applicable. For approved projects the Principal Investigator will be informed that any changes to the protocol must first be submitted to the IRB in the form of an amendment application, which must be reviewed and approved by the IRB before any change is made.

#### **E. Charges for IRB Review:**

A fee of \$2500 will be applied to all externally funded protocols reviewed by the IRB and is due once the protocol has been approved and the contract or grant has been finalized.

A continuing review fee of \$750 will be applied annually. Federally funded research projects are exempt from these fees. Exemptions or reductions of these fees may be applied for to the Senior Vice President for Research of the Kessler Foundation.