ATTACHMENT A

I. INSTRUCTIONS FOR DETERMINING REVIEW CATEGORY OF APPLICATION

The Institutional Review Board (IRB) serving Kessler Foundation is required by federal and institutional regulations to review all proposed research projects involving human participants prior to initiation of research.

Research is defined as “a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge”.

Human subjects means "a living individual about whom an investigator ... conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information...".

See CITATION 46.102 (d) and (f) for complete definitions *(Attachment B, page 2)*

REVIEW CATEGORY

Exempt Activities: Certain research projects, for example those involving human participants in educational settings or the study of existing data, may be considered exempt from IRB review. To avoid confusion, refer to the federal regulation cited below. An investigator requesting such exemption is still required to submit a complete application packet for review by the Research Committee and for verification of exempt status by the IRB. The cover form must point to the specific regulation that justifies the exemption from IRB review.

See CITATION 46.101(b) *(Attachment B, page 1)*

Expedited Activities: Research involving no more than minimal risk and in which human subject involvement is strictly defined may be eligible for an expedited IRB review. Refer to the CITATION listed below for a complete understanding of this category. An investigator requesting expedited review must submit a complete application packet for review by the Research Committee and for expedited approval by the IRB. The cover form must point to the specific regulation that justifies the expedited IRB review.

See CITATION 46.110 *(Attachment B, page 3)*

Full IRB Review: All research projects not covered by expedited or exempt activities must be reviewed by the Research Committee and the full Institutional Review Board at its monthly meeting.

II. INSTRUCTIONS FOR SUBMITTING A RESEARCH APPLICATION

A. SUBMITTAL REQUIREMENTS

1. For project under “**Full IRB Review**”, the original and 14 copies of the research proposal are required for submittal to the committee. For protocols that can be categorized as “**Exempt**” or “**Expedited**” research activities, the original and 1 copy of the entire application packet should be submitted. In addition to the required hard copies, the entire packet (cover form, research protocol, and informed consent form) must be submitted in electronic format via email. This will allow accurate entry of the project into the research database.

2. All required forms are available on the IRB website

http://kesslerfoundation.org/researchcenter/institutionalreviewboard.php. Please call the IRB Office at973-243-6972 for any additional questions or concerns.

3. Be sure to complete all sections of the Initial Application Form. Incomplete forms will be returned to the principal investigator.

4. An informed consent form must be included in the application packet unless the project falls within the IRB Exempt category.

5. One "Project Approval Signature Form" (the last page(s) of the initial application form) is necessary for each facility at which the research project will be conducted. The signatories include:

   a) Department Directors: Directors whose departments (personnel/equipment/ space) would, in any way, be involved in the research project must be informed of the potential research project and indicate their approval by signing the form.

   b) Laboratory Director: If the project will be conducted in collaboration with a specific program within Kessler Foundation, appropriate signatures must be obtained:

   c) Chairperson, Research Committee (After approval by the Research Review Committee)

   d) Chief Medical Officer, KIR (all new PIs from KIR)

6. If desired, research applications may be reviewed for completeness by the IRB Coordinator prior to final submittal.

B. REVIEW PROCESS

Review of research applications is a two-stage process. Research protocols, if not funded by a pharmaceutical sponsor, are first reviewed by the Research Committee which determines the scientific integrity of the research methodology, then by the IRB to ensure that the rights and welfare of the human subjects are protected. The following procedures are used in the review process:

1. All research applications are due to the IRB Coordinator by 4:00 P.M. on the last second of each month.(See IRB deadlines and Meeting dates)

2. Research Committee review takes place on the first Tuesday of every month. The Principal Investigator presents the protocol to the Committee at the meeting and answers any questions before being excused from the meeting.

3. Upon review by the Research Committee, a protocol is either:

   a) Approved as it stands;
   b) Approved pending minor changes to the research methodology; or
   c) Tabled due to requirement for major revisions.

4. Depending on the outcome of the Research Committee Review, the following actions take place:

   a) If the protocol is approved as written, the Project Approval Signature Form is signed by the chairperson of the Research Committee and the application is forwarded to the Institutional Review Board for review of human subject issues.

   b) If **minor** changes are required, a memo is sent to the principal investigator outlining the necessary changes. In order to meet the particular monthly deadline for IRB review, the revised protocol requiring full committee review must be returned to the Chair of the

Research Committee or to the IRB Coordinator as soon as possible. If the changes are found to be adequate, the chairperson of the Research Committee signs the Project Approval Signature Form and the protocol is reviewed at the IRB meeting which takes place on the last Wednesday or Thursday of the month.

c) If **major** changes are required, a memo is sent to the principal investigator outlining the necessary changes. The revised protocol is then due by the last working day of the month for re-review at the next meeting of the Research Committee. If the changes are adequate, the Project Approval Signature Form is signed by the Chairperson of the Research Committee and the protocol is forwarded to the IRB for review. Otherwise, it is returned to the investigator for further work.

5. The IRB review may result in one of five courses of action:

a) *Approval*: A notification of approval is sent to the applicant within one week of the expedited IRB review (for exempt and expedited proposals) or one week of the IRB meeting (for full proposals).

b) *Approval pending minor revisions*: The Principal Investigator is apprised of the required changes via memo. Upon submission of the revised protocol, the revisions are approved by the IRB Chair. An approval notice is then sent to the PI.

c) *Approval with revisions and re-review by a subcommittee*: A memo is sent to the PI outlining the requested revisions. Upon receipt, these changes are forwarded to the designated subcommittee. When the subcommittee approves the protocol, an approval notice is sent to the PI.

d) *Project tabled due to major concerns regarding participant safety*: A letter is sent to the PI with the committee's review and recommendations requesting resubmission of a new application. The new application is due on the third Monday of the following month so that the protocol can be re-reviewed by the IRB.

e) *Disapproved*: A letter is sent to the PI requesting resubmission of a new application. This debriefing letter outlines the reasons why the application was disapproved and suggests that major principles of the protocol be changed for the application to be reconsidered.