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)

Limited IRB Review: This new category was added in the regulations issued by the Office of Human Research Protection (OHRP) in 2019. It applies to studies that involve a “Benign Behavioral Intervention (BBI)” in conjunction with the collection of information from an ADULT subject… if the subject prospectively agrees to the intervention…” The regulation states: “…benign behavioral interventions (BBIs) are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing… Examples would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.” The IRB has implemented Limited IRB Review by requiring a shortened consent form that eliminates a number of sections from the standard adult Kessler consent form template.

In implementing the limited IRB review system, the IRB has opted to include other “harmless” studies such as those that are limited to completion of questionnaires that do not address sensitive issues.

Investigators requesting Limited IRB Review must submit a complete IRB application packet for review by the Research Committee (if applicable).

Protocols approved under Limited IRB Review are not required to be submitted to the IRB for annual continuation review.

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.

Protocols approved under Expedited Review are not required to be submitted to the IRB for annual continuation review.

See CITATION 46.110 (Attachment B, page 3)

Full IRB Review: All research projects not covered by limited IRB review or expedited review or not determined to be exempt from review by the IRB must be reviewed by the Research Committee (when appropriate) and the full Institutional Review Board at its monthly meeting. Protocols approval by the full IRB are required to be submitted annually to the IRB for continuation reviews.

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", "Limited IRB Review" or "Expedited" Review, 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 at 973-243-6972 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 PIs from KIR).

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

B. REVIEW PROCESS

Review of research applications is a two-stage process. Research protocols, if not funded by an external 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 for full IRB review are due to the IRB Manager by 4:00 P.M. on the first Monday of each month.(See IRB deadlines and Meeting dates). Applications for limited IRB review and expedited review can be submitted at any time.

2. Research Committee review takes place via email. Two reviewers are assigned for Residents, Post-docs & Trainees, One reviewer is assigned for an Established Researcher.

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 monthly deadline for IRB review, the revised protocol requiring full IRB committee review must be returned to the Chair of the

Research Committee or to the IRB Manager 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 assigned to the appropriate IRB review category (Limited, Expedited or Full Committee review).

c) If major changes are required by the Research Committee, a memo is sent to the principal investigator outlining the necessary changes. 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 a determination of exemption from IRB review or one week from the completion of limited or expedited IRB reviews. For Full IRB Committee reviews, approval notification will be sent one week after the IRB meeting.

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

c) Approval with revisions and re-review by the original review mechanism (Limited and Expedited reviews or Full IRB Committee): A memo is sent to the PI outlining the requested revisions. Upon receipt, these changes are forwarded for re-review to the original reviewer (for Limited and Expedited Reviews) or the Full IRB for Full IRB reviewed protocols.

d) Project tabled due to major concerns regarding participant safety or major revisions required in the written consent form: A letter is sent to the PI with the reviewers' comments and recommendations requesting resubmission of a new application. The new application will be reviewed as soon as possible.

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.