
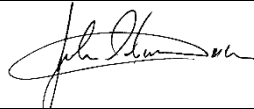


KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Multi-site Collaborative Research Studies Where Kessler Foundation IRB Serves as the Single IRB of Record for All Participating Centers.	POLICY # 5039
APPROVED: Richard J. Greene, M.D., Ph.D. IRB Chair 	EFFECTIVE DATE: January 20, 2020 REVISED DATE:
John DeLuca, Ph.D. Vice President for Research 	

I. PURPOSE

To provide guidelines and procedures for conducting multi-site collaborative research studies where Kessler Foundation IRB serves as the single IRB of record for all participating centers.

II. POLICY

In multi-site collaborative research studies, a single IRB at one of the sites can serve as the IRB of record for all participating sites. This Policy describes the procedures to be followed when Kessler Foundation IRB agrees to be the single IRB of record for a multi-site study.

Background: In January 2018 the NIH announced a new policy that requires the use of a single IRB of record for NIH-funded multi-site studies conducted in the United States. Other federal agencies and some private funding agencies have followed the NIH's lead in requiring the use of a single IRB of record for multi-site studies.

III. PROCEDURE

When Kessler Foundation IRB (KF-IRB) serves as the single IRB of record for a multi-site study the following functions will be assumed by the KF-IRB for all sites:

1. The initial IRB application including the study protocol and consent forms from all sites will be reviewed and the risk level of the study determined. The KF-IRB will take one of the following actions on the initial application: approval, conditional

approval pending required changes, disapproval or action will be tabled pending resubmission of a revised initial application.

2. Each participating external institution will execute the attached agreement with Kessler Foundation to delegate the IRB functions for the study to the KF-IRB. The agreement commits each participating external institution to:
 - a) Carrying out the collaborative research study in compliance with all DHHS-Office of Human Research Protection regulations on human subjects' protection as detailed in 45CFR part 46 and in compliance with state and local laws. The site Principal Investigator is the individual primarily responsible for conducting the research study in compliance with federal regulations and state and local laws.
 - b) Using the KF-IRB written consent form template customized to address local circumstances to enroll subjects in the study. Proposed customized changes will be reviewed and approved by KF-IRB.
 - c) Submitting to the KF-IRB an annual continuation application for the study including a copy of the currently approved consent form.
 - d) Submitting to the KF-IRB for review and approval any proposed amendment to the approved study.
 - e) Submitting to KF-IRB for review within 48 hours of any serious adverse event that occurred to an enrolled subject.
 - f) Submitting to KF-IRB for review within 5 business days of any adverse event of moderate or greater severity associated with the intervention.
 - g) Submitting to KF-IRB within 5 business days any instances of protocol deviations or non-compliance.
 - h) Submitting to KF-IRB for approval in advance for any proposed changes (exceptions) to the protocol for an individual subject.
 - i) Participating in an annual audit of de-identified research records of a random sample of study subjects enrolled at the external institution. The audit will be done by KF-IRB staff using de-identified research records sent to KF-IRB either in hard copy or electronically. The results of the audit will be sent to the participating institution including requests to remedy any deficiencies identified.

3. Reimbursement to Kessler Foundation for costs associated with KF-IRB assuming the IRB functions for all participating institutions in a multi-site study will be arranged before the study begins, either by including these costs as direct costs to the grant or contract supporting the study, or by a reimbursement schedule whereby each participating site reimburses Kessler Foundation \$3,000 for the initial IRB review and \$1,000 annually for the continuation reviews.

Reliance Agreement To Name Kessler Foundation IRB The Single IRB of Record For A Multi-Site Collaborative Research Study

This agreement is between Kessler Foundation, 120 Eagle Rock Ave, Suite 100, East Hanover, N.J. 07936 (Institution A) and _____ (Institution B). Both institutions are participating in the multi-site, collaborative research study:

Title _____
Principal Investigator Name _____ Institution _____
Sponsor _____

As part of its role in this collaborative study, Institution B agrees to delegate the IRB function for this study at its institution to the single IRB of record for the study, the Kessler Foundation IRB (KF-IRB). In agreeing to delegate the IRB function for this study to the KF-IRB, Institution B agrees to the following:

- a) Carrying out the collaborative research study in compliance with all DHHS-Office of Human Research Protection regulations on human subjects' protection as detailed in 45CFR part 46 and in compliance with state and local laws. The site Principal Investigator at Institution B is the individual primarily responsible for conducting the study in compliance with federal regulations and state and local laws.
- b) Submitting an initial application form and consent forms(s) to be used at Institution B to KF-IRB as part of the initial application submission for review and action by KF-IRB.
- c) Using the KF-IRB written consent form template customized to address local circumstances to enroll subjects in the study at Institution B. Proposed customized changes will be reviewed and approved by KF-IRB
- d) Submitting to the KF-IRB an annual continuation application for the study including a copy of the currently approved consent form being used at Institution B.
- e) Submitting to the KF-IRB for review and approval any proposed amendment to the approved study.
- f) Submitting to KF-IRB for review within 48 hours of any serious adverse event that occurred to an enrolled subject at Institution B.
- g) Submitting to KF-IRB for review within 5 business days of any adverse event of moderate or greater severity associated with the intervention that occurred at Institution B.
- h) Submitting to KF-IRB within 5 business days any instances of protocol deviations or non-compliance that occurred at Institution B.

- i) Submitting to KF-IRB for approval in advance for any proposed changes (exceptions) to the protocol for an individual subject at Institution B.
- j) Participating in an annual audit of de-identified research records of a random sample of study subjects enrolled at the external institution. The audit will be done by KF-IRB staff using de-identified research records sent to KF-IRB either in hard copy or electronically. The results of the audit will be sent to the participating institution including requests to remedy any deficiencies identified.
- k) Reimbursement to Kessler Foundation for costs associated with KF-IRB assuming the IRB functions for all participating institutions in this multi-site study will be arranged before the study begins, either by including these costs as direct costs to the grant or contract supporting the study, or by a reimbursement schedule whereby each participating site reimburses Kessler Foundation \$3,000 for the initial IRB review and \$1,000 annually for the continuation reviews.

Signatories to this agreement:

Institution B:

Name:

Signature and date: _____

Title:

Email Address:

Phone Number:

Kessler Foundation:

Name: John DeLuca, Ph.D.

Signature and date: _____

Title: SVP for Research

Email Address: jdeluca@kesslerfoundation.org

Phone Number: 973-324-3572

Site Principal Investigators:

	Institution B	Kessler Foundation
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Contact Persons at IRBs

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00001357

Expiration Date

4.19.22