

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:

1. 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.
2. 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.
3. 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
4. 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.
5. Submitting to the KF-IRB for review and approval any proposed amendment to the approved study.
6. Submitting to KF-IRB for review within 48 hours of any serious adverse event that occurred to an enrolled subject at Institution B.
7. 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.
8. Submitting to KF-IRB within 5 business days any instances of protocol deviations or non-compliance that occurred at Institution B.





1. Submitting to KF-IRB for approval in advance for any proposed changes (exceptions) to the protocol for an individual subject at Institution B.
2. 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 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

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Site Principal Investigators:

 Institution B Kessler Foundation

Name:

Title:

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Contact Persons at IRBs

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Title: IRB Manager

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IRB FWA # 00001357

Expiration Date 4.4.27