

KESSLER FOUNDATION
INSTITUTIONAL REVIEW BOARD

**APPLICATION FOR CONTINUATION OF APPROVAL /
PROJECT COMPLETION REPORT**

All active human studies at Kessler Foundation must be reviewed by the IRB at intervals appropriate to the degree of risk but not less than annually, for continuation of approval. Research not receiving annual approval by the anniversary date will be discontinued in accordance with Federal Regulations and the Single Project Assurances filed with the Office for Protection from Research Risks (OPRR).

SUBMISSION Instructions:

- Please email **all** required documents to the IRB@KesslerFoundation.org.
- Do not submit hard copies unless specifically requested by the IRB Office.
- **FULL BOARD** – recommend submission 2 months prior to the expiration date (see deadline and Meeting Dates)
 1. 1 signed application, revised and clean copies of consent form, abstract/protocol, and advertisements (if applicable)
 2. Adverse event log (if new adverse events have occurred since the last continuation)
- **EXPEDITED** - recommend submission at least 1 month prior to the expiration date
 1. 1 signed application, revised and clean copies of consent form, abstract/protocol, and advertisements (if applicable)
 2. Adverse event log (if new adverse events have occurred since the last continuation)
- **COMPLETION OF THE PROJECT** – recommend submission at least 1 month prior to the expiration date
 1. 1 signed application and abstract/protocol
 2. Adverse event log

Thank you very much for your cooperation in promptly returning the form. **If you need any assistance please contact IRB Manager Donna Servidio at dservidio@kesslerfoundation.org or 973-965-6672**

Protocol Number:

Expiration Date:

Title:

Principal Investigator:

Telephone Number:

Co-investigator(s):

Review Category:

Initial approval date:

1. Has the title been changed since this project was approved or last reviewed?

Yes

No

If yes, indicate new title: _____

2. Have there been any changes with regard to the investigators listed on the original IRB application for this project?

Yes No

If yes, identify persons who have joined or left the group: _____

3. Please check the appropriate box(es) :

Continuation of approval requested for:

Protocol Advertisement

Data collection completed; continuation of approval requested for data analysis only

Project terminated by investigators; close file

4. Please complete the following:

Number of participants:

Planned: _____ Completed study: _____

Enrolled since last Continuation: _____ Withdrew from study: _____
(Provide information below regarding reasons for withdrawal)

Total enrollment to date: _____

5. Describe the progress on this project since the last continuation or initial approval.

6. Are the study records, including signed informed consent forms, kept in a locked file cabinet at the study site?

Yes No

If No, please explain: _____

7. Is the number of consent forms and the number of participants enrolled to date the same?

Yes No

If No, please explain: _____

8. Percentage of study completed (Please estimate): _____

Projected completion date: ____ / ____ / ____

9. List and explain any unexpected observations and/or any adverse effects to participants. If untoward effects have occurred, what measures have been undertaken to remedy problems/reduce risks? Please submit the adverse event log forms for the period since the last continuation (If not all participants have had adverse events, submit a memo with the logs stating the number of participants that had adverse events and the number that did not).

10. Has there been new information learned since the study began that might affect subject participation? Yes No

If yes, have subjects been informed of any important new information that might affect their willingness to continue participating in the research

Yes No

- How has that information been disclosed to subjects?
- In a revised consent form (identify/highlight revisions)
 - In a letter to the subjects (attach copy)
 - Verbally to the subject

11. Indicate any actual or potential ethical problems regarding this project:

12. Do any of the investigators have a direct or indirect personal financial or other interest or advisory relationship to the sponsor, manufacturer or to the owner of any test article being used in this research?

Yes No

If yes, please explain: _____

13. Modifications proposed for the study (Substantial modification may require submission of an amendment application. Use additional sheets if necessary). **If there are no modifications, state "NONE"**

14. Have you encountered any problems with starting or conducting this study?

15. What has been learned from this work to date? Describe any benefits produced for the participants or for medical science

16. Please list abstracts or publications resulting from the study and provide one copy of each:

Continuing review fee of \$1000 will be applied annual protocols reviewed by the Kessler Foundation IRB when applicable and is due once the protocol has been approved.

The use of human subjects in this protocol has been carried out in accordance with the previously approved protocol, consent, and conditions required by the IRB.

Signature of Lab Director or appropriate Supervisor

Signature of Principal Investigator

Report Submission Date: ____ / ____ / ____.