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 type or print legibly in **BLACK INK.**
- Please submit **all** required documents:
- **FULL BOARD:** (see deadline and Meeting Dates)
  1. 1 signed original application, revised and clean copies of consent form, abstract/protocol
  2. 14 collated copies including: application, revised consent form, abstract/protocol
  3. Adverse event log
  4. A copy of each of content above in electronic format via email
- **EXPEDITED REVIEW- two weeks prior to the expiration date**, so that your application can be reviewed by the IRB prior to the expiration date:
  1. 1 signed original &1 collated copy of application, revised and clean copies of consent form, abstract/protocol
  2. Adverse event log
  3. A copy of each of content above in electronic format via email
- **COMPLETION OF THE PROJECT – please include the following:**
  1. 1 signed original &1 collated copy of application and abstract/protocol
  2. Adverse event log
  3. A copy of each of content above in electronic format via email

If you need any assistance contact IRB Manager Donna Servidio IRB at dservidio@kesslerfoundation.org

Protocol Number: Expiration Date:

Title:

Principal Telephone Number:

Investigator: Co- Review Category: ....

investigator(s):

Initial approval date:

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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:

Total enrollment to date: _____

(Provide information below regarding reasons for withdrawal)

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 a new application. Use additional sheets if necessary). **If there are no modifications, state "NONE"**

_____

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_____

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

_____

_____

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_____

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 $750 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

_____ Report Submission Date: ____ /____ /____.
Signature of Principal Investigator