KESSLER FOUNDATION

INSTITUTIONAL REVIEW BOARD

REQUEST FOR APPROVAL OF AMENDMENT TO A PREVIOUSLY APPROVED PROJECT

(TO BE COMPLETED BY PRINCIPAL INVESTIGATOR)

SUBMISSION Instructions:

- Please email **all** required documents to IRB@KesslerFoundation.org.
- Do not submit hard copies unless specifically requested by the IRB Office.
- **Tracked changes** should be shown on the consent form, protocol and/or other revised documents.
- **Please provide a cover letter** that provides an overview of the changes being made, the reasons for making these changes, the investigators' assessment of the extent to which the change(s) will affect the risk-to-benefit ratio of study participation, and the rationale for this risk assessment. Amendments that have the potential to increase risk to study participants or expand recruitment to populations with potential for increased risk will require Full Board Review. Revisions considered to involve major changes in design or other procedures will also require Full Board Review. Please contact the IRB at the address above if you have questions about the type of review that will apply to your proposed revision(s).

If you need any assistance, please contact Donna Servidio IRB Manager at dservidio@kesslerfoundation.org or 973-965-6672.

IRB Protocol #

Exact Title of IRB-approved Project:

Principal Investigator:	Phone #: Email:
Co-Investigators:	

Date of the most recent continuation of approval: _____
Please provide the date of the last review of your project.

Expiration date of project approval: _____
This date is indicated in your most recent letter of approval.

I. Are you submitting amendments to the Study Protocol? ☐ Yes ☐ No

If not, skip this section and go to section II.

1. Please submit the text of the amendment to the study protocol. Itemize the protocol changes, and include a concise description of each change. Please resubmit the revised protocol with the changes highlighted (tracked).

List Changes:

2. Do the protocol changes necessitate a change in the title of the project? ☐ Yes ☐ No

If yes, please enter the revised title below.

New Title:

In addition, please revise the title appearing on the informed consent document, and submit the revised document for approval. (Consent document need not be revised if subject recruitment has ended.)

3. Is subject recruitment still ongoing? ☐ Yes ☐ No

4. Will the protocol changes affect the research subjects directly? ☐ Yes ☐ No

If yes, revise the current informed consent document and submit it for approval.

5. Will the protocol changes impose greater risks on the subjects than originally estimated? ☐ Yes ☐ No

If yes, please clearly define what the nature and magnitude of the additional risks are, and whether or not the benefits of this study still outweigh the risks.

6. Should subjects who are already in the study be informed about the protocol changes? ☐ Yes ☐ No

If yes, please indicate how and how soon the information will be conveyed to the subjects. If it will be in writing, please submit the text for approval.

II. Are you submitting a new/changed advertisement/news release for the study? ☐ Yes ☐ No

If not, please skip this section and go to section III.
If yes, please submit the text of the publicity document for approval.

III. Are you submitting amendments to the Informed Consent Document? ☐ Yes ☐ No

If not, skip this section and go to Section IV.

1. Please attach a copy of the revised consent document with changes highlighted.

2. What are the reasons for making changes in the consent document?

☐ to accommodate changes in the investigative team	☐ to accommodate study protocol amendments
☐ to improve clarity of information given	☐ to correct typographical errors
Other:	

3. Are you submitting a New Consent Form? ☐ Yes ☐ No

IV. Are you submitting changes in the investigative team? ☐ Yes ☐ No

If not, skip this section and go to Section V.

1. Does the change involve the Principal Investigator? ☐ Yes ☐ No

If yes, please change the name of the Principal Investigator appearing in the Consent Form and submit the revised document for approval.

Name:	(If joining) Phone: Email:	☐ Leaving ☐ Joining
Name:	(If joining) Phone: Email:	☐ Leaving ☐ Joining

2. Does the change involve any co-investigators? ☐ Yes ☐ No

Name:	☐ Leaving ☐ Joining
Name:	☐ Leaving ☐ Joining
Name:	☐ Leaving ☐ Joining

V.

Are you submitting amendments to the investigator's brochure? ☐ Yes ☐ No

Are you submitting a new investigator's brochure? ☐ Yes ☐ No

This section is applicable to projects involving the use of a test article (investigational drug, biologic or device). If not relevant, skip this section and go to Section VI.

1. Please submit a copy of the text of the amended or updated Investigator's Brochure.
2. Please summarize the new information provided in the amended brochure.

3. Does the new information provided in the amended brochure suggest that the use of the test article may impose greater risks to the subjects than originally estimated?
   ☐ Yes ☐ No

If yes, please clearly define what the nature and magnitude of the additional risks are, whether or not the benefits of this study still outweigh the risks.

4. Should the new information provided in the amended brochure be included in the informed consent document?
   ☐ Yes ☐ No

If yes please revise the current informed consent document, and submit the revised copy for approval. (Consent document need not be revised if subject recruitment has ended; please indicate so.)

VI. Are you submitting amendments to any other aspect of the study, which are likely to affect the research subjects directly, but are not covered in sections I-V?

☐ Yes ☐ No

If not, skip this section. Otherwise, provide sufficient information and documentation of the unclassified amendments, sufficient for the IRB to judge their impact on human subjects of this research.

Signature of Lab Director
(or appropriate Supervisor)

Date

Signature of Principal Investigator

Date