



Protocol Amendment

For Requesting an Amendment to an Already Approved Research Project

All forms must be typewritten, signed, and submitted via email to itaneja@etch.com

Please use all black font. Delete instructions (green text)

All modifications to human subjects' research must be reviewed and approved prior to implementation.

Minor modifications Minor modifications to previously approved projects include those that do not alter the risk–benefit assessment for the research. Examples include changes in the investigators; minor changes in the consent form(s), recruiting materials, measures, or procedures; minor changes in compensation, time of participation, or subject recruitment; or the use of a new site that is not materially different from a previously approved site. Minor modifications may also include changes to other parameters, whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol.

Major modifications Major modifications include significant protocol changes that would cause subjects to engage in activities not previously approved; or that involve an increased level of risk to the physical, emotional, or psychological well-being of participants (including the loss of confidentiality); or that involve a decreased benefit; or that otherwise result in alteration of the risk–benefit assessment for the research. For example, adding a new subject population, adding new measures that significantly differ from those currently approved, changing inclusion or exclusion criteria, changing the informed consent process, and changing procedures affecting subject confidentiality are all potentially major modifications.

Section 1. PROTOCOL INFORMATION

1A. Principal Investigator:

1B. Protocol Number:

1C. Project Title:

Section 2. AMENDMENT INFORMATION

2A. Amendment Number (start with 01):

2B. In the PI's judgment, which category of modification is this? Minor Major Uncertain

2C. Describe the requested changes:

2D. Describe the rationale for the proposed changes:

2E. Do the proposed changes affect the risk-benefit ratio? Yes No Unsure

Section 3. REVISED MATERIALS

For revisions to currently approved procedures or to add new procedures, resubmit the protocol application incorporating the revisions throughout. Amendments may also modify consent/assent forms,



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recruitment materials, measures, etc. Ensure that all new and revised documents are attached with this amendment. Also attach clean copy of consent (without highlights) to be stamped. Label it 'Clean copy of Consent'

3A. List revised documents that are submitted with this amendment:

3B. Revisions to existing documents must be indicated through track changes, highlighting, or other means and submitted as a Word document: Revisions indicated

3C. List new documents that are submitted with this amendment:

Section 4. INVESTIGATOR ASSURANCES

I have reviewed the contents of this form, with attachments, and I certify that the information provided is complete and accurate to the best of my knowledge.

The original signature of the PI is required before this form can be processed (electronic signatures are acceptable).

Principal Investigator

Date