AMENDMENT APPLICATION

Per requirements of federal regulations 45 CFR 46.103(b)(4) and 21 CFR 56.108(a)(3)(4), changes in approved research cannot be initiated without IRB review and approval unless necessary to eliminate apparent immediate hazards to the subject or provide important information germane to informed consent. In this circumstance, the IRB must be notified immediately.

Please use this form to describe the modifications proposed to modify your research that may involve changes in procedures personnel, compensation, recruitment methods or revising any subject materials. All modifications must be approved by the IRB PRIOR to implementing any changes.

## 1. Amendment Type

Please specify:

Principal Investigator generated

Sponsor-generated

Please specify:

Minor modification

Major modification

A minor modification is one which makes no substantial alternation in (i) the level of risks to subjects; (ii) the research designed or methodology; (iii) the number of subjects enrolled in the research (no greater than 10% of the total requested); (iv) the qualifications of the research team; or (v) the institution or location to support safe conduct of the research.

**Examples include**: changes in the research team; minor working changes in the consent form(s), recruiting materials or measures, minor changes in compensation, time of participation, or subject recruitment.

The Proposed Amendment/Modification involves a change in: (check all that apply)

Principal Investigator

Compensation

Consent/Assent Form

Consent process

Data analysis, statistical design

Data and safety monitoring plan

Eligibility criteria

Methods to ensure privacy/confidentiality

Personnel (i.e. adding or removing research personnel)

Protocol title

Recruitment methods or materials

Sponsor/Funding source

Study design (protocol, study length, study objectives)

Subject materials (questionnaires, surveys, etc.)

Subject numbers, types or sources

Other: Click here to enter text.

## 2. Detailed description of Amendment/Modification

2.1. Describe the requested change(s) and clearly reference materials to be amended **(e.g., personnel, consent process, study materials, etc.)**. Provide a clear rationale for the proposed change(s).

Click here to enter text.

## 3. Effects of the Amendment/Modification

3.1 In your opinion, will the amendment affect the risks or benefits to the subjects?

Choose an item.

If yes, please provide justification for the amendment.

Click here to enter text.

3.2 Will the amendment require a change in the informed consent document or process?

Choose an item.

If yes, please explain the nature of the change:

Click here to enter text.

3.3 Will the amendment require re-consenting of study subjects?

Choose an item.

If yes, please explain which subjects will be re-consented (all or a sub-set) and how they will be re-consented:

Click here to enter text.

## 4. Impact on existing subjects

4.1 In your opinion, could the proposed amendment impact a subject’s health, well-being, or willingness to participate in the study?

Choose an item.

If yes, how will existing subjects be informed?

Click here to enter text.

## 5. Include relevant documents with your submission

Copies of revised consent form, changes to the protocol, or any other study materials must be submitted with the changes highlighted/tracked. If you have made revisions to the most recent approved documents by the IRB, submit BOTH a “tracked changes” version of a document along with updated version #’s and dates will enable the IRB to quickly locate the proposed changes.

## 6. Personnel Changes

Changes in personnel must include:

1. Modifications to the [Human Subjects Application – Part 1](https://www.du.edu/orsp/media/documents/new_irb_forms/irb_part_one.docx) (Table A.2.3).

2. Modifications to the consent/assent forms, as appropriate.

2. Evidence of current (within 4 years) Human Subjects Protection Training (CITI certification) for all personnel added to the study.

4. If the Principal Investigator changes, the IRBNet Project Overview page must be edited to reflect the new PI. This modification will apply the new PI name to all IRB correspondence generated through IRBNet.

## 7. Principal Investigator Assurance Statement

I have read and I agree with the following:

* No revisions or changes may be implemented until this amendment has been approved by the IRB.
* The proposed changes are necessary for scientific or administrative reasons.
* If these changes are approved by the IRB, they become a permanent change to the protocol
* All changes are true and accurate to the best of my knowledge.

The Principal Investigator must electronically sign this study package prior to submitting the protocol to the IRB for review. When you sign this study as the Principal Investigator, you are also agreeing to the terms in the Principal Investigator Assurance above.

If you are a student investigator, your Faculty Sponsor must electronically sign this study package verifying they reviewed and approve of this amendment.