AMENDMENT Request Form

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 propose changes in procedures, personnel, compensation, recruitment methods, or to revise 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 – Examples: personnel changes, the consent form, recruitment or study materials, minor changes in compensation, time of participation, or subject recruitment

[ ]  Major modification – Examples: increased risk to participants, and/or substantive changes in research questions or study design

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 list materials to be amended (e.g., IRB Application, consent form, recruitment materials, etc.). Provide a clear rationale for the proposed change(s).

Click here to enter text.

2.2. If you are adding research personnel, list each one of their names here **AND** update section A in the IRB Application and upload it with this amendment request form.

Click here to enter text.

**NEW REQUIREMENT: All research team members must create an IRBNet account and link their CITI training account to it. Please follow these instructions to share project access for all team members and link training:**

* [Sharing Access to Your Projects in IRBNet](https://www.du.edu/node/66610)
* [Linking Your CITI Account to IRBNet](https://www.du.edu/node/66556)

## 3. Effects of the Amendment/Modification

3.1 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 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 the revised consent form, changes to the protocol, or any other study materials must be submitted with both a “tracked changes” version and a “clean” version.

## 6. Personnel Changes

Changes in personnel must include:

1. Modifications to the [IRB Application](https://www.du.edu/sites/default/files/2024-03/IRB%20Application_March_24.docx) (Table A.2.1).

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

3. Shared project access for all personnel and linked CITI Accounts in IRBNet. Please see instructions here.

4. If the Principal Investigator changes, please follow instructions here.

## 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.

As the Principal Investigator, you are agreeing to the terms in the Principal Investigator Assurance above.

## 8. Instructions to submit this form

1. Open the current IRBNet project and create a new package.
2. For package type, select **“Amendment/Modification.”**
3. Upload this completed form and any other new or revised study documents.
4. The PI listed in IRBNet needs to sign the package. Another person may **NOT** sign on behalf of the PI.
5. If the PI is a student, then **BOTH** the student and Faculty Sponsor need to sign the package. Another person may **NOT** sign on behalf of the Faculty Sponsor.
6. Submit the package.