**Modification Form**

**Submission Date:** Click or tap here to enter text.

All modifications to human subject research must receive IRB approval before subjects are involved in the revised protocol. Research activities include, but not limited to: recruiting participants, interacting with participants, collecting data, or analyzing data.

* Submit all revised or new documents that are being changed or added per the amendment.
* Indicate changes on revised documents through track changes.
* Submit all documents in Word format.

**Exempt Projects**: Only significant changes need review. Modifications do not need to be submitted for exempt studies so long as the research remains minimal risk and stays within the boundaries of the exemption categories that the IRB found were applicable to the research. Additional [guidance](https://research.northeastern.edu/hsrp/get-started/modifications/).

For guidance on modifying exempt and non-exempt IRB protocols, please refer to [HSR Guidance page](https://research.northeastern.edu/hsrp/guidance/).

**PROTOCOL INFORMATION**

|  |
| --- |
| **Principal Investigator:** Click or tap here to enter text. |
| **Student Investigator [if applicable]:** Click or tap here to enter text. |
| **IRB Number:** Click or tap here to enter text. |
| **Protocol Title:** Click or tap here to enter text. |

**MODIFICATION DESCRIPTION**

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| --- |
| **Describe the requested changes[[1]](#footnote-1):** Click or tap here to enter text. |
| **Describe the rationale for the proposed changes:** Click or tap here to enter text. |
| **Do the proposed changes affect the risk to benefit ratio:** [ ] Yes [ ] No [ ] Unsure |

**REVISED & NEW MATERIAL**

|  |
| --- |
| **For modifications to currently approved procedures or to add new procedures, resubmit the protocol application incorporating the revisions throughout. Modifications may require changes o informed consent/assent documents, recruitment materials, data collection instruments, measures, etc. Ensure that all new and revised documents are attached with this modification.** |
| **List all revised documents that are submitted with the amendment:**Click or tap here to enter text. |
| **List all new documents that are submitted with this amendment:**Click or tap here to enter text. |

**PRINCIPAL INVESTIGATOR ASSURANCE**

I have reviewed the contents of this form, with attachments and certify the information provided is complete and accurate

Signature: Date:

*Principal Investigator / Faculty Advisor*

Signature: Date:

*Student Investigator*

1. if the modification involves a change in PI, indicate the original PI and the new API on the form. For all other changes to the research team, please update the research team form and submit to IRVBReview@northeastern.edu. [↑](#footnote-ref-1)