**Protocol Renewal Form**

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

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| It is the responsibility of the Principal Investigator (PI) to ensure continued approval of his or her human participant research study. Please complete this form and submit to IRBReview@northeastern.edu prior to the study’s expiration date. to ensure proper processing of the protocol renewal.*Note: If IRB approval of the human research expires, all study procedures related to the protocol under review must cease, including recruitment, advertisement, screening, enrollment, consent, interventions, interactions, and collection of private identifiable information.*  |

**PROTOCOL INFORMATION**

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| **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. |

**FUNDING**

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| Is your study currently funded? [ ]  Yes [ ]  NoIf yes, please provide the funding source(s) and grant/contract #(s): Click or tap here to enter text.Has the proposal been submitted through (Check all that apply)[ ]  Research Administration/Finance [ ]  Corporations & Foundations [ ]  Provost |
| Does your study have previous or expired funding? [ ]  Yes [ ]  NoIf yes, funding source(s):; grant/contract #(s): End Date(s): Click or tap here to enter text. |

**COLLABORATING INSTITUTIONS & INVESTIGATORS**

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| Are there any external institutions and/or individuals involved in this study? [ ]  Yes [ ]  NoIf yes, please provide specifics on the following:[ ]  Institutional Authorization Agreement in place Click or tap here to enter text.[ ]  Individual Investigator AgreementClick or tap here to enter text.[ ]  Other domestic IRB approvals in place Click or tap here to enter text.[ ]  International IRB or ethics committees in place  |

**STUDY STATUS**

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| Enrollment goal on the approved protocol? Click or tap here to enter text. |
| Total number of subjects enrolled (completed the consent process) since the study was approved, including any who have withdrawn: Click or tap here to enter text. |
| Are subjects still being enrolled? [ ]  Yes [ ]  No |
| Have any subjects withdrawn? [ ]  Yes [ ]  No If yes, please attach a summary of the reasons for withdrawal and any associated risks\*[ ]  Attached*\* In the summary, please provide numbers for the following, as appropriate: Screen failures, lost to follow-up, subject withdraw from study, PI withdraw from study.*  |
| Is data still being collected (with current or future subjects)? [ ]  Yes [ ]  No |
| Is data identifiable? Please note that audio and video recordings are considered identifiable. [ ]  Yes [ ]  No[[1]](#footnote-1) |
| is there a record of the names of subjects who participated in the study? [ ]  Yes [ ]  No If yes, where is the record retained and is it secure? Click or tap here to enter text. |
| Are there signed consent documents being retained? [ ]  Yes [ ]  NoIf yes where are they retained and is it secure? Click or tap here to enter text. |

**MODIFICATIONS**

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| Are you requesting any changes at this time? [ ]  Yes [ ]  NoIf yes, *please complete and submit a Modification form and provide any new or revised documents per the modification(s).* *Please revise the research team form if there are any changes to individuals associated with the study.* |

**UNANTICIPATED INCIDENCES & SUBJECT COMPLAINTS**

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| Have there been any unanticipated incidences (including adverse events)? [ ]  Yes [ ]  NoIf yes, and they *have not* been reported to the IRB, please provide a summary of the incident or event(s). [ ]  AttachedIf yes, and they *have* been reported to the IRB, attach a summary of the incident or event(s) and resolution.[ ]  Attached |
| have any subjects expressed any complaints about the project since its initiation? [ ]  Yes [ ]  No If yes, please provide detailsClick or tap here to enter text. |

**SIGNIFICANT NEW FINDINGS**

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| Is there any recent literature, interim finding, or other finding, if any, that might affect the risks or benefits to subjects or the subjects’ desire to continue to participate in this project? [ ]  Yes [ ]  NoIf yes, attach a summary.[ ]  Attached |

**FINANCIAL INTERESTS**

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| **H**ave there been any changes to the conflict of interest associated with this protocol? [ ]  Yes [ ]  NoIf yes, please provide details Click or tap here to enter text. |

**PRINCIPAL INVESTIGATOR ASSURANCE**

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| * I certify that the information provided in this application, and in all attachments, is complete and correct.
* I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of this study, and the ethical performance of this project.
* I agree to comply with all Northeastern University policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

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1. *Continuing IRB approval is not necessary for analysis of completely de-identified data. Please provide our office with a closure form instead of this renewal form if your data is completely de-identified and you have no plans to enroll new subjects or collect new data with currently enrolled subjects.*  [↑](#footnote-ref-1)