|  |
| --- |
| **Protocol Closure Form****Submission Date:** Click or tap here to enter text. |
| A Principal Investigator (PI) can request protocol closure at any time for any of the following reasons* + Subject recruitment and enrollment have ceased
	+ No additional data will be collected
	+ No follow-up with subjects is planned
	+ Identifiable data is no longer being analyzed
	+ Manuscript preparation that requires the use of personally identifiable information is complete
* The PI is leaving the University.
* The student affiliated with the protocol has graduated and the research is concluded.
* Research was never initiated

*Note: In order for a project to be eligible for closure, all data must be completely deidentified with no existing identity key.* |

**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. |

**REASON FOR STUDY CLOSURE: Select all that apply**

|  |
| --- |
| [ ]  Human participation is complete, there is no planned follow-up, and data is stripped of all identifiable information.  |
| [ ]  Data analysis is complete.  |
| [ ]  The PI is moving to another institution or retiring. |
| [ ]  Not enough participants enrolled to conduct the study. |
| [ ]  There is no more funding, time, or personnel to conduct the study. |
| [ ]  The student affiliated with the research has graduated. |
| [ ]  Other, please specify: Click or tap here to enter text. |

**RESEARCH STATUS**

|  |
| --- |
| Total number of subjects enrolled in the study: Click or tap here to enter text. |
| Total number of subjects who withdrew over the course of the study: Click or tap here to enter text. |
| Since the last IRB review, have any unanticipated incidences or adverse events occurred that have not been reported to the IRB? [ ]  Yes [ ]  NoIf yes, please provide a summary of the incident or event(s) and the resolution. [ ]  Attached |

**PRINICIPAL INVESTIGATOR ASSURANCE**

|  |
| --- |
| * 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.

             \_\_\_\_\_\_\_\_\_\_Principal Investigator Date |