IRB STUDY CLOSURE

# FINAL REVIEW REPORT

The Principal Investigator (PI) should complete and submit this form as a new package under their existing project in IRBNet when either:

* All aspects of the research proposal have been concluded. This means:
	+ 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. Identifiable data includes any subject identifiers (name, address, phone, email, etc.), a key or code that can link the data to individual subjects, or audio or video recordings from which a subject’s identity can be ascertained.
	+ Manuscript preparation that requires the use of personally identifiable information is complete.
* The PI is leaving the University.

## 1. Study Closure

### 1.1. What is the reason for study closure?

[ ]  Project completed and all interventions or interactions with participants have concluded.

[ ]  Project not funded – project never began and/or no human subjects were enrolled.

[ ]  Analysis is continuing with de-identified data only. Any audio or video recordings have been transcribed without identifiers, and original recordings have been destroyed or stored for archival purposes.

[ ]  PI is leaving DU.

[ ]  Project cancelled for other reason, please specify: Click here to enter text.

## 2. Summary

### 2.1. Briefly summarize the results of the study, including any plans for scholarly/scientific presentations or publications.

Click here to enter text.

### 2.2. Subject Enrollment

Complete Table 2.5.A. below:

#### Table 2.2.A. Subject Enrollment

|  |  |
| --- | --- |
| Total enrollment number approved by the IRB |       |
| Total number of subjects consented |       |
| Total number of withdrawals |       |

## 3. Reports to the IRB

### 3.1. Have all subject complaints, unanticipated problems, and protocol deviations been reported to the IRB?

[ ]  Yes [ ]  No

IF NO, YOU MUST SUBMIT A [REPORTABLE NEW INFORMATION FORM](https://www.du.edu/sites/default/files/2021-10/Protocol%20Deviations%2C%20Adverse%20Events%2C%20Unanticipated%20Problems%20Form.docx) WITH YOUR STUDY CLOSURE/FINAL REPORT FORM.

## 4. Record Storage

### 4.1. How will study records be stored to maintain subject privacy and confidentiality?

Click here to enter text.

### 4.2. Where will study records be stored to maintain subject privacy and confidentiality?

Click here to enter text.

### 4.3. How long will study records be stored? Please note – consent forms are required to be maintained for a minimum of 3 years after the conclusion of your project.

Click here to enter text.