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.