

# STUDY CLOSURE

## FINAL REVIEW REPORT

A research project no longer involves human subjects and requires IRB oversight once the investigators have finished:

- Obtaining data through interaction or intervention with subjects or;
- Obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing identifiable private information.

Once all such activities described in the IRB approved protocol are finished, the research project no longer needs to undergo continuing review. For example, when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers, no further continuing review is necessary.

### 1. STUDY CLOSURE

#### 1.1. WHAT IS THE REASON FOR STUDY CLOSURE?

- Project was never initiated
- Project began, but no subjects were enrolled & no data collected
- Research has been completed; there will be no further data collection (including long term follow-up or re-contact) or data analysis of identifiable/ coded data
- PI is leaving DU
- Student PI is graduating or has graduated

#### 1.2. WHAT IS THE STUDY'S EXPIRATION DATE:

#### 1.3. HAS ALL STUDY ACTIVITY CEASED?

- The study activity and data analysis are complete
- The study investigator chooses not to continue the research
- The sponsor has decided that it may not continue
- Other: please explain below

OTHER:

## Institutional Review Board (IRB)

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**NOTE:** If research is terminated by a sponsor, the PI must inform both the reviewing IRB and, if the project is funded, the DU Office of Sponsored Programs.

## 2. SUMMARY

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2.1. BRIEFLY SUMMARIZE THE RESULTS OF THE STUDY, INCLUDING ANY PLANS FOR SCHOLARLY/SCIENTIFIC PRESENTATIONS OR PUBLICATIONS.

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2.2. HAVE ALL INTERVENTIONS/TREATMENTS BEEN COMPLETED?

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Yes  No

2.3. IS DATA ANALYSIS COMPLETE?

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Yes  No

2.4. IS THE RESEARCH IN THE EVALUATION, MANUSCRIPT WRITING, OR DATA ANALYSIS-ONLY STAGE?

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Yes  No

**NOTE:** A continuing review application is required so long as the research uses identifiable data posing a risk of breach of confidentiality to the participants. If the investigator is not using identifiable data, the protocol can be closed and no further IRB oversight is required

2.5. SUBJECT ENROLLMENT

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Complete Table 2.5.A. below:

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**Institutional Review Board (IRB)**

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**TABLE 2.5.A. SUBJECT ENROLLMENT**

Total enrollment number approved by the IRB	
Total number of subjects consented	
Total number of withdrawals	
Total number withdrawn by the Investigator	

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**3. REPORTS TO THE IRB**

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**3.1. HAVE ALL SUBJECT COMPLAINTS, UNANTICIPATED PROBLEMS, AND PROTOCOL DEVIATIONS BEEN REPORTED TO THE IRB?**

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Yes    No

Please attach publications resulting from this study to your package in IRBNet.

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**4. RECORD STORAGE**

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**4.1. HOW WILL STUDY RECORDS BE STORED TO MAINTAIN SUBJECT PRIVACY AND CONFIDENTIALITY?**

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**4.2. WHERE WILL STUDY RECORDS BE STORED TO MAINTAIN SUBJECT PRIVACY AND CONFIDENTIALITY?**

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**4.3. HOW LONG WILL STUDY RECORDS BE STORED?**

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