

## **CUNY HRPP Policy: Study Closure**

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### **1. Purpose**

The purpose of this policy document is to define the various ways in which a research study may be closed, either by the principal investigator (PI) or the HRPP/IRB. Please note that this Policy does not cover suspensions or terminations. For information regarding suspensions or terminations, please refer to [CUNY HRPP Policy: Suspension or Termination of Human Subject Research](#).

### **2. Study Closures by the PI**

#### **2.1. End of Study or End of Human Subject Involvement**

A PI may close out a study that no longer involves human subjects, and therefore no longer requires continuing review, when BOTH of the following criteria are met:

1. The investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects; **AND**
2. The investigators have finished using, studying, or analyzing identifiable private information.

##### **2.1.1. Example**

A PI may close out a study when the only remaining activity of a research project involves the analysis of aggregate data sets without individual subject identifiers.

##### **2.1.2. Study Closure Process**

When an investigator has completed a research project involving human subjects, or when human subjects are no longer involved in a research project, the PI must submit a Final Report Form. Upon review of the Final Report Form, the PI will receive either an acknowledgment of study closure or a request for additional information from the HRPP Office. The PI remains responsible for retaining research records in accordance with applicable regulations, CUNY policies and sponsor requirements.

### **2.2. Withdrawal**

A PI may withdraw a submitted HRPP/IRB application as follows:

#### **2.2.1. Submissions Pending HRPP/IRB Review**

A PI may withdraw a submission related to an exempt protocol that has not yet received HRPP final determination, or an IRB application prior to a final determination by the IRB at any time.

#### **2.2.2. Submissions Under Review**

Once the exempt or IRB review has begun, the PI must request withdrawal by submitting a memorandum to the HRPP Office.

### **3. Administrative Closure by the HRPP**

#### **3.1. Expired Studies**

If a study has been expired for 90 days, and the PI has not submitted a continuing review application or a final report form, the HRPP/IRB will close the study. The IRB will evaluate whether any previously enrolled subjects are at risk, and take any necessary steps to protect the subjects. If a PI wishes to re-open a study after this 90-day closure, s/he must submit a new application, including any modifications, referencing the original study's IRB number.

##### **3.1.1. PI Responsibility**

If the approval of a given study expires, and continuing review approval has not been issued by the IRB, the investigator is required to stop all subject contact, data collection and data analysis until the continuation is approved by the IRB.

##### **3.1.2. Re-opening Expired Study Following Closure**

Any new protocols submitted for continuation of a previously closed protocol must indicate whether any research related activities took place since the expiration date. If so, the researcher must clearly describe all such activities and provide a corrective action plan for ensuring that this does not recur.

#### **3.2. Failure to Respond for 90 Days**

If the HRPP or IRB requests additional information or modifications from the PI, and the PI does not respond for 90 days, the HRPP/IRB will close the study. In case of studies that previously received IRB approval, the IRB will evaluate whether any previously enrolled subjects are at risk, and take any necessary steps to protect the subjects. If a PI wishes to re-open a study after this 90-day closure, s/he must submit a new application, including any modifications, referencing the original study's IRB number.

##### **3.2.1. PI Responsibility**

In case of studies that previously received IRB approval,, the investigator is required to stop all subject contact, data collection and data analysis upon receipt of the closure notice.

##### **3.2.2. Re-opening Study Following Closure**

Any new protocols submitted for continuation of a previously closed protocol must indicate whether any research related activities took place since the study closure. If so, the researcher must clearly describe all such activities and provide a corrective action plan for ensuring that this does not recur.