

I. PURPOSE

The purpose of this SOP is to outline the criteria for when a study involving human subjects may be closed by the investigator. The IRB requires documentation of closure so that CHOP can track active human subjects research.

II. POLICY STATEMENT

The completion of a study is considered a change in research activity and must be documented in eIRB.

III. SCOPE

These policies and procedures apply to all research under the oversight of the CHOP IRB.

IV. DEFINITIONS

eIRB: The electronic IRB management system.

Human Subject (DHHS): A living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen a device is used. Under the FDA regulations and guidance, a human subject may include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical device research.

Private Information: Includes information about data or behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving no subjects. This may include identifiable private information obtained from a primary subject about a third party.

Relying Institution: The institution that has assigned an external IRB to serve as the Reviewing IRB under an IRB Authorization Agreement.

V. PROCEDURES

A. Determining When a Study May be Closed

As long as human subjects research is ongoing, including analysis of collected data that contains identifiable private information or identifiable biospecimens, the study must maintain IRB approval or exemption.

1. When CHOP's IRB oversight is limited to CHOP, the investigators must report study closure via eIRB when either of the following conditions are met:
 - (a) When individually identifiable data and biospecimens are no longer being collected and all identifiable private information has been removed from the data set and biospecimens that will be used for analysis purposes.
 - (b) When the investigator will not be involved in data management and analysis (e.g., multi-center clinical trials), when all data collection is completed at CHOP and the study sponsor has completed all closeout activities, even when human subjects research activity is ongoing at other study sites.
2. When CHOP's IRB oversight includes at least one Relying Institution, the CHOP investigators may not submit a request for study closure until human subjects research activities are complete at each Relying Institution.

B. Final Reports

1. Study closure must be submitted via eIRB. This may be done using the "Study Progress Report" Activity.
2. Requests for study closure may be reviewed by the Chair or designee or using IRB Office administrative procedures to ensure that all required information has been submitted. Closure requests submitted via the Study Progress Report activity will be automatically acknowledged in eIRB.
3. The investigator will be notified of study closure once the study closure is complete.

VI. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46.103	21 CFR 56.103
45 CFR 46.108	21 CFR 56.108
45 CFR 46.109	21 CFR 56.109

VII. REFERENCES TO OTHER APPLICABLE SOPS

VIII. RESPONSIBILITIES

Title	Responsibility
Director, Human Subjects Research	The Director is responsible for establishing and implementing processes for making research closure decisions.

IX. ATTACHMENTS

None

X. REVISIONS:

- 07-20-2006 Initial approval
- 11-28-2006 Revised Continuing Review form to change terminology from “termination” to “completion” per AAHRPP recommendations.
- 06-10-2010 Revised to clarify that studies may be closed when all human subjects research activities have ceased.
- 02-13-2013 Revised to clarify that completions do not require review by the IRB, but can be processed by IRB staff and that paper forms are no longer in use.
- 09-25-2018 Revised to update the definitions, correct references to other applicable SOPs, and address Relying Institutions.
- 01-22-2019 Revised to update the 2018 Common Rule office procedural including submitting closures through the Progress Update activity.
- 06-09-2022 Administrative updates

XI. APPROVAL:

Approval Indicator: Approved by Amy Schwarzhoff and Barbara Engel on 06/09/22
Amy Schwarzhoff, Director, Human Subjects Research and Barbara Engel, Chair, CPHS