# HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL & IMPLEMENTATION

## OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

**SOP Number: 11A**

**SOP Title: CLOSURE OF AN IRB-APPROVED PROTOCOL**

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB Chairs, IRB Administrators, Protocol Navigators**

**Approval:** Michael Gottesman — **Deputy Director for Intramural Research**

9/4/15 — **Date**

**Revision Implementation date:** 9/4/2015

**Materials Superseded: SOP 11A (ver. 1), dated 6-27-13**

# SOP 11A CLOSURE OF AN IRB-APPROVED PROTOCOL

## TABLE OF CONTENTS

11A.1 PURPOSE ..... 2
11A.2 POLICY ..... 2
11A.3 DEFINITIONS ..... 2
11A.4 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR ..... 2
11A.5 PROCEDURES FOR IRB REVIEW OF PROTOCOL CLOSURE ..... 4
REFERENCES ..... 5

# SOP 11A CLOSURE OF AN IRB-APPROVED PROTOCOL

## 11A.1 PURPOSE

This SOP outlines responsibilities of PIs and IRBs for closure of IRB-approved protocols.

## 11A.2 POLICY

Principal Investigators (PIs) are responsible for notifying the IRB whenever an IRB-approved study will be closed, regardless of the reason for closure. Data collection and analysis for the study are not permissible after study closure.[1]

## 11A.3 DEFINITIONS

A. **Study Closure:** occurs when research-related interventions or interactions with human subjects have been completed *and* all data or specimen collection and analysis as described in the IRB-approved research plan have ceased. Study closure is an action taken by the PI and may occur for any of the following reasons:

   1. **Completed:** The study has been concluded as described in the protocol.

   2. **Premature Closure:** The study has permanently stopped earlier than anticipated by the protocol.

   3. **Study is withdrawn:** A study is stopped prior to enrollment of the first participant.

## 11A.4 RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR

The PI has the following responsibilities at the time of study closure:

A. An “Intramural Clinical Protocol Study Closure Application” must be completed and submitted to the IRB in the applicable electronic IRB system.

B. Research records subject to HRPP policies are to be maintained by the PI in accordance with his/her Institute or Center’s record retention policies, applicable

[1] Study data and/or samples may be used if transferred to another IRB approved protocol or an OHSRP/IC designee exemption has been obtained. See **section 11.A.5.C and 11.A.5.D.**

Federal law and policy, and for a time period of no less than three years after the completion of the research. The research records may include the subject's original signed informed consent document if this document is not maintained elsewhere (i.e., the subject's medical record). Research records shall be accessible for inspection and copying by authorized representatives of OHRP at reasonable times and in a reasonable manner. Additional requirements for record retention and access may apply to FDA-regulated research (see SOP 15 – Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications.)

C. If an investigator, responsible for maintaining research records, leaves the NIH, the investigator should engage an appropriate Institute or Center Official to identify the successor responsible for maintaining the research records at NIH and, if copies are shared (if approved), at other locations; for at least the period of time required under Department of Health & Human Services (DHHS) human subjects regulations, and possibly longer depending on applicable laws. For more information see 46 CFR 46.115 (b), OHRP: Investigator Responsibilities – FAQs: see Appendix A- References which also lists "Guidelines for the Conduct of Research in the Intramural Research Program at NIH" as well as the "NIH Manual Chapter 1743: Keeping and Destroying Records".

D. If premature closure is anticipated (e.g., the study is to be closed earlier than anticipated based on recommendation of the DSMB), the PI should work with the IRB to inform currently enrolled study subjects about the closure and, as appropriate, other research or clinical options that may be available. Additional procedures may need to be established to ensure that the rights and welfare of subjects are protected. For example, it may need to be determined whether it is in the best interests of currently enrolled subjects to be transitioned to medical management outside the research context and, if so, the investigator should explain to the subject the reasons for this action. (OHRP Guidance documents: "Guidance on IRB Continuing Review of Research (2010) and "Withdrawal of Subjects from Research: Data Retention and Other Related Issues: OHRP Guidance (2010)", see **Appendix A – References**).

E. If the PI is an investigator or a sponsor/investigator for an IND protocol, he/she will also have additional responsibilities. See, e.g. as applicable, Revised SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications, Revised SOP 15A – Research Regulated by the Food and Drug Administration (FDA): Information and Policies Specific to Research Involving Investigational New Drugs (Including Biological Products) and Revised SOP 15B - Research Regulated by the Food and Drug Administration (FDA): Information and Policies for Investigational Device Exemption (IDE) Applications**.**

Data or specimen collection and analysis are not permissible after study closure. Once a study is closed, the PI is no longer required to obtain continuing review

and approval by the IRB for that protocol. If access to specimens or data is expected to be needed for future use, the investigator should make provisions prior to closing the original protocol (see **Section 11A.5** below). After study closure, if the PI wishes to undertake additional, new or future, research with data or materials collected or analyzed in the closed study, or conduct interactions or interventions with human subjects, the PI may need new IRB review (See SOP 5 - NIH Research Activities with Human Data/Specimens and SOP 6 - Determinations, Including Exemptions Made by the Office of Human Subjects Research Protections (OHSRP) under 45 CFR 46.)

## 11A.5 PROCEDURES FOR IRB REVIEW OF PROTOCOL CLOSURE

The NIH IRB has the following responsibilities at the time of study closure:

A. Review the Intramural Clinical Protocol Study Closure Application submitted by the PI.

B. Study Closure may undergo expedited review if the criteria for expedited review are met. (see SOP 7A - Requirements for Expedited Review of Research by NIH Institutional Review Boards)

C. Confirm that the PI has developed an appropriate plan for the disposition of specimens (see SOP 5 - NIH Research Activities with Human Data/Specimens and SOP 6 - Procedures For Activities Not Requiring IRB Review and approve the plan, for example:

   1. Specimens will be used up or destroyed.

   2. Specimens will retain identifiers or be coded and be transferred for another IRB-approved protocol and/or stored for future use.

   3. Specimens will be irreversibly stripped of all identifiers and stored for future use in a NIH-controlled freezer.

   4. Specimens will be transferred to a repository for future use.

D. Confirm that the PI has developed an appropriate plan for the disposition of data and approve the plan, for example:

   1. Data with codes/identifiers will be transferred for use by another IRB-approved protocol and/or stored for future use.

   2. Data will be irreversibly stripped of all identifiers and stored for future use.

E. Data and specimens must be stored according to applicable law, policy and regulations.

F. If premature closure of a study is anticipated (e.g., the study is to be closed earlier than anticipated based on recommendation of the DSMB), the IRB should work with the PI to develop a plan to ensure that the rights and welfare of currently enrolled subjects are protected. (see **Section 11A.4.D** above)

G. In accord with Revised SOP 4 - Human Research Protection Program (HRPP) Documentation and Records, IRB records relating to the protocol shall be retained for at least 3 years after completion of the research.

**REFERENCES**

A. Department of Health & Human Services Human Subject Protection Regulations 45 CFR 46: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

B. Institutional Review Boards, 21 CFR 56: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56

C. OHRP: Investigator Responsibilities – FAQs: http://answers.hhs.gov/ohrp/categories/1567

D. Guidance on IRB Continuing Review of Research (2010): http://www.hhs.gov/ohrp/policy/continuingreview2010.html

E. Withdrawal of Subjects from Research: Data Retention and Other Related Issues: OHRP Guidance (2010): http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html

F. Investigational New Drug (IND) Applications, 21 CFR 312: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312

G. Investigational Device Exemptions, 21 CFR 812: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812

H. Guidelines for the Conduct of Research in the Intramural Research Program at NIH: https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-conduct_research-6_11_07.pdf

I. NIH Manual Chapter 1743: Keeping and Destroying Records: http://oma.od.nih.gov/manualchapters/management/1743/