



## Research Standards and Institutional Review Board Study Closure Form

**Instructions:** Complete this form when an approved human subject research is **CONCLUDED** or **CANCELLED**. Studies that involved long-term follow-up of subjects or studies involving data analysis must remain open, even if enrollment of new subjects has ended. *Whenever possible, please include a separate final summary of the study with this form or a sponsor letter (if funded) requesting closure of the study.*

HT IRB Protocol Number:

Name of Study:

Principal Investigator:

Principal Investigator Department, Phone Number and Email Address:

Co-Investigators:

Number of Total Subjects Enrolled:

Institutional Review Approval date:

Date of Study Closure:

The above study has been closed to data collection (select one below):

- Data analysis, presentation and/or reporting of findings are completed
- Data analysis, presentation and/or reporting of findings are ongoing
- Human Subjects involvement is complete (e.g., there is no follow-up planned with subjects, data no longer contain identifiers, and there are no identifying codes to the de-identified data that can link the data to individuals)
- The research is no longer funded
- The PI never initiated the study
- The research project has been open for a period of three or more years and the PI has enrolled no subjects in the study, collected no data from records, nor collected/received specimens during this interval
- The PI is leaving the institution
- The sponsor is requesting closure. Provide reason:
- The study is being closed for another reason. Please describe reason for closure:

Study records must be retained even if a study is closed or canceled before it is completed. For federally funded, supported, conducted or regulated research, there are specific requirements that must be followed. You should familiarize yourself with these requirements.

For FDA-regulated research involving:

- Drugs (21 CFR 312.57 and 312.62): Retain records for 2 years after a marketing application is approved, or, 2 years after FDA is notified that investigational use has stopped, or longer if required by the sponsor
- Devices (21 CFR 812.140): Similar

For DHHS-funded, supported, or conducted research, records must be retained for **3 years** after the last expenditure report on the grant.

All records will be retained by in a secure location by the principal investigator for **at least three (3) years** after the study closure date.

These maintained records will include:

- |  |                              |                             |                              |
|--|------------------------------|-----------------------------|------------------------------|
| Research proposal:                       | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| IRB Approval letter:                     | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Informed consent sample document:        | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Progress reports:                        | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Reports of adverse events:               | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Correspondence with IRB:                 | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Signed informed consent documents:       | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Hard copies of completed questionnaires: | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Electronic Databases:                    | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Copies of Statistical Analyses:          | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |
| Copies of Reports and Papers:            | <input type="checkbox"/> Yes | <input type="checkbox"/> No | <input type="checkbox"/> N/A |

Printed Name of Principal Investigator:

Signature of Principal Investigator:

Date: