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| **Study Stage:**  Termination |



**Purpose:** This template assists the Principal Investigator and study team to fulfill their responsibilities regarding study close-out when all study activities are terminated.

**Useful to:** Principal Investigators, study coordinators, and other research study team members

**Instructions:**

* Complete this template to help ensure all of the necessary documents are accounted for at the close-out of the research study.
* Customize this document to meet the needs and requirements of the study.
* Use one form for each study.
* Check the boxes that apply for each item. Check N/A if the item does not apply to your study.
* For a more detailed list of items, the relevant version and dates column can include specific versions & dates of the various documents.
* If study files will be stored electronically or off-site, indicate the location(s) where these can be found (Dropbox, maize storage etc.)

**Best Practice Recommendations:**

* If your study sponsor provides a Document Inventory at Study Termination form or Study Closure Document, complete as instructed. If a sponsor does not provide a log for a specific study, study teams may use this template and customize it based on study-specific requirements.
* This template can be used for studies conducted under ICH GCP (see ICH GCP section 8 ‘essential documents’)
* This template can be used for FDA regulated studies when the investigator is not the sponsor; it can be simplified for other studies that are not bound by FDA regulations or ICH GCP.
* Electronic documents must be stored on a safe, UM-managed server.
* Note: If the investigator is a sponsor-investigator, the study team should reference ICH GCP for a complete list of document management required for sponsors.

**Template History:**

**Reference (s):**

ICH GCP: Essential documents Sections 8.2-8.4

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

**UMICH:**

[Protect Sensitive Data / safecomputing.umich.eduProtect Sensitive Data / safecomputing.umich.edu](https://safecomputing.umich.edu/protect-the-u/safely-use-sensitive-data/protect-sensitive-data)

**Last Updated:** 6/7/2022

**Version:** 2.3

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| **Study Name:** | **IRB HUM #:** |
| **Principal Investigator:** | **Study Team member(s)** **completing form:** |

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| Reason for Study Closure/Termination: |
| Electronic location (s) of study material (electronic system/server/file folders): |
| Location(s) of On-site Storage (Room #, Address of Physical Storage Site, etc.): |
| Location(s) of Off-site Storage (Room#, Address of Physical Storage Site, etc.): |

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| **Title of Document** | **Relevant Versions & Dates** | **Present at Site 1**  **(Paper)** | **Stored Electronically** | **N/A** | **Notes (including off-site storage location, if applicable)** |
| All Investigator Brochures submitted to the IRB |  |  |  |  |  |
| All IRB-approved documents (signed versions if applicable)   * Protocol * Consents * Advertisements and materials given to study participants | Initial and Amended versions |  |  |  |  |
| All IRB approval and acknowledgement letters from initial application through termination (protocols, consents, ORIOs, continuing reviews, adverse events, etc.) |  |  |  |  |  |
| Blank Case Report Form (s) | All |  |  |  |  |
| Financial aspects of the study (Financial disclosures, agreements) |  |  |  |  |  |
| IRB Board Roster |  |  |  |  |  |
| Regulatory Authorities Approval notification  (i.e. FDA, NIH, DOD) |  |  |  |  |  |
| Curriculum vitae and/or other relevant documents (i.e. Medical licenses, etc.) evidencing qualifications of investigator(s) and sub-investigators (and in some cases other study team members) |  |  |  |  |  |
| Normal value(s) / range(s) for medical/laboratory / technical procedure(s) and/or test(s) (initial and any updated ranges) |  |  |  |  |  |
| Medical/ Laboratory/Technical procedures/tests  (To document competence of facility to perform required test(s), and support reliability of results)  -certification or accreditation (i.e. CAP or CLIA) or  -Established quality control and/or external quality assessment or other validation (where required) |  |  |  |  |  |
| Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or Investigator's Brochure) |  |  |  |  |  |
| Shipping records for investigational product(s) and trial-related materials |  |  |  |  |  |
| Investigational product(s) accountability at the site. This could include certificate of analysis (COAs) |  |  |  |  |  |
| Documentation of investigational  product(s) destruction & returns |  |  |  |  |  |
| Decoding procedures for blinded trials (this may be in the protocol) |  |  |  |  |  |
| Trial monitoring reports & DSMB meeting documentation (if applicable)  (Initial – Termination) |  |  |  |  |  |
| All study training logs  (Initial – Termination) |  |  |  |  |  |
| Relevant communications other than site visits  -Letters  -Meeting notes  -Emails  -Sponsor close-out letter  -Notes of telephone calls |  |  |  |  |  |
| Signed informed consent documents by participants |  |  |  |  |  |
| Source documents/ participant research charts (include original documents related to the trial, to medical treatment, and history of subject, including investigational drug administration) |  |  |  |  |  |
| Signed, dated, and completed case report forms(CRFs) |  |  |  |  |  |
| Documentation of CRF corrections |  |  |  |  |  |
| Notification by originating investigator to sponsor of serious adverse events and related reports |  |  |  |  |  |
| Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s) of unexpected serious adverse drug reactions and other safety information |  |  |  |  |  |
| Notification by sponsor to investigators of safety information |  |  |  |  |  |
| Interim or annual reports to IRB and authority(ies) |  |  |  |  |  |
| Subject screening log |  |  |  |  |  |
| Subject identification code |  |  |  |  |  |
| Subject enrollment log |  |  |  |  |  |
| Delegation of Authority log (s) |  |  |  |  |  |
| Record of retained body fluids/tissues samples (if any) |  |  |  |  |  |
| Were all identifiers removed (if necessary) from study records? Enter information in the notes area. |  |  |  |  |  |
| Final report by investigator / institution to IRB where required, and where applicable, to the regulatory authority(ies) |  |  |  |  |  |

1Update this to fit the location of the records that are being stored