MERCY HEALTH

Institutional Policy and Procedure
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Title Investigative Site – General Administration
GA 105 Records Management, Accountability and Retention

Originator Institutional Official

Approval J Hollins MD

1. Policy

Files specific to each subject that include confidential health information (Source Documentation) shall be maintained in a secure location and access limited to authorized staff.

Source Documents shall be assembled and maintained in the same manner for all subjects. Unless being used, source Documents shall be stored separately from study records identified by a subject ID code.

A subject's medical record, Source Documents (hard copy and electronic) and the information contained therein may be used in the course of a clinical trial only as consented to or authorized by the subject, and a copy of the signed informed consent form shall be placed in the section of the medical record.

Only authorized staff may obtain and use medical records and Source Documents. The integrity of medical records and the information therein is the responsibility of the individual whose name appears on the Requisition Form or File Locater Log and that person shall be accountable for misuse, whether intentional or accidental. Medical records and Source Documents may not be removed from Mercy Health.

All records shall be under the control of authorized staff at all times and access or use shall be tracked.

Upon completion of a research study, Study Files, CRFs or a copy of e-CRFs, and Regulatory Files shall be maintained on site in storage for a period of <1 year, or however long the study contract states, or if specified by hospital policy after which such files and documentation shall be archived in a secure, off-site facility. All stored and/or archived documents and files shall be retrievable for 7 years.

2. Scope

This SOP describes how medical records and documentation are to be accessed, tracked and accounted for when used for research related activities, which may include review, data abstraction, photocopying and data verification, as well as subject visits.

3. Responsibility

Responsibilities for implementing this SOP are indicated as follows:

General administration: See Attachment GA 101-A: List of Key Personnel and Responsibilities at Mercy Health.

Specific studies: See Attachment GA 101-B: Delegation of Authority Protocol.

4. Applicable Regulations and Guidelines

FDA 21 CFR 312.60—General responsibilities of investigators

21 CFR 312.62—Investigator recordkeeping and record retention

21 CFR 312.68—Inspection of investigator's records and reports

21 CFR 812.140(a)—Investigator records

ICH E6: Harmonized Tripartite Guideline for GCP

5.5 Trial Management, Data Handling and Record Keeping

5.15 Record Access

5. SOP Attachments

GA 105-A: Request for Medical Records

GA 105-B: File/Document Access Log

GA 105-C: Telephone Contact Log

GA 105-D: Storage Label/Cover Sheet

6. Process Overview

A. Accessing and Accounting for Research Files and Medical Records

B. Documentation of Study Communications

C. Copying, Scanning, E-mailing or Faxing Medical Records and Source Documents

D. Storing and Archiving Study Documents

7. Specific Procedures

A. Accessing and Accounting for Research Files and Medical Records

#	Who	Task	Attachments	Related SOPs
A-1	Clinical Research Nurse/Coordinator	For each study, create a series of file folders or start a binder for documents collected during the study. Label a series of folders with the name of the protocol. Identify a section in the records area to store CRFs, Regulatory Files, Study Files and Source Documents.	GA 105-A RA 201-A PM 303-A - C PM 304-A SM 405-A	GA 105 RA 201 PM 303, 304 SM 405

		Label file cabinets and shelves as needed. Create a master Access Log.		
A-2		As study-related documents are received, place each in a labeled file and check off that the document has been filed.		
A-3		Maintain and update the file folders or binder as necessary, adding appropriate documents as they are generated or received.		
A-4		Ensure that subject records and regulatory files are kept confidential and are stored in a secure, limited-access location.		
A-5		Prior to appointments scheduled by monitors and auditors, review content of regulatory files and subject records for completeness. Ensure that files are organized and complete following the appointment.	PM 305-A	PM 305
A-1		When regulatory or study files, or documents from the files, are removed, enter the name of the person removing the file or document, time, location, contact information and expected return date/time on the Access Log.	GA 105-C	
A-2		Return the record or document as soon as possible and indicate that it has been returned on the Access Log.		
A-3		Periodically review files to compare contents with the log and Study Files Content Checklist.	RA 201-B	
A-4		If there are discrepancies, follow up with the individual(s) indicated on the log.		
A-5		When the study is over, review the contents of the regulatory files and subject records for completeness by comparing with the checklists.	PM 306-A	PM 306
A-6		Medical Records: If medical records for subjects are maintained separately in a study file within the research area, copies of all such documents must be filed, along with a copy of the consent form, in the patient's medical record and labeled with contact information for <<the Principal Investigator>>.		
A-7		To requisition one or more medical records for research-related activities, complete a Request Form and submit to the appropriate office.		
A-8		Request medical records 3-5 days in advance of the day needed.		
A-9		For electronic medical records use, ensure that appropriate paperwork is completed to provide sponsor, CRO or auditors limited access to patient study records. Outside party access must be limited to patients who have signed an informed consent document for the study. Access to electronic records should be limited to read only.		

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NOTE:

B. Documentation of Study Communications

#	*Who*	*Task*	*Attachments*	*Related SOPs*
B-1	Clinical Research Nurse/Coordinator	Document phone conversations that address the study and/or regulatory, legal or financial matters.	GA 105-B	
B-2		Keep originals or photocopies of all relevant documentation, including facsimile confirmations and e-mail correspondence, and file in the study binder with appropriate documents.		
B-3		Copy sponsor/CRO on IRB communications such as SAEs, IND safety reports, IRB acknowledgment of reports received, amendment approvals, revised informed consent form and continuing approval for study.	SM 404-A, B	SM 404
B-4		All incoming correspondence with study specific information (i.e. study newsletters, monitor follow-up letters) should be reviewed by the PI prior to filing in the study binder. The PI should initial and date correspondence when reviewed.		
B-5		Financial correspondence should be maintained in a separate location independent of the study binder.		
NOTE:				

C. Copying, Scanning, E-Mailing, or Faxing Medical Records and Source Documents

#	*Who*	*Task*	*Attachments*	*Related SOPs*
C-1	Clinical Research Nurse/Coordinator	When copying/scanning medical records/source documents, use the copier/scanner located at 260 Jefferson Ave . Never use a copier located in a public or highly trafficked area.	GA 105-A SM 404-A, B	GA 105 SM 404
C-1		Prepare records for copying in a private, uncluttered area as follows:		
C-2		· Remove each record/document to be copied and replace it with a place holder. Close the file and either replace in the filing cabinet or in another secure area.	GA 105-C	
C-3		· Copy/scan the documents, keeping them face down when not copying.		
C-4		· Return the original documents to the file.		
C-5		· In a private, uncluttered work area, using a permanent, wide stroke, black marker, obliterate all identifiers (be sure to include numbers, such as patient identifiers, social security numbers, etc.).		
C-6		· Make a 2nd set of copies by copying the copies that were de-identified.		
C-7		· Destroy and dispose of the first set of copies, which were de-identified using the black marker.		
C-8		· Use the 2nd set of copies. If applicable, write the subject's code on an upper corner of each page.		

NOTE:

D. Storing and Archiving Study Documents

#	*Who*	*Task*	*Attachments*	*Related SOPs*
D-1	Clinical Research Nurse/Coordinator /	The contract should specify the number of years study documentation needs to be retained.	GA 105-D RA 201-A - C	GA 105 RA201
D-2		When the study is over, review the contents of regulatory files and subject records for completeness by comparing with the checklists.		
D-3		Obtain written confirmation from the appropriate regulatory authority or sponsor confirming that the study has ended at Mercy Health. If federally funded, obtain confirmation that final analysis of data has been completed.		
D-4		Following procedures in SOP 105, store on site until it has been determined that files can be archived.		
D-5		Prepare the files for storage: Inventory the contents of regulatory, study and source documentation files. Follow up on and track any missing documentation.		
D-6		Try to ascertain the likelihood of a sponsor audit or regulatory inspection anticipated within the next 12 months for determination on whether document archive should be delayed. Label storage boxes clearly and completely including protocol number, description of contents (i.e. subject files xx-xx, regulatory documents, etc.), number of boxes as 1 of X, 2 of X, etc. Document inventory of storage boxes. Store in a secure location until ready to archive.		
D-7		Archive regulatory files and subject records. Arrange to archive all patient files and source documents for 7 years.		
D-8		Make arrangements, and document such arrangements, that the sponsor shall be notified if there is any change to the place of archiving.	GA 104-A, B	GA 104
NOTE:				