STANDARD OPERATING PROCEDURES

TITLE: Research Records Retention & Storage

1.0 OBJECTIVE:

1.1 This Standard Operating Procedure (SOP) describes the policy and procedure for the proper retention and storage of research records for studies that are initiated and/or coordinated through Florida Hospital (FH), and/or any FH affiliates, such as Florida Physicians Medical Group (FPMG), Centra Care, etc. This SOP is in place to protect the integrity, confidentiality, and availability of research data at FH, and to ensure that research records at FH are maintained and stored in accordance with the applicable regulations and institutional guidelines.

1.2 This procedure is intended to ensure compliance with all applicable Food and Drug Administration (FDA) Code of Federal Regulations, the International Conference on Harmonization (ICH) Guidelines (E6) for Good Clinical Practices (GCPs), Department of Health and Human Services (DHHS), Office for Civil Rights (OCR), FH Research Institutional guidelines, FH Institutional Review Board’s Policies, and Procedures for HIPAA Privacy in Research and Confidentiality for clinical studies, where applicable. See references below.

DEFINITIONS:

MEDICAL RECORD: The Medical Record may be either a hospital or affiliate office record and is a file that is created and maintained for every individual and each clinical event of being evaluated and/or treated as either an inpatient, outpatient, ambulatory or emergency patient. The Medical Record contains patient specific information, as appropriate, to the care, treatment, and services provided, and it may be paper-based, in an electronic format, or a combination of both. The Medical Record is the property of Florida Hospital and/or its affiliates as stated above and shall not be removed except by subpoena, court order, or applicable State of Florida statute. Medical records relating to study subjects that are not submitted to the sponsor may include some of the same information as is included in the Research Records; however the sponsor has no claim of ownership to those documents or the information they contain.

RESEARCH RECORD: The Research Record includes all data recorded, collected, and/or results arrived at per the requirements of a research study protocol or scientific inquiry. The Research Record may include but is not limited to; research proposals, research protocol, laboratory records, both physical and electronic, progress reports, abstracts, theses, case report forms or their equivalent, electronic data records, regulatory files, IRB communications, signed informed consent forms, as well as any other documents or materials created for the Study and required to be submitted to a Sponsor or its agent, such as protocol required X-rays, MRIs, or other types of medical images, ECGs, EEGs, or other types of tracings or printouts, or data summaries, oral presentations, internal reports, journal articles, thesis dissertations and any documents or...
2.0 RESPONSIBILITIES: Copies of all research records must be retained by the principal investigator because federal regulations require that copies of these records be made available in the event of an FDA or other regulatory audit. Research records should be retained for study subjects including those who died during a clinical study or those who were enrolled but did not complete the study for any reason (See the FH ORA Data Management SOP).

2.1 The Principal Investigator will serve as the custodian of the research records for the projects approved at FH and as responsible agent for research record preservation, retention, and storage.

2.1.1 If the Principal Investigator is an employee of Florida Hospital or one of its affiliates he/she serves as the custodian on behalf of the institution.

2.1.2 If the research project is an Investigator Initiated Study, and there is no funder and/or sponsor, no other institutions participating in the study, and no contract in place claiming ownership of the research records, then the ownership of the research records lies within the institution of Florida Hospital.

2.2 Principal Investigator primary responsibilities regarding Research Records Retention & Storage that he/she may NOT delegate:

2.2.1 The responsibility of transferring custody of the research records.

2.3 Principal Investigator responsibilities that he/she MAY choose to delegate:

2.3.1 The responsibility of retaining the research records for the proper amount of time per applicable regulations.
2.3.2 The responsibility of maintaining the confidentiality of the research records and the privacy of the research subjects in his/her studies.
2.3.3 The responsibility of securing and maintaining adequate facilities, and storage space to maintain the research records in a physically secure area under the immediate control of the affiliated FH research department.
2.3.4 The Principal Investigator may choose to transfer custody of research records for a specific project to the affiliated FH research department, and therefore all related research records retention and storage responsibilities for that project as well. If the PI chooses to transfer custody of the records of a specific project, the transfer must be documented in a Note To File (NTF), and kept with the study regulatory documents. If the project is funded by a sponsor or other funding source, refer to the executed contract regarding any requirements related to research records custody, and notify them of the transfer of custody, and location of records.
3.0 PROCEDURES:

PLEASE NOTE: If there is a conflict of record retention time between two or more separate regulations, laws, or FH policy, all of which are pertinent to your project, the longer retention period will be followed. Furthermore, a fully executed contract involving a specific research study and any research record ownership, storage, and/or retention requirements agreed upon within the contract, may supersede the requirements of this SOP.

3.1 Research Records Retention Requirements for Industry or Commercially Sponsored Studies:

3.1.1 If the study is commercially sponsored or funded, the research records are placed in the custody of the Principal Investigator at each participating site. However, ownership of the research records will be stated in the contract with the sponsor. The contract must be reviewed for the specifics of research records ownership, as well as storage and retention requirements that the sponsor has outlined in the agreed upon, fully executed contract. The Sponsor may include additional research record retention requirements in the close out letter at the conclusion of the research study.

3.1.2 If the study is FDA regulated, an Investigational New Drug (IND) or Investigational Device Exemption (IDE) study, or a Humanitarian Use Device (HUD), then the FDA regulations for length of records retention must be followed accordingly. Currently, at the time of this SOP approval, effective date of Version 1, the FDA regulations for research records retention/storage for INDs and/or IDEs are as follows, (please always review the regulations for any possible changes following the date these were cited).

- FDA Regulation for INDs, 21 CFR Part 312.62: Investigators must retain records referred to as for a period of: 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated, OR If no application is to be filed, OR If the application is not approved for such indication, until 2 years after the investigation is discontinued and the FDA is notified
- FDA Regulation for IDEs, 21 CFR Part 812.140: The investigator will maintain the required records for a period of 2 years after the latter of the following two dates: (1) The date on which the investigation is terminated or completed, OR (2) The date that the records are no longer required for purposes of supporting a premarket approval application, OR (3) A notice of completion of a product development protocol. (HUDs should follow the same regulations as required for IDEs.)

3.1.3 If the study does not involve an IND or IDE and therefore, is not FDA regulated, then the minimum record retention period is seven (7) years in order to satisfy DHHS, OCR, and HIPAA regulations, as well as Florida State Law.
3.2 Research Records Retention Requirements for Non-Funded, Investigator-Initiated Studies in Human Subject Research:

3.2.1 If the study does not involve an IND or IDE and therefore, is not FDA regulated, then the minimum record retention period is seven (7) years in order to satisfy DHHS, OCR, and HIPAA regulations, as well as Florida State Law.

3.2.2 If it is possible that the research may support a future IND or IDE, then the records should be maintained per the FDA regulations regarding INDS and/or IDEs.

3.3 Research Records Retention Requirements for a Sponsor-Investigator, who holds the IND or IDE:

3.3.1 These studies fall into the FDA regulated studies for INDS and/or IDEs, and therefore are subject to the FDA regulations cited above in section 3.1.3

3.4 Research Records Retention Requirements for Research NOT involving Human Subjects

3.4.1 For research that does not involve human subjects, the research records retention period is a minimum of three (3) years.

3.5 Storage Conditions and Security of the storage area or facility

3.5.1 The storage area or facility should be conducive to the stability and protection of the records, preventing accidental or premature destruction of the records.

3.5.2 The storage area must be secure, and have limited physical and/or electronic access to research records in order to protect them from accidental or un-intentional release to unauthorized persons and to prevent the alteration, destruction, or loss of research records.

3.5.3 The storage area must have limited access in order to prevent the potential release of a sponsor’s proprietary information (such as the protocol, investigator’s brochure, and/or investigational device manual or Instructions for Use, IFU) and therefore prevent a breach of contract.

3.5.4 If research records are stored off-site (not on FH property or within the affiliated PI’s place of business), then an arrangement that protects the confidentiality of the research records must be in place, such as a Business Associate Agreement (BAA) between FH and the off-site storage facility prior to placing any records there for storage. FH currently does not stipulate which off-site storage facilities may be used for the storage of any hospital medical records or institutional research records. That decision is left up to the discretion of the department or in the case of research, the PI, or current custodian of the research records. Currently, at the time of this SOP approval, effective date of Version 1, FH has a Business Agreement in place with Iron Mountain and Assured Record Storage, Inc.
3.6 Changes in Research Records Custody and/or Location:

3.6.1 On the occasion of a Responsible Investigator of research records leaving the institution prior to the end of the required record retention period, he/she must transfer custody of the records to someone within FH. Custody of the records may be transferred to the affiliated FH research department or another investigator on the project that is either a FH employee or affiliate of FH (Internal question: Do we need an agreement on the disposition of research records, & we need to specify a right of access to those records.)

3.6.2 If the custody of the research records must be transferred to another Investigator for any reason, the original Investigator must find another investigator willing to accept responsibility for the research records.

3.6.3 Regardless of the reason, any time the custody of research records is transferred; written notice of the transfer should be documented in a Note to File (NTF) to the sponsor if applicable, and the affiliated FH research department. This written notification should be maintained in the study regulatory file.

3.6.4 The Investigator should inform the sponsor or appropriate party prior to moving the stored or archived study files to another location, and inform them of the new location. Documentation of the records relocation and the sponsor notification should be kept on file in the research project regulatory files.

3.7 Labeling and tracking stored records:

3.7.1 The stored or archived study files should be clearly and accurately labeled, and the storage location for each set of study files should be documented and kept somewhere for quick and easy access if the documents need to be retrieved.

3.7.2 The files and/or storage containers should be labeled with the following information:

- Study title
- Protocol number
- FH project number
- Principal Investigator name
- FH Research Department name and/or cost center
- Start and end dates of the project

3.8 Destruction of Research Records: When the proper storage period for the Research Records has been fulfilled, the destruction or transfer of the research records may be considered as follows:

3.8.1 Request permission to destroy - The Investigator should obtain written notification or permission from the Sponsor prior to any record destruction. If the sponsor grants permission for research records destruction, follow their guidelines for destroying the records.

3.8.2 If the sponsor does not have any specific guidelines for destroying research records, or if the study is an Investigator Initiated study, and is not funded by a sponsor, then follow the current FH process for the proper destruction of Protected Health Information (PHI).

3.8.3 A Note to File (NTF) should be maintained documenting the following:

- Study title
STANDARD OPERATING PROCEDURES

- Protocol number
- FH project number
- Principal Investigator name
- FH Research Department name and/or cost center
- Start and end dates of the project
- Date of destruction of the research records

3.8.4 It should also be noted in this document, the process used for destroying the records, such as, “the research records were placed in a locked shredder bin managed and provided by XXX shredding company”.

ADDITIONAL RECORD-KEEPING REQUIREMENTS:

3.9 Additional specific research records storage & retention requirements may be associated with research that includes, but is not limited to:

3.8.1 Use of hazardous radioactive or biological materials
3.8.2 Recombinant DNA
3.8.3 Animals
3.8.4 Funded by a grant and/or the federal government-See related Grants Policy
3.8.5 Records of Research Misconduct Proceedings
3.8.6 Research in support of a patent or other protected Intellectual Property (IP)
STANDARD OPERATING PROCEDURES


International Conference on Harmonization (ICH) Guidelines (E6) for Good Clinical Practices (GCPs): 4.9.4, 5.5.6, 5.5.7, 5.5.8, 5.5.10, 5.5.11, 5.5.12

Department of Health and Human Services (DHHS) protection of human subjects regulations: 45 CFR 46.115(a) and (b), 45 CFR 46.117

Office for Civil Rights and Health Insurance Portability and Accountability Act of 1996 (HIPAA)

Reviewed: Michelle Kilponen
Operations Specialist

Date: 7/19/11

Approved: Michelle Dolske, PhD
Administrative Director
Office of Research Administration

Date: 7/19/11