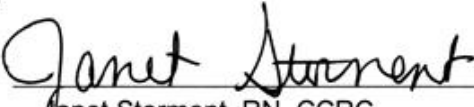

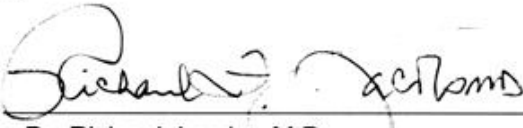




SOP No.: HSR-101-1.0	Replaces: (new)	Effective date: 1/31/2005
SOP title: Human Research Record Retention		
Signatures:		
Author:  Janet Storment, RN, CCRC Clinical Trials Administrator		Date: <u>1-24-05</u>
Reviewer:  Tanda Grisham, J.D. Legal and Human Protections Administrator		Date: <u>1-24-05</u>
Approval:  Dr. Richard Jacobs, M.D. President, Research		Date: <u>1-24-05</u>

1. Scope: The purpose of this Standard Operating Procedure is to ensure that Human Research Study records are maintained in accordance with all State and Federal regulations, and ACH policies.

ACHRI through ACH, contracts with a commercial off-site storage facility to store, control, protect and destroy inactive records. Human Research Study records will be packaged and stored in accordance with ACH Records Retention Policy #K 14 [k14_records_retention_policy.pdf](#) .

2. Applicability and Distribution: This SOP applies to (1) Principal Investigators conducting human subjects research on the ACH or ACHRI campus, and (2) ACHRI personnel responsible for helping Investigators follow this SOP. It will be made available to all Investigators and to ACHRI personnel in the administrative offices. Distribution of controlled hard copies will be documented per Attachment A.



3. Responsibilities:

ACHRI: The Research Institute is responsible for ensuring that documents are stored according to the current version of this SOP, and will ensure that sponsored research study budgets include provisions for long term storage.

Principal Investigator: It is the Principal Investigator's responsibility to comply with the current version of this SOP.

Regulatory Compliance Specialist: The specialist must ensure that this SOP is updated should there be a change in the state or federal regulatory requirements, or ACH policy requirements, for record retention.

4. Definitions:

Research Record is recorded information, in any medium, including paper, microfilm, magnetic tape, CDs, and any electronic form. Records include, but are not limited to, original document, patient diaries, electronically-captured data, and letters and emails necessary for reconstruction of study conduct that are generated and/or received while conducting the human research project.

5. Methods/Procedures: As of January 31, 2005, All Human Research Studies must have adequate storage funds secured in the study budgets.

ACHRI will work with the Investigator and Sponsors to ensure that adequate funds are secured to provide for long term storage and will work to ensure that inactive records are maintained, preserved and destroyed in accordance to with ACH/ACHRI policies, State and Federal Laws, regulations and contractual agreements.

The Investigator will contact ACHRI when the Human Research Study has closed in order to coordinate adequate storage of the Human Research Study records.

For Investigator Initiated Human Research Studies [with or without outside sponsor or contractual obligation] the Investigator must retain the study records in accordance with ACH, State and Federal Laws and regulations.

Destruction of Records:

ACHRI will establish the length of time that Human Research Study records are retained based upon relevant statutes, rules and regulations and contractual agreements from the sponsor involved.

Records may only be destroyed after the specified retention period has expired. ACHRI will notify the Investigator and Sponsor of the pending destruction. ACHRI may release the records to the Sponsor upon Sponsor's request thereby relieving ACHRI and/or Investigator of further storage obligations. If the Investigator or sponsor requests that storage continue past the recommended date, ACHRI will invoice the Investigator or Sponsor for the additional cost for storage. Per ACH Record Retention Policy #K-14, records relevant to the subject matter or a governmental investigation or litigation will not be destroyed until the investigation has been finally resolved.



GRANDFATHER CLAUSE:

Human Research Studies with contracts and budgets negotiated prior to January 31, 2005 that do not contain storage provisions will be entered into the storage ACHRI is providing above. Please contact ACHRI at 4-7373 to make necessary arrangements.

CLINICAL TRIAL RECORD RETENTION REQUIREMENT:

AGENCY	RETENTION PERIOD
Federal Drug Administration - Title 21 Part 312.57 PART 312 -- INVESTIGATIONAL NEW DRUG APPLICATION Investigational New Drugs (IND)	2 years after a marketing application is approved or 2 years after the investigation is discontinued and the FDA is notified.
Federal Drug Administration – Title 21 Part 812.140 PART 812 -- INVESTIGATIONAL DEVICE EXEMPTIONS Investigational Devices (IDE)	2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date the records are no longer required for purposes of supporting a pre-market approval application or a notice of completion of a product development protocol.
Department of Health and Human Services – Title 45, Subtitle A Part 74 http://frwebgate1.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=58774623178+64+0+0&WAIAction=retrieve	3 years from the date of submission of the final expenditure report
National Institutes of Health http://grants2.nih.gov/grants/policy/nihgps_2003/index.htm	3 years from the date the annual FSR is submitted
State of Arkansas – Medical Records Minors	10 years after discharge plus 2 years past the age of majority (in Arkansas it is 18 years of age). Example: subject age 0 record retention will be 20 years; Subject age 8 record retention will be 12 years; Subject age 17 record retention will be 10 years.
Arkansas Children’s Hospital - Records Retention Policy #K 14.	Same as State law: 10 years after discharge plus 2 years past majority.



<p>International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Section 4.9.5 Records and Reports http://www.ich.org/UrlGrpServer.jserv?@_ID=276&@_TEMPLATE=254</p>	<p>Retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product</p>
---	--

6. Revision history:

Date of Revision	Changed by	Original text (old version number)	Replaced with (new version number)
		new SOP	n/a



ATTACHMENT A to SOP

Distribution of Controlled Copies of SOP HSR- 101-1.0

SOP ID	SOP effective date	Given to	Date	Copy number	Date replaced with new version