

Standard Operating Procedure (SOP)

SOP #: 401.140	HRP-140 IRB Records Retention
Executive Owner: Vice President Research Operations	Effective Date: 7/15/2015
	Review Date: 10/03/2019

Scope	This SOP applies to HRPP staff members.
Purpose	This procedure establishes the process to retain IRB records. This procedure begins every seven months. This procedure ends when all records that are no longer required to be retained are destroyed.
Qualified Personnel	HRPP staff members carry out these procedures.
Training	Not applicable.
Supplies & Equipment	Not applicable.
Procedure	<ol style="list-style-type: none"> 1. Study files designated by legal counsel as being on “legal hold” are not to be destroyed until the legal hold is removed. 2. Study files relating to research requiring continuing review which has not been conducted are retained for at least 7 years after the last IRB action. 3. Study files relating to research requiring continuing review which has been conducted are retained for at least 7 years after completion of the research, regardless of whether there was subject enrollment. 4. Study files relating to research not requiring continuing review are retained for at least 7 years after the last IRB action. 5. Incomplete study files that were never finalized and sent to <Committee Review> or <Non-Committee Review> are retained for at least 7 years after the last IRB action. 6. The following documents are retained indefinitely: <ol style="list-style-type: none"> 6.1. IRB meeting minutes 6.2. A resume or curriculum vitae for each IRB member 6.3. Current and previous versions of IRB member rosters 6.4. Current and previous versions of controlled documents 7. Review the study files that can be destroyed. <ol style="list-style-type: none"> 7.1. Omit destruction of records on a legal hold. 7.2. Previously approved studies requiring continuing review: Seven years after the date on which all research sites overseen by Florida Hospital’s IRB have been completed either through closure, <Termination of IRB Approval>, disapproval, or lapse of approval 7.3. Research never approved and research not requiring continuing review: Seven years after the last IRB action or after withdrawal by the submitter 8. Shred paper documents and dispose the shredded materials securely.

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9. Notify information technology to destroy electronic documents by either deleting the files or replacing the files with stub files documenting the date of deletion.
10. Document your name and the date of destruction with the following for each study file destroyed:
 - 10.1. Study title
 - 10.2. IRB ID
 - 10.3. Date of completion
 - 10.4. Paper, electronic, or both

Definition(s)

IRB: Institutional Review Board

Reference(s)

21 CFR §56.115
45 CFR §46.115

Related Documents

Not applicable.

Keywords

IRB, institutional review board, IRB member