



HRP-105 | 2/2/2024

OHRP FDA WRITTEN PROCEDURE CROSSWALK

The purpose of this document is to provide cross reference between IRB written procedure guidance prepared jointly by the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA)¹ as published in May 2018 and the standard delivered HRPP Toolkit. This document is to be used for the purposes of determining what information should be covered in written procedures rather than a tool for assessing compliance. It may be utilized for HRPP self-evaluation and/or as audit/inspection support.

I. IRB Initial and Continuing Review of Research; Reporting IRB Findings and Actions

REGULATORY REQUIREMENT – Each IRB must follow written procedures for conducting initial and continuing review of research and for reporting IRB findings and actions to the investigator and the institution [45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1)]

RECOMMENDATIONS - Operational details should include the following to address HHS and FDA requirements for IRB written procedures:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes
1. Conducting reviews at a meeting of the convened IRB ² including:	
Documents submitted to the IRB for review (e.g., protocol, informed consent form, recruitment materials).	HRP-040 - SOP - IRB Meeting Preparation
Reviewer system utilized by the convened IRB (e.g., primary reviewer(s)).	HRP-040 - SOP - IRB Meeting Preparation
Documents routinely distributed to all IRB members and those that may be distributed to specific IRB members (e.g., primary reviewer(s)).	HRP-040 - SOP - IRB Meeting Preparation
Range of possible actions the convened IRB can take.	HRP-041 - SOP - IRB Meeting Conduct

¹ <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#toc>

² https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn4

Format of a convened meeting (e.g., in person, videoconferencing, other mechanism).	HRP-041 - SOP - IRB Meeting Conduct
Defining and maintaining quorum and the process followed if quorum is lost. ³	HRP-042 - SOP - IRB Meeting Attendance Monitoring
Managing IRB members/alternates with conflicting interests.	HRP-050 - SOP - Conflicting Interests of IRB Members
2. Conducting review via expedited review procedures ⁴ including:	
Documents submitted to the IRB for review.	HRP-021 - SOP - Pre-Review
Reviewer system utilized for expedited review (e.g., IRB chairperson or other experienced reviewer(s) designated by the chairperson from among the members of the IRB).	HRP-030 - SOP - Designated Reviewers
Range of possible actions the designated expedited reviewer can take.	HRP-032 - SOP - Non-Committee Review Conduct
Method used for keeping all IRB members advised of research proposals approved via expedited review.	HRP-043 - SOP - IRB Meeting Minutes
3. Determining that the criteria for IRB approval of research are met. ⁵	HRP-314 – WORKSHEET – Criteria for Approval
4. Information about reviewing the informed consent form and the informed consent process ⁶ including:	
Consideration of the required and additional elements of informed consent.	HRP-314 - WORKSHEET - Criteria for Approval
Translation of the informed consent form for non-English speaking subjects, when applicable.	HRP-090 - SOP - Informed Consent Process for Research
For HHS-conducted or -supported research, consideration of a waiver or alteration of the consent procedure. ⁷	HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
For both HHS-conducted or -supported research and FDA-regulated research, consideration of a waiver of documentation of consent.	HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
5. Considering whether the study involves subjects that are likely to be vulnerable to coercion or undue influence, and, if so, whether additional	HRP-314 - WORKSHEET - Criteria for Approval

³ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn5

⁴ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn7

⁵ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn6

⁶ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn8

⁷ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn9

safeguards have been included to protect the rights and welfare of these subjects ⁸	
6. Reviewing studies requesting exceptions from informed consent requirements for emergency research ⁹	HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research
7. For FDA-regulated research, assessing whether the investigator and/or sponsor determined that an investigational new drug application (IND) or investigational device exemption (IDE) is required for the proposed study, if applicable, and the basis for this determination ¹⁰	HRP-306 - WORKSHEET - Drugs and Biologics HRP-307 - WORKSHEET - Devices
8. For FDA-regulated medical device research, making and documenting the significant/nonsignificant risk (SR/NSR) determination ¹¹	HRP-418 - CHECKLIST - Non-Significant Risk Device
9. For HHS-conducted or -supported research, determining the applicability of additional protections for pregnant women, human fetuses and neonates, and for prisoners ¹²	HRP-412 - CHECKLIST - Pregnant Women HRP-413 - CHECKLIST - Non-Viable Neonates HRP-414 - CHECKLIST - Neonates of Uncertain Viability HRP-415 - CHECKLIST - Prisoners
10. Reviewing research involving children as subjects in accordance with applicable regulations. ¹³	HRP-416 – CHECKLIST - Children
11. Reviewing the qualifications of the investigator(s) and study staff, and the adequacy of the site where the research will be conducted, including any institutional requirements for sponsor-investigator studies, if applicable.	Note: HRP-314 - WORKSHEET - Criteria for Approval requires that the research has the resources necessary to protect subjects (i.e. time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.). However, as the parameters of these resources will vary based on institutional capabilities and research protocol requirements, institutionally specific language should be incorporated into HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN. HRP-103 - INVESTIGATOR MANUAL HRP-306 - WORKSHEET - Drugs and Biologics HRP-307 - WORKSHEET - Devices

⁸ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn10

⁹ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn11

¹⁰ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn12

¹¹ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn13

¹² https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn14

¹³ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn15

12. Determining and documenting the effective date of initial approval and calculating the date for subsequent continuing review.	HRP-041 - SOP - IRB Meeting Conduct
13. Communicating the IRB's findings and actions to both the investigator and the institution ¹⁴ , including:	
Which institutional office(s)/official(s) are notified.	HRP-052 - SOP - Post-Review
Communicating to the investigator any modifications or clarifications required by the IRB as a condition of approval.	HRP-052 - SOP - Post-Review HRP-303 - WORKSHEET - Communication of Review Results HRP-512 - LETTER - Mods Req to Secure Approval
Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.	HRP-021 - SOP - Pre-Review
Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.	HRP-052 - SOP - Post-Review
14. For FDA-regulated research, reviewing a request for expanded access or treatment use. ¹⁵	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
15. For FDA-regulated research, reviewing the emergency use of a test article. ¹⁶	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
16. For FDA-regulated research, reviewing a request for the use of a Humanitarian Use Device (HUD). ¹⁷	HRP-323 - WORKSHEET - Criteria for Approval HUD

II. Frequency of IRB Review; Verification Regarding Material Changes

Regulatory Requirement - Each IRB must follow written procedures for determining which projects require review more often than annually and determining which projects need verification from sources other than the investigator that no material changes have occurred since previous IRB review [45 CFR 46.103(b)(4)(ii), 21 CFR 56.108(a)(2)]

RECOMMENDATIONS - Operational details should include information about:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes
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¹⁴ <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#toc>

¹⁵ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn17

¹⁶ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn18

¹⁷ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn19

17. Determining the approval period/continuing review interval of the proposed research, including:	HRP-302 - WORKSHEET - Approval Intervals
General criteria used to make these determinations (e.g., the nature of the study and risks posed by the study; the degree of uncertainty regarding the risks involved; the vulnerability of the subject population; the experience of the investigator; the IRB's previous experience with the investigator and/or sponsor; the projected rate of enrollment; whether the study involves novel therapies).	HRP-041 - SOP - IRB Meeting Conduct
Documenting the approval period/continuing review interval (e.g., in the IRB meeting minutes or elsewhere in the IRB records).	HRP-041 - SOP - IRB Meeting Conduct
Communicating the IRB's determinations regarding the approval period/continuing review interval to the investigator.	HRP-052 - SOP - Post-Review
18. Determining whether the proposed research requires verification from sources other than the investigator, such as the sponsor, or other third party, that no material changes have occurred since the last IRB review, including the general criteria utilized to make the determination (e.g., complex projects; investigators with previous compliance issues; continuing review report indicates changes not previously reported; randomly selected projects).	HRP-212 - FORM - Continuing Review

III. Reporting of Proposed Changes to the IRB; Prior IRB Review and Approval of Changes

REGULATORY REQUIREMENT – Each IRB must follow written procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects [45 CFR 46.103(b)(4)(iii), 21 CFR 56.108(a)(3) and (4)]

RECOMMENDATIONS - Operational details should include information about:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes
19. Reporting changes in research to the IRB, including:	
Informing investigators that they may not initiate changes to research without prior IRB review and approval except when necessary to eliminate apparent immediate hazards to subjects (e.g., through	HRP-103 - INVESTIGATOR MANUAL

training programs, materials for investigators, specific directives included in approval letters to investigators).	
Ensuring that changes in research are being reported to the IRB before they are initiated (e.g., random audits of research records).	HRP-103 - INVESTIGATOR MANUAL HRP-430 - CHECKLIST - Investigator Quality Improvement Assessment
Process for notifying the IRB of any changes made to eliminate apparent immediate hazards to subjects that did not have prior IRB approval.	HRP-103 - INVESTIGATOR MANUAL
20. Reviewing changes in research, including:	
What might qualify as a minor change in research.	HRP-313 - WORKSHEET - Expedited Review
Documents submitted to the IRB for changes in research.	HRP-213 - FORM - Modification
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take.	HRP-041 - SOP - IRB Meeting Conduct HRP-402 - CHECKLIST - Non-Committee Review
Assessment of whether the IRB-approved informed consent form requires revision.	HRP-314 - WORKSHEET - Criteria for Approval
21. Communicating the IRB's findings and actions for changes in research to both the investigator and the institution ¹⁸ , including:	
Which institutional office(s)/official(s) are notified.	HRP-052 - SOP - Post-Review
Communicating to the investigator and the institution any modifications or clarifications required by the IRB as a condition of approval.	HRP-041 - SOP - IRB Meeting Conduct HRP-043 - SOP - IRB Meeting Minutes HRP-052 - SOP - Post-Review
Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.	HRP-021 - SOP - Pre-Review
Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.	HRP-041 - SOP - IRB Meeting Conduct HRP-043 - SOP - IRB Meeting Minutes

¹⁸ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn20

IV. Reporting of Unanticipated Problems, Serious or Continuing Noncompliance, and Any Suspension or Termination of IRB Approval

REGULATORY REQUIREMENT - Each IRB must follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA of any unanticipated problems involving risks to human subjects or others, any instance of serious or continuing noncompliance with the applicable HHS and/or FDA regulations, or the requirements or determinations of the IRB, and any suspension or termination of IRB approval [45 CFR 46.103(a) and (b)(5), 21 CFR 56.108(b)]

RECOMMENDATIONS - Operational details should include information about:

Activity as Defined by Guidance	Relevant HRPP Toolkit ID Numbers and Notes
22. Identifying who is responsible for promptly reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP, and/or FDA any ¹⁹	HRP-024 - SOP - New Information
Unanticipated problems involving risks to human subjects or others.	HRP-024 - SOP - New Information
Serious or continuing noncompliance.	HRP-024 - SOP - New Information
Suspension or termination of IRB approval.	HRP-024 - SOP - New Information HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
23. Reviewing information about unanticipated problems involving risks to human subjects or others ²⁰ , including:	
What might qualify as an unanticipated problem involving risks to human subjects or others, including adverse events that should be considered unanticipated problems.	HRP-214 - FORM - Reportable New Information
Documents submitted to the IRB regarding an unanticipated problem (e.g., written summary of the unanticipated problem, the outcome, and any steps taken to prevent recurrence).	HRP-214 - FORM - Reportable New Information
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.	HRP-024 - SOP - New Information

¹⁹ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn21

²⁰ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn22

24. Reviewing information about serious or continuing noncompliance with the regulations or IRB requirements or determinations ²¹ , including:	
What might qualify as serious or continuing noncompliance.	HRP-001 - SOP - Definitions
Documents submitted to the IRB regarding serious or continuing noncompliance (e.g., written summary of the noncompliance, the outcome, and any steps taken to prevent recurrence).	HRP-214 - FORM - Reportable New Information
Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.	HRP-024 - SOP - New Information
25. Suspending or terminating approval of research that is not being conducted in accordance with the IRB's requirements, or that has been associated with unexpected serious harm to subjects ²² , including:	
Circumstances in which suspending or terminating IRB approval might be appropriate.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Consideration of subjects already enrolled (e.g., informing subjects about the suspension or termination).	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Orderly termination of the study, or transfer of the study or study subjects, if applicable.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB
Communicating the reason(s) for the IRB's decision to suspend or terminate approval of the research.	HRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB

v. Additional Topics the Institution/IRB May Consider

a. Scope and Authority

Activity	Relevant HRPP Toolkit ID Numbers and Notes
26. The development and scope of the written procedures (e.g., who is responsible for preparing and maintaining them, including writing,	HRP-061 - SOP - Quarterly Evaluations of the HRPP

²¹ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn23

²² https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn24

revising, and approving; how often they are reviewed and updated, who they apply to; what happens if they are not followed).	
27. The institutional authority under which the IRB is established and authorized, and the independence afforded the IRB to carry out its duties.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
28. The ethical principles that govern the IRB in assuring that the rights and welfare of human subjects are protected.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
29. Important regulatory definitions that guide the IRB's review processes and procedures (e.g., the definition of research, clinical investigation, human subject, minimal risk).	HRP-001 - SOP - Definitions
30. Other relevant federal regulations that may apply to human subject research (e.g., Health Insurance Portability and Accountability Act regulations, Department of Defense regulations).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
31. Which institutional office(s) or official(s), if any, is responsible for further review and approval, or disapproval, of research that is approved by the IRB. ²³	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
32. The IRB's relationship to the administration of the institution, the other committees and department chairpersons within the institution, the research investigators, other institutions, and the regulatory agencies.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

b. IRB Membership

Activity	Relevant HRPP Toolkit ID Numbers and Notes
33. The number of members on the IRB ²⁴ .	HRP-080 - SOP - IRB Formation and Registration
34. Ensuring diversity in IRB membership (e.g., representation of both genders, multiple professions, scientific and nonscientific members, nonaffiliated members) ²⁵ .	HRP-304 - WORKSHEET - IRB Composition HRP-601 - DATABASE - IRB Roster

²³ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn25

²⁴ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn26

²⁵ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn27

35. Selecting and appointing the IRB chairperson, the members, and alternate members if any, including:	
The length of term or service, general description of duties, attendance requirements, performance evaluation, including removal if necessary.	HRP-082 - SOP - IRB Membership Addition HRP-083 - SOP - IRB Membership Removal
The qualifications of the IRB chairperson, members and any alternate members ²⁶ .	HRP-082 - SOP - IRB Membership Addition HRP-304 - WORKSHEET - IRB Composition
The criteria used to categorize members and alternate members as scientist, nonscientist, and nonaffiliated ²⁷ .	HRP-082 - SOP - IRB Membership Addition HRP-202 - FORM - IRB Member Information
36. Defining what constitutes a conflicting interest for the IRB chairperson, members, and alternate members, and managing any such conflicting interest, including recusal from a meeting to ensure that a chairperson, member, or alternate member with a conflicting interest does not vote or count towards the quorum ²⁸ .	HRP-050 - SOP - Conflicting Interests of IRB Members
37. Training and education provided to the IRB chairperson, IRB members, alternate members, administrative support staff, and investigators.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

c. IRB Functions and Operations

Activity	Relevant HRPP Toolkit ID Numbers and Notes
38. Determining whether a study is subject to IRB review (e.g., what types of studies must be reviewed, which regulations apply, who makes the determination).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
39. Determining which HHS-conducted or -supported research studies qualify as exempt from the HHS regulations, including who makes the determination.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

²⁶ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn28

²⁷ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn29

²⁸ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn30

40. Implementing cooperative IRB review arrangements, when applicable, such as joint review, reliance on the review of another qualified IRB, or similar arrangements aimed at avoiding duplication of effort ²⁹ .	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
41. Process for reporting the emergency use of an FDA-regulated test article to the IRB ³⁰ .	HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access
42. The use of consultants by the IRB ³¹ , including a description of the process to identify the need for a consultant, to choose a consultant, and the consultant's participation in the review of research.	HRP-041 - SOP - IRB Meeting Conduct
43. Identifying and managing an investigator with a conflicting interest.	HRP-055 - SOP - Financial Conflicts of Interests
44. Determining the applicability of state and local laws ³² .	Note: As state and local law varies from institution to institution, local language should be incorporated into relevant Toolkit documents as needed.
45. Tracking study approvals and scheduling continuing review to prevent lapses in IRB approval, including procedures to follow if IRB approval lapses.	HRP-062 - SOP - Daily Tasks HRP-063 - SOP - Expiration of IRB Approval
46. Handling subject complaints, problems, concerns and questions about rights as a research subject.	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN HRP-024 - SOP - New Information
47. Administrative support staff duties.	Note: Individual SOPs indicate the party responsible for carrying out procedures. HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN specifies additional duties and responsibilities in the Components section.
48. Keeping the IRB informed of study completion and close out to ensure record retention in compliance with 45 CFR 46.115(b) and/or 21 CFR 56.115(b).	HRP-103 - INVESTIGATOR MANUAL

²⁹ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn31

³⁰ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn32

³¹ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn33

³² https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn34

49. Registering the IRB and maintaining IRB registration ³³ via the HHS Internet-based registration system ³⁴ .	HRP-080 - SOP - IRB Formation and Registration
50. Providing access to information about IRB requirements and written procedures (e.g., posting the information on a website accessible to the investigators, sponsors, and others).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN
51. Contingency plans for transferring oversight of one or more studies to another institution or IRB in the event the IRB is unable to continue oversight of the study (e.g., the IRB closes, suffers loss due to fire, natural disaster).	HRP-101 - HUMAN RESEARCH PROTECTION PROGRAM PLAN

d. IRB Records

Activity	Relevant HRPP Toolkit ID Numbers and Notes
52. Maintaining records required to be retained ³⁵ , and other records (e.g., IRB member training records).	HRP-072 - SOP - IRB Records Retention
53. Where records are stored (e.g., on site, off-site archives), and the format for record storage (e.g., hard copy, electronic or both).	HRP-070 - SOP - IRB Records
54. Preparing and maintaining minutes of IRB meetings ³⁶ .	HRP-043 - SOP - IRB Meeting Minutes
55. Retaining records for at least 3 years after completion of the research, and ensuring records are accessible for inspection ³⁷ .	HRP-072 - SOP - IRB Records Retention

³³ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn35

³⁴ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn36

³⁵ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn37

³⁶ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn38

³⁷ https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn39