HRP-105 | 02/01/2024

**OHRP FDA WRITTEN PROCEDURE CROSSWALK**

The purpose of this document is to provide cross reference between IRB written procedure guidance prepared jointly by theDepartment of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA)[[1]](#footnote-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.

1. **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:

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| **Activity as Defined by Guidance** | **Relevant HRPP Toolkit ID Numbers and Notes** |
| 1. Conducting reviews at a meeting of the convened IRB[[2]](#footnote-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 |
| 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]](#footnote-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]](#footnote-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]](#footnote-5) | HRP-314 – WORKSHEET – Criteria for Approval  |
| 4. Information about reviewing the informed consent form and the informed consent process[[6]](#footnote-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]](#footnote-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 safeguards have been included to protect the rights and welfare of these subjects[[8]](#footnote-8) | HRP-314 - WORKSHEET - Criteria for Approval |
| 6. Reviewing studies requesting exceptions from informed consent requirements for emergency research[[9]](#footnote-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]](#footnote-10) | HRP-306 - WORKSHEET - Drugs and BiologicsHRP-307 - WORKSHEET - Devices |
| 8. For FDA-regulated medical device research, making and documenting the significant/nonsignificant risk (SR/NSR) determination[[11]](#footnote-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]](#footnote-12) | HRP-412 - CHECKLIST - Pregnant WomenHRP-413 - CHECKLIST - Non-Viable Neonates HRP-414 - CHECKLIST - Neonates of Uncertain ViabilityHRP-415 - CHECKLIST - Prisoners |
| 10. Reviewing research involving children as subjects in accordance with applicable regulations.[[13]](#footnote-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 MANUALHRP-306 - WORKSHEET - Drugs and BiologicsHRP-307 - WORKSHEET - Devices |
| 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](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn16)[[14]](#footnote-14)[, including:](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn16) |  |
| 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-ReviewHRP-303 - WORKSHEET - Communication of Review ResultsHRP-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]](#footnote-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]](#footnote-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]](#footnote-17) | HRP-323 - WORKSHEET - Criteria for Approval HUD |

1. **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:

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| **Activity as Defined by Guidance** | **Relevant HRPP Toolkit ID Numbers and Notes** |
| 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 |

1. **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:

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| **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 training programs, materials for investigators, specific directives included in approval letters to investigators). | HRP-103 - INVESTIGATOR MANUAL |
| 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 ConductHRP-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]](#footnote-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 ConductHRP-043 - SOP - IRB Meeting MinutesHRP-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 ConductHRP-043 - SOP - IRB Meeting Minutes |

1. **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:

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| **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]](#footnote-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 InformationHRP-026 - SOP - Suspension or Termination Issued Outside of Convened IRB |
| 23. [Reviewing information about unanticipated problems involving risks to human subjects or others](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn22)[[20]](#footnote-20)[, including:](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn22) |  |
| 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 |
| 24. Reviewing information about serious or continuing noncompliance with the regulations or IRB requirements or determinations[[21]](#footnote-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]](#footnote-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 |

1. **Additional Topics the Institution/IRB May Consider**

**a. Scope and Authority**

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| **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, revising, and approving; how often they are reviewed and updated, who they apply to; what happens if they are not followed). | HRP-061 - SOP - Quarterly Evaluations of the HRPP |
| 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]](#footnote-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**

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| **Activity** | **Relevant HRPP Toolkit ID Numbers and Notes** |
| 33. The number of members on the IRB[[24]](#footnote-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)](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn27)[[25]](#footnote-25)[.](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn27) | HRP-304 - WORKSHEET - IRB CompositionHRP-601 - DATABASE - IRB Roster |
| 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 AdditionHRP-083 - SOP - IRB Membership Removal |
| The qualifications of the IRB chairperson, members and any alternate members[[26]](#footnote-26). | HRP-082 - SOP - IRB Membership AdditionHRP-304 - WORKSHEET - IRB Composition |
| The criteria used to categorize members and alternate members as scientist, nonscientist, and nonaffiliated[[27]](#footnote-27). | HRP-082 - SOP - IRB Membership AdditionHRP-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]](#footnote-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**

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| **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 |
| 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]](#footnote-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]](#footnote-30).  | HRP-023 - SOP - Emergency Use, Compassionate Use, Indiv Patient Expanded Access |
| 42. The use of consultants by the IRB[[31]](#footnote-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. | VCU Conflicts of Interest in Research policy:<https://vcu.public.doctract.com/doctract/documentportal/08DA32A63EDBCC96C898EA6EC61CFF0A> |
| 44. Determining the applicability of state and local laws[[32]](#footnote-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 - Periodic TasksHRP-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 PLANHRP-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 |
| 49. Registering the IRB and maintaining IRB registration[[33]](#footnote-33) via the HHS Internet-based registration system[[34]](#footnote-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**

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| **Activity** | **Relevant HRPP Toolkit ID Numbers and Notes** |
| 52. Maintaining records required to be retained[[35]](#footnote-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]](#footnote-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]](#footnote-37). | HRP-072 - SOP - IRB Records Retention |

1. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#toc> [↑](#footnote-ref-1)
2. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn4> [↑](#footnote-ref-2)
3. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn5> [↑](#footnote-ref-3)
4. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn7> [↑](#footnote-ref-4)
5. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn6> [↑](#footnote-ref-5)
6. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn8> [↑](#footnote-ref-6)
7. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn9> [↑](#footnote-ref-7)
8. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn10> [↑](#footnote-ref-8)
9. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn11> [↑](#footnote-ref-9)
10. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn12> [↑](#footnote-ref-10)
11. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn13> [↑](#footnote-ref-11)
12. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn14> [↑](#footnote-ref-12)
13. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn15> [↑](#footnote-ref-13)
14. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#toc> [↑](#footnote-ref-14)
15. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn17> [↑](#footnote-ref-15)
16. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn18> [↑](#footnote-ref-16)
17. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn19> [↑](#footnote-ref-17)
18. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn20> [↑](#footnote-ref-18)
19. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn21> [↑](#footnote-ref-19)
20. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn22> [↑](#footnote-ref-20)
21. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn23> [↑](#footnote-ref-21)
22. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn24> [↑](#footnote-ref-22)
23. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn25> [↑](#footnote-ref-23)
24. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn26> [↑](#footnote-ref-24)
25. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn27> [↑](#footnote-ref-25)
26. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn28> [↑](#footnote-ref-26)
27. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn29> [↑](#footnote-ref-27)
28. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn30> [↑](#footnote-ref-28)
29. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn31> [↑](#footnote-ref-29)
30. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn32> [↑](#footnote-ref-30)
31. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn33> [↑](#footnote-ref-31)
32. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn34> [↑](#footnote-ref-32)
33. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn35> [↑](#footnote-ref-33)
34. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn36> [↑](#footnote-ref-34)
35. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn37> [↑](#footnote-ref-35)
36. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn38> [↑](#footnote-ref-36)
37. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html#_ftn39> [↑](#footnote-ref-37)