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# Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs

**U.S. Department of Health and Human Services  
Office for Human Research Protections (OHRP)**

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Office of Good Clinical Practice (OGCP)  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
Center for Devices and Radiological Health (CDRH)  
Office of Regulatory Affairs (ORA)**

**May 2018**

Contains Nonbinding Recommendations

# Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs

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## Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs

This guidance represents the Office for Human Research Protections' (OHRP's) and the Food and Drug Administration's (FDA's) current thinking on this topic. This guidance does not create or confer any rights for or on any person and does not operate to bind OHRP, FDA, or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate OHRP or FDA staff responsible for implementing this guidance. If you cannot identify the appropriate OHRP or FDA staff, call the appropriate number listed on the second title page of this guidance.

### I. INTRODUCTION

This guidance has been prepared jointly by the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA). To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts. In addition, on December 13, 2016, the 21st Century Cures Act (Cures Act) (Pub. L. 114-255) was signed into law. Title III, section 3023 of the Cures Act requires the Secretary of HHS to harmonize differences between the HHS human subject regulations and FDA's human subject regulations. This guidance document is consistent with the goals of section 3023 of the Cures Act. This guidance is intended for institutions and institutional review boards (IRBs) responsible for review and oversight of human subject research under the HHS and FDA regulations.

OHRP and FDA believe that when institutions and IRBs develop and follow clear written procedures, there is an increased likelihood that the rights and welfare of human subjects will be protected. The purpose of this guidance is to assist staff at institutions and IRBs who are responsible for preparing and maintaining written procedures. The guidance includes a Written Procedures Checklist (also referred to in this guidance as the Checklist) that incorporates the HHS and FDA regulatory requirements for written procedures for the IRB and recommendations on the type of operational details to include to support each of these requirements. In addition, the Checklist includes some additional topics the institution/IRB may consider when developing comprehensive procedures.

OHRP's and FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes OHRP's and FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *must* in OHRP and FDA joint guidance means that something is required under the HHS regulations at 45 CFR part 46 or the FDA regulations at 21 CFR parts 50 and 56. The use of the word *should* in OHRP and FDA joint guidance means that something is suggested or recommended, but not required.

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Note: References in this guidance to HHS regulations at 45 CFR part 46, subpart A, are to this subpart in effect at the time this guidance is published, and not to subpart A as amended by a final rule published January 19, 2017 (82 Fed. Reg. 7149) and not to an interim final rule published January 22, 2018 (83Fed.Reg. 2885).

### **II. BACKGROUND**

IRBs must comply with HHS and FDA regulations in 45 CFR part 46 and 21 CFR parts 50 and 56, respectively, when reviewing research subject to those regulations. Both the HHS regulations at 45 CFR 46.103(b)(4) and (5) and the FDA regulations at 21 CFR 56.108(a) and (b) state that IRBs must follow written procedures for the following functions and operations:

1. Conducting initial and continuing review of research and reporting findings and actions to the investigator and the institution;
2. 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;
3. 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;
4. Ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head (i.e., OHRP) for research conducted or supported by HHS, and FDA for FDA-regulated research of any:
  - Unanticipated problems involving risks to human subjects or others;
  - Instance of serious or continuing noncompliance with the applicable HHS and FDA regulations or the requirements or determinations of the IRB;
  - Suspension or termination of IRB approval.

### **III. DISCUSSION**

OHRP and FDA frequently receive questions about the scope and content of written procedures. We recognize that written procedures may vary among institutions and IRBs because of differences in the way organizations are structured, the type of research studies reviewed by the IRB, institutional policy or administrative practices, the number of IRBs at the institution, affiliation with an institution, and local and state laws and regulations. To provide guidance on the appropriate content of written procedures, while considering these variations, this guidance provides a Written Procedures Checklist to assist institutions and IRBs in preparing and maintaining detailed written procedures. The Checklist is designed to prompt a thorough evaluation of written procedures that help to ensure the protection of human research subjects.

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HHS and FDA regulations<sup>1</sup> allow flexibility in both format and content of written procedures, which gives IRBs the ability to establish procedures best suited to their own operations. Written procedures may be maintained electronically or may be paper-based and formatted in a style that conforms to the needs of the institution. Institutions/IRBs may choose to create written procedures that focus solely on the regulatory responsibilities of the IRB, or they may choose to also incorporate institutional policies and procedures that are a function of the institution's Human Research Protections Program (HRPP). Detailed administrative procedures for the IRB support staff (e.g., how and where to track study approvals for calculating continuing review) may be included, or may be managed through other locally written policies and procedures (e.g., work instructions, standard operating procedures (SOPs), or a staff operations manual). Institutions and IRBs should use the flexibility afforded by the regulations to adopt written procedures that are suitable for their organizations.

OHRP and FDA have observed that some IRBs develop written procedures for the IRB that simply restate the regulations at 45 CFR 46.103(b)(4) and (5), and at 21 CFR 56.108(a) and (b). In general, this approach does not provide sufficient detail about the IRB's operations to ensure that the IRB's operations meet the applicable regulatory requirements. Developing meaningful content for written procedures involves a comprehensive and critical assessment of the IRB's responsibilities, functions, and operations, and the institution's organizational structure. Written procedures should be sufficiently detailed to help IRB members and institutional administrative staff understand how to carry out their duties in a consistent and effective way that ensures that the rights and welfare of subjects are protected and that the IRB operates in compliance with the regulations. When preparing written procedures, institutions/IRBs should generally identify who carries out specific duties by reference to position title (e.g., IRB chairperson) rather than by name to avoid the need to update written procedures if duties change, or there are changes in IRB membership.

Both OHRP and FDA have issued many guidance documents<sup>2</sup> that cover numerous topics that may serve as useful resources to staff at institutions and IRBs who prepare written procedures. For example, guidance on IRB continuing review of research<sup>3</sup> offers recommendations about the type of information to include in written procedures specific to continuing review, which should be incorporated into the written procedures for the IRB. We recommend that institutions/IRBs review all relevant OHRP and FDA guidance documents when preparing written procedures.

Institutions/IRBs may decide to make their written procedures available to ensure that others (e.g., investigators, sponsors) are aware of the IRB's requirements, and to facilitate compliance. Some institutions/IRBs post their written procedures on a website to provide broad access. Written procedures should be reviewed on a regular basis and updated as necessary to ensure they reflect the institution's/IRB's current processes.

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<sup>1</sup>See 45 CFR 46.103(b)(4) and (5), 21 CFR 56.108(a) and (b).

<sup>2</sup>See <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/alphabetical-list/index.html>, <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.htm>, <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm>.

<sup>3</sup>See <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html>, <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf>.

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### IV. WRITTEN PROCEDURES CHECKLIST

Sections I-IV of the Written Procedures Checklist identify each HHS and FDA regulatory requirement for written procedures for the IRB set forth in 45 CFR 46.103(b)(4) and (5) and 21 CFR 56.108(a) and (b) (**REGULATORY REQUIREMENT**) along with suggestions (**RECOMMENDATIONS**) about operational details to include in support of each regulatory requirement. Section V of the Written Procedures Checklist identifies some additional topics the institution/IRB may consider when developing comprehensive procedures.

Although the IRB must follow written procedures for functions and operations specifically described at 45 CFR 46.103(b)(4) and (5), and/or 21 CFR 56.108(a) and (b), there are other IRB activities that require findings and determinations for which the underlying regulations do not explicitly require the IRB to follow a written procedure. The Checklist includes footnotes that identify these underlying regulations, as well as other relevant regulations that we recommend institutions and IRBs consider when preparing written procedures.

For example, an IRB that reviews studies involving children must follow the regulatory requirements for additional safeguards for children at 45 CFR part 46, subpart D, and/or 21 CFR part 50, subpart D, and approve only those studies that satisfy the conditions of all applicable sections of those subparts. Although the subpart D regulations do not explicitly require an IRB to follow a written procedure for review of studies involving children, OHRP and FDA recommend that written procedures for the IRB address the review of such studies (see recommendation #10 in the Checklist under the regulatory requirement regarding written procedures for conducting initial and continuing review).

As previously stated, institutions and IRBs have flexibility in how they choose to format their written procedures and how much detail to include. For example, topics listed in the Checklist may not be applicable to all institutions/IRBs. On the other hand, the institution/IRB may determine that additional topics not found in the Checklist should be included (e.g., written procedures related to how the IRB interacts with an Institutional Biosafety Committee or a Radioactive Drug Research Committee). In addition, institutions/IRBs may choose to combine items in the Checklist as needed to avoid redundancy, or use a different order than that presented in the Checklist.

OHRP and FDA remind institutions and IRBs that the Checklist is intended to facilitate an improved understanding of regulatory requirements in 45 CFR 46.103(b)(4) and (5) and 21 CFR 56.108(a) and (b) for written procedures for the IRB, to provide recommendations on the operational details to include in support of these regulatory requirements, and to provide some additional topics the institution/IRB may consider when developing comprehensive procedures. The Checklist is intended to be a tool to assist in determining what information should be covered in written procedures rather than a tool for assessing compliance.

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### WRITTEN PROCEDURES CHECKLIST

ACTIVITY	WRITTEN PROCEDURE? <small>Check <i>yes</i> if the IRB or institution/HRPP has a written procedure on this topic, <i>no</i> if it does not, and <i>N/A</i> if not applicable.</small>			NOTES (if any)
	YES	NO	N/A	
<b>I. IRB Initial and Continuing Review of Research; Reporting IRB Findings and Actions</b>				
<b><u>REGULATORY REQUIREMENT</u></b> – 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)]				
<b><u>RECOMMENDATIONS</u></b> – Operational details should include information about:				
1. Conducting review at a meeting of the convened IRB, <sup>4</sup> including: <ul style="list-style-type: none"> <li>• Documents submitted to the IRB for review (e.g., protocol, informed consent form, recruitment materials).</li> <li>• Reviewer system utilized by the convened IRB (e.g., primary reviewer(s)).</li> <li>• Documents routinely distributed to all IRB members and those that may be distributed to specific IRB members (e.g., primary reviewer(s)).</li> <li>• Range of possible actions the convened IRB can take.</li> <li>• Format of a convened meeting (e.g., in person, videoconferencing, other mechanism).</li> <li>• Defining and maintaining quorum and the process followed if quorum is lost.<sup>5</sup></li> <li>• Managing IRB members/alternates with conflicting interests.</li> </ul>				
2. Conducting review via expedited review procedures, <sup>6</sup> including: <ul style="list-style-type: none"> <li>• Documents submitted to the IRB for review.</li> <li>• 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).</li> <li>• Range of possible actions the designated expedited reviewer can take.</li> <li>• Method used for keeping all IRB members advised of research proposals approved via expedited review.</li> </ul>				
3. Determining that the criteria for IRB approval of research are met. <sup>7</sup>				

<sup>4</sup>See 45 CFR 46.108(b), 21 CFR 56.108(c).

<sup>5</sup>See 45 CFR 46.108(b), 21 CFR 56.108(c).

<sup>6</sup>See 45 CFR 46.110, 21 CFR 56.110.

<sup>7</sup>See 45 CFR 46.111, 21 CFR 56.111.

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ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
4. Reviewing the informed consent form and the informed consent process, <sup>8</sup> including: <ul style="list-style-type: none"> <li>• Consideration of the required and additional elements of informed consent.</li> <li>• Translation of the informed consent form for non-English speaking subjects, when applicable.</li> <li>• For HHS-conducted or -supported research, consideration of a waiver or alteration of the consent procedure.<sup>9</sup></li> <li>• For both HHS-conducted or -supported research and FDA-regulated research, consideration of a waiver of documentation of consent.</li> </ul>				
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. <sup>10</sup>				
6. Reviewing studies requesting an exception from informed consent requirements for emergency research. <sup>11</sup>				
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. <sup>12</sup>				
8. For FDA-regulated medical device research, making and documenting the significant/nonsignificant risk (SR/NSR) determination. <sup>13</sup>				
9. For HHS-conducted or -supported research, determining the applicability of additional protections for pregnant women, human fetuses and neonates, and for prisoners. <sup>14</sup>				
10. Reviewing research involving children as subjects in accordance with applicable regulations. <sup>15</sup>				

<sup>8</sup>See 45 CFR 46.111(a)(4) and (5), 21 CFR 56.111(a)(4) and (5), 45 CFR 46.116, 21 CFR 50.20, 21 CFR 50.25, 45 CFR 46.117, 21 CFR 50.27.

<sup>9</sup>On December 13, 2016, the President signed the 21<sup>st</sup> Century Cures Act (P.L. 114-255) into law. Title III, section 3024 of the 21st Century Cures Act amended sections 520(g)(3) and 505(i)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide FDA with the authority to permit an exception from informed consent when the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subjects. FDA intends to promulgate regulations to permit this exception and to specify appropriate human subject protection safeguards. FDA issued guidance in July 2017 for sponsors, investigators, and IRBs on enforcement of FDA regulations governing informed consent requirements for clinical investigations that involve no more than minimal risk to human subjects – see <https://www.fda.gov/RegulatoryInformation/Guidances/ucm566474.htm>.

<sup>10</sup>See 45 CFR 46.111(b), 21 CFR 56.111(b).

<sup>11</sup>See OPRR Letter for Informed Consent Requirements in Emergency Research at <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html> for HHS-conducted or -supported research, and 21 CFR 50.24 for FDA-regulated studies.

<sup>12</sup>See 21 CFR 312.2, 812.2.

<sup>13</sup>See 21 CFR 812.66.

<sup>14</sup>See 45 CFR part 46 subparts B and C.

<sup>15</sup>See 45 CFR part 46 subpart D, 21 CFR part 50 subpart D, 45 CFR 46.111(b), 21 CFR 56.111(c).

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ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
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.				
12. Determining and documenting the effective date of initial approval, and calculating the date for subsequent continuing review.				
13. Communicating the IRB's findings and actions to both the investigator and the institution, <sup>16</sup> including: <ul style="list-style-type: none"> <li>• Which institutional office(s)/official(s) are notified.</li> <li>• Communicating to the investigator any modifications or clarifications required by the IRB as a condition of approval.</li> <li>• Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.</li> <li>• Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.</li> </ul>				
14. For FDA-regulated research, reviewing a request for expanded access or treatment use. <sup>17</sup>				
15. For FDA-regulated research, reviewing the emergency use of a test article. <sup>18</sup>				
16. For FDA-regulated research, reviewing a request for the use of a Humanitarian Use Device (HUD). <sup>19</sup>				
<b>II. Frequency of IRB Review; Verification Regarding Material Changes</b>				
<b>REGULATORY REQUIREMENT</b> – 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)]				
<b>RECOMMENDATIONS</b> – Operational details should include information about:				

<sup>16</sup>See 45 CFR 46.103(b)(4)(i), 21 CFR 56.108(a)(1), 45 CFR 46.109(d), 21 CFR 56.109(e).

<sup>17</sup>See 21 CFR 312.305(c), 812.36.

<sup>18</sup>See 21 CFR 50.23, 56.102(d), 56.104(c).

<sup>19</sup>See 21 CFR 814.124.

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ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
17. Determining the approval period/continuing review interval of the proposed research, including: <ul style="list-style-type: none"> <li>• 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).</li> <li>• Documenting the approval period/continuing review interval (e.g., in the IRB meeting minutes or elsewhere in the IRB records).</li> <li>• Communicating the IRB’s determinations regarding the approval period/continuing review interval to the investigator.</li> </ul>				
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).				
<b>III. Reporting of Proposed Changes to the IRB; Prior IRB Review and Approval of Changes</b>				
<b>REGULATORY REQUIREMENT</b> – 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)]				
<b>RECOMMENDATIONS</b> – Operational details should include information about:				
19. Reporting changes in research to the IRB, including: <ul style="list-style-type: none"> <li>• 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).</li> <li>• Ensuring that changes in research are being reported to the IRB before they are initiated (e.g., random audits of research records).</li> <li>• Process for notifying the IRB of any changes made to eliminate apparent immediate hazards to subjects that did not have prior IRB approval.</li> </ul>				

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ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
20. Reviewing changes in research, including: <ul style="list-style-type: none"> <li>• What might qualify as a minor change in research.</li> <li>• Documents submitted to the IRB for changes in research.</li> <li>• Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take.</li> <li>• Assessment of whether the IRB-approved informed consent form requires revision.</li> </ul>				
21. Communicating the IRB’s findings and actions for changes in research to both the investigator and the institution, <sup>20</sup> including: <ul style="list-style-type: none"> <li>• Which institutional office(s)/official(s) are notified.</li> <li>• Communicating to the investigator and the institution any modifications or clarifications required by the IRB as a condition of approval.</li> <li>• Reviewing and acting on the investigator's response to any required modifications or clarifications required by the IRB as a condition of approval.</li> <li>• Communicating the reason(s) for a decision to disapprove, and the process followed to allow the investigator to respond.</li> </ul>				
<b>IV. Reporting of Unanticipated Problems, Serious or Continuing Noncompliance, and Any Suspension or Termination of IRB Approval</b>				
<b>REGULATORY REQUIREMENT</b> – 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)]				
<b>RECOMMENDATIONS</b> – Operational details should include information about:				
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: <sup>21</sup> <ul style="list-style-type: none"> <li>• Unanticipated problems involving risks to human subjects or others.</li> <li>• Serious or continuing noncompliance.</li> <li>• Suspension or termination of IRB approval.</li> </ul>				

<sup>20</sup>See 45 CFR 46.109(d), 21 CFR 56.109(e).

<sup>21</sup>See 45 CFR 46.103(a) and (b)(5), 21 CFR 56.108(b).

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ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
23. Reviewing information about unanticipated problems involving risks to human subjects or others, <sup>22</sup> including: <ul style="list-style-type: none"> <li>• What might qualify as an unanticipated problem involving risks to human subjects or others, including adverse events that should be considered unanticipated problems.</li> <li>• 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).</li> <li>• Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.</li> </ul>				
24. Reviewing information about serious or continuing noncompliance with the regulations or IRB requirements or determinations, <sup>23</sup> including: <ul style="list-style-type: none"> <li>• What might qualify as serious or continuing noncompliance.</li> <li>• 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).</li> <li>• Type of review (e.g., full board review vs. expedited review), and the range of possible actions the IRB may take, if any.</li> </ul>				
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, <sup>24</sup> including: <ul style="list-style-type: none"> <li>• Circumstances in which suspending or terminating IRB approval might be appropriate.</li> <li>• Consideration of subjects already enrolled (e.g., informing subjects about the suspension or termination).</li> <li>• Orderly termination of the study, or transfer of the study or study subjects, if applicable.</li> <li>• Communicating the reason(s) for the IRB's decision to suspend or terminate approval of the research.</li> </ul>				
<b>V. Additional Topics the Institution/IRB May Consider:</b>				
<b>Scope and Authority</b>				
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).				

<sup>22</sup>See 45 CFR 46.103(b)(5)(i), 21 CFR 56.108(b)(1).

<sup>23</sup>See 45 CFR 46.103(b)(5)(i), 21 CFR 56.108(b)(2).

<sup>24</sup>See 45 CFR 46.113, 21 CFR 56.113.

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ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
27. The institutional authority under which the IRB is established and authorized, and the independence afforded the IRB to carry out its duties.				
28. The ethical principles that govern the IRB in assuring that the rights and welfare of human subjects are protected.				
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).				
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).				
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. <sup>25</sup>				
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.				
<b>IRB Membership</b>				
33. The number of members on the IRB. <sup>26</sup>				
34. Ensuring diversity in IRB membership (e.g., representation of both genders, multiple professions, scientific and nonscientific members, nonaffiliated members). <sup>27</sup>				
35. Selecting and appointing the IRB chairperson, the members, and alternate members if any, including: <ul style="list-style-type: none"> <li>• The length of term or service, general description of duties, attendance requirements, performance evaluation, including removal if necessary.</li> <li>• The qualifications of the IRB chairperson, members and any alternate members.<sup>28</sup></li> <li>• The criteria used to categorize members and alternate members as scientist, nonscientist, and nonaffiliated.<sup>29</sup></li> </ul>				

<sup>25</sup>See 45 CFR 46.112, 21 CFR 56.112.

<sup>26</sup>See 45 CFR 46.107(a), 21 CFR 56.107(a).

<sup>27</sup>See 45 CFR 46.107, 21 CFR 56.107.

<sup>28</sup>See 45 CFR 46.107(a), 21 CFR 56.107(a).

<sup>29</sup>See 45 CFR 46.107(c) and (d), 21 CFR 56.107(c) and (d).

## Contains Nonbinding Recommendations

ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
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. <sup>30</sup>				
37. Training and education provided to the IRB chairperson, IRB members, alternate members, administrative support staff, and investigators.				
<b>IRB Functions and Operations</b>				
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).				
39. Determining which HHS-conducted or -supported research studies qualify as exempt from the HHS regulations, including who makes the determination.				
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. <sup>31</sup>				
41. Process for reporting the emergency use of an FDA-regulated test article to the IRB. <sup>32</sup>				
42. The use of consultants by the IRB, <sup>33</sup> 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.				
43. Identifying and managing an investigator with a conflicting interest.				
44. Determining the applicability of state and local laws. <sup>34</sup>				
45. Tracking study approvals and scheduling continuing review to prevent lapses in IRB approval, including procedures to follow if IRB approval lapses.				
46. Handling subject complaints, problems, concerns and questions about rights as a research subject.				
47. Administrative support staff duties.				

<sup>30</sup>See 45 CFR 46.107(e), 21 CFR 56.107(e).

<sup>31</sup>See 45 CFR 46.114, 21 CFR 56.114.

<sup>32</sup>See 21 CFR 50.23, 21 CFR 56.102(d), 21 CFR 56.104(c).

<sup>33</sup>See 45 CFR 46.107(f), 21 CFR 56.107(f).

<sup>34</sup>See 45 CFR 46.101(f), 21 CFR 56.103(c).

## Contains Nonbinding Recommendations

ACTIVITY	WRITTEN PROCEDURE?			NOTES (if any)
	YES	NO	N/A	
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).				
49. Registering the IRB and maintaining IRB registration <sup>35</sup> via the HHS Internet-based registration system. <sup>36</sup>				
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).				
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).				
<b>IRB Records</b>				
52. Maintaining records required to be retained, <sup>37</sup> and other records (e.g., IRB member training records).				
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).				
54. Preparing and maintaining minutes of IRB meetings. <sup>38</sup>				
55. Retaining records for at least 3 years after completion of the research, and ensuring records are accessible for inspection. <sup>39</sup>				

<sup>35</sup>See 45 CFR part 46 subpart E, 21 CFR 56.106.

<sup>36</sup>See <https://ohrp.cit.nih.gov/efile/IrbStart.aspx>.

<sup>37</sup>See 45 CFR 46.115, 21 CFR 56.115.

<sup>38</sup>See 45 CFR 46.115(a)(2), 21 CFR 56.115(a)(2).

<sup>39</sup>See 45 CFR 46.115(b), 21 CFR 56.115(b).