|  |  |  |  |
| --- | --- | --- | --- |
|  | IRB Written Procedures Self-Assessment | | |
| Institution Name |  |
| Contact Name |  |

# Instructions

Completion of the IRB Written Procedures Self-Assessment[[1]](#footnote-1) (Form A) is a component of the CARE-Q Certification Process. Indicate where each of the IRB requirements or activities are documented. In the *Written Material* column, provide a brief description of each document, including the intended audience (e.g., IRB members, IRB staff, investigators/research team, research community). If the relevant information is embedded in the document, list the specific page and section of the document. In the Notes column, provide any clarifying information and/or operational details.

Acceptable documentation may include IRB Policies and Procedures (P&P), IRB consent templates, IRB application, other submission forms, procedural checklists provided to IRB members and/or researchers, and IRB web pages. Do not include non-institutional materials such as standardized instruments, FDA/OHRP guidance or source documents.

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

Each IRB must follow written procedures for conducting review of research and for reporting IRB findings to the investigator and the institution.[[2]](#footnote-2)

|  |  |  |  |
| --- | --- | --- | --- |
| **1** | **When conducting review at a meeting of the convened IRB,**[[3]](#footnote-3) **describe or list the following:** | **Written Material** | **Notes** *(as needed)* |
| a | **Documents submitted to the IRB office for review** (e.g., protocol, informed consent form, recruitment materials). |  |  |
| b | **Reviewer system utilized by the convened IRB** (e.g., primary reviewers). |  |  |
| 1. c | **Documents routinely distributed to all IRB members and those that may be distributed to specific IRB members** (e.g., primary reviewers). |  |  |
| 1. d | **Range of possible actions the convened IRB can take.** |  |  |
| 1. e | **Format of a convened meeting** (e.g., in person, videoconferencing, other mechanism). |  |  |
| 1. f | **Definition of quorum and the process followed if quorum is lost**.[[4]](#footnote-4) |  |  |
| 1. g | **Management of IRB members / alternates with conflicting interests.** |  |  |
| 1. h | **When there is not at least one person on the IRB with appropriate scientific or scholarly expertise to conduct an in-depth review of the protocol, how does the IRB defer review to another meeting or obtain consultation?** |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **2** | **When conducting a review using expedited review procedures,**[[5]](#footnote-5)  **describe or list the following:** | **Written Material** | **Notes** *(as needed)* |
| 1. a | **Documents submitted** to the IRB for review. |  |  |
| 1. b | **Reviewer system utilized for expedited review** (e.g., IRB chairperson or other experienced reviewers designated by the chairperson from among the members of the IRB). |  |  |
| 1. c | **Range of possible actions** the designated expedited reviewer can take. |  |  |
| 1. d | **Method used for keeping all IRB members advised** of research proposals approved for expedited review. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **3** | **How does the IRB determine that the criteria for IRB approval of research are met? [[6]](#footnote-6)**  Address each of the following points below: | **Written Material** | **Notes** *(as needed)* |
| a | How the IRB **determines that all approval criteria are satisfied** before approving the study. |  |  |
| b | Where the IRB **documents its review determinations** (e.g., in the meeting minutes or elsewhere in the IRB records). |  |  |
| c | How the IRB **assesses risk of the research**, including whether risks can be minimized through appropriate measures. |  |  |
| d | How the IRB **assesses any potential benefits** to the subjects or others that may be reasonably expected to result, and **whether this provides a reasonable basis for assuming the risks** of the research. |  |  |
| e | How the IRB **determines whether the selection of subjects is equitable** (e.g., the adequacy of the inclusion and exclusion criteria). |  |  |
| f | How the IRB **assesses the informed consent process and determines that informed consent is sought and documented in accordance with other applicable regulations**. |  |  |
| g | How the IRB **determines whether provisions to monitor data collected are adequate to ensure the safety of subjects**, and **provisions to protect the privacy of subjects and confidentiality of the data are adequate**, where appropriate. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **4** | 1. **How are the consent form and informed consent process [[7]](#footnote-7) reviewed?** 2. Including the following: | **Written Material** | **Notes** *(as needed)* |
| a | Considerations of **required and additional elements of informed consent**. |  |  |
| b | **Translations of the informed consent form** for non-English speaking subjects, when applicable. |  |  |
| c | For non-English-speaking subjects, **when and how investigators must use the “short form,” and how this is documented by IRB**.[[8]](#footnote-8) |  |  |
| d | For HHS-conducted or -supported research, consideration of a **waiver or alteration of the consent procedure**.[[9]](#footnote-9),[[10]](#footnote-10) |  |  |
| e | For HHS-conducted or –supported research and FDA-regulated research, consideration of a **waiver of documentation of consent**. |  |  |
| f | Under what circumstances the **IRB or a third party observes the consent process**.[[11]](#footnote-11) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **5** | 1. **How does the IRB consider whether a 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 their rights and welfare? [[12]](#footnote-12)** | **Written Material** | **Notes** *(as needed)* |
| a | For subjects who may have **impaired capacity to consent**, how does the IRB **review the consent process and assess provisions for ensuring that subjects are able to make a decision to participate** in the study? [[13]](#footnote-13) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **6** | 1. **When an investigator requests an exception from informed consent requirements for Emergency Research,**[[14]](#footnote-14) **how is that study reviewed?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **7** | 1. **For FDA-regulated research, how does the IRB assess whether the investigator and/or the sponsor has determined that an IND or IDE is required for the proposed study (if applicable), and the basis for this determination.[[15]](#footnote-15)** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **8** | **For FDA-regulated medical device research, how is the significant/ nonsignificant risk (SR/NSR) determination**[[16]](#footnote-16) **made and documented.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **9** | **For HHS-conducted or –supported research, how does the IRB assess the applicability of additional protections for Pregnant Women, Human Fetuses and Neonates, and for Prisoners. [[17]](#footnote-17)**  **How does the IRB consider and document that each of the required subpart criteria are met?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **10** | **In reviewing research involving children as subjects, how does the IRB ensure that applicable regulations are followed? [[18]](#footnote-18)**  **How does the IRB consider and document that each of the required subpart criteria are met?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **11** | **How does the IRB review the qualifications of the investigators and study staff, and assess the adequacy of the site where the research will be conducted, including any institutional requirements for sponsor-investigator studies (if applicable)?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **12** | **How does the IRB determine and document the effective date of initial approval, and calculate the date for subsequent continuing review?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **13** | **Describe how the IRB communicates its findings and actions to both investigators and the institution (with timelines, when appropriate).** [[19]](#footnote-19)Operational details should include: | **Written Material** | **Notes** *(as needed)* |
| a | Which **institutional offices / officials are notified** of the IRB’s findings and actions? |  |  |
| b | How are **investigators informed of IRB approvals as well as of modifications or clarifications** that are required by the IRB as a condition of approval? |  |  |
| c | How the **IRB reviews and acts upon the investigator’s response** to any required modifications or clarifications required by the IRB as a condition of approval. |  |  |
| d | How the **IRB communicates the reasons for a decision to disapprove, and the process followed to allow the investigator to respond**. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **14** | **For FDA-regulated research, how does the IRB review a request for expanded access or treatment use?** [[20]](#footnote-20) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **15** | **For FDA-regulated research, how does the IRB review the emergency use of a test article?** [[21]](#footnote-21) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **16** | **For FDA regulated research, how does the IRB review a request for the use of a Humanitarian Use Device (HUD)?** [[22]](#footnote-22) | **Written Material** | **Notes** *(as needed)* |
|  |  |

# II. Frequency of IRB Review; Verification Regarding Material Changes

*Each IRB must follow written procedures for determining which projects require review more often than annually and determine which projects need verification from sources other than the investigator that no material changes have occurred since the previous IRB review.*[[23]](#footnote-23)

|  |  |  |  |
| --- | --- | --- | --- |
| **17** | **How does the IRB determine the approval period / continuing review interval?** [[24]](#footnote-24)  Address the following: | **Written Material** | **Notes** *(as needed)* |
| a | **General criteria used to make these determinations** (e.g., the nature of the study and the 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). |  |  |
| b | **Where the IRB documents the approval period / continuing review interval** (e.g., in the IRB meeting minutes or elsewhere in the IRB records). |  |  |
| c | **How the IRB communicates its determinations regarding the approval period/continuing review interval to the investigator.** |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **18** | **During continuing review, how does the IRB determine 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 previous IRB review?** [[25]](#footnote-25) | **Written Material** | **Notes** *(as needed)* |
|  | **Address the general criteria used to make this determination** (e.g., complex projects; investigators with previous compliance issues; a continuing review report that indicates changes not previously reported; randomly selected projects) |  |  |

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

*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.*[[26]](#footnote-26)

|  |  |  |  |
| --- | --- | --- | --- |
| **19** | **Reporting changes in research to the IRB.**  Operational details should include: | **Written Material** | **Notes** *(as needed)* |
| a | How the IRB **informs 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**[[27]](#footnote-27) (e.g., through training programs and materials for investigators, specific directives included in approval letters to investigators). |  |  |
| b | **Steps taken to ensure that changes in research are being reported to the IRB before they are initiated** (e.g., random audits of research records). |  |  |
| c | **Process investigators should follow to notify the IRB of any changes made to eliminate apparent immediate hazards to subjects that did not have prior IRB approval.** |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **20** | **Reviewing changes in research.** Operational details should include: | **Written Material** | **Notes** *(as needed)* |
| a | **What might qualify as a ‘*minor change*’ in research.** |  |  |
| b | **Documents to be submitted to the IRB** (e.g., summary of changes to the protocol, amended protocol). |  |  |
| c | **Type of review** (e.g., full board review vs. expedited review) **required and the range of possible actions the IRB may take.** |  |  |
| d | **Assessment of whether the IRB-approved informed consent form requires revision.** |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **21** | **Communicating to the investigator and the institution the IRB’s findings and actions for changes in research.[[28]](#footnote-28)**  Operational details should include: | **Written Material** | **Notes** *(as needed)* |
| a | **Which institutional offices/officials are notified.** |  |  |
| b | **How modifications or clarifications required by the IRB as a condition of approval are communicated to the investigator as a condition of approval.** |  |  |
| c | How the IRB subsequently **reviews and acts upon the investigator’s responses** to any required modifications or clarifications. |  |  |
| d | How the IRB **communicates the reasons for a decision to disapprove the change in research activity, and the process followed to allow the investigator to respond.** |  |  |

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

*Each IRB must follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, 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 non-compliance with the applicable HHS and/or FDA regulations, or the requirements or determinations of the IRB and any suspension or termination of IRB approval.*[[29]](#footnote-29)

|  |  |  |  |
| --- | --- | --- | --- |
| **22** | **Identify who (e.g., the investigator, institutional office, institutional official) is responsible for promptly reporting to the IRB, appropriate institutional officials, and, as applicable, any department or agency head, OHRP and/or FDA any of the following:** [[30]](#footnote-30) | **Written Material** | **Notes** *(as needed)* |
| a | Unanticipated problems involving risk to human subjects or others |  |  |
| b | Serious or continuing noncompliance |  |  |
| c | Suspension or termination of IRB approval |  |  |
| d | Summarize the timelines required for reporting each type of reportable event to the IRB, institutional officials, any department or agency head, ORHP and/or FDA.[[31]](#footnote-31) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **23** | **How does the IRB review information about unanticipated problems involving risk to human subjects or others.[[32]](#footnote-32)**  Operational details should include: | **Written Material** | **Notes** *(as needed)* |
| a | **What might qualify as an unanticipated problem involving risk to subjects or others** (including adverse events that should be considered unanticipated problems). |  |  |
| b | **What documents should be 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). |  |  |
| c | Type of review (e.g., full board vs. expedited review) and the range of possible actions the IRB may take, if any. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **24** | **How does the IRB review information about serious or continuing noncompliance with the regulations or IRB requirements and determinations?**[[33]](#footnote-33)  Operation details should include: | **Written Material** | **Notes** *(as needed)* |
| a | What might qualify as **serious or continuing noncompliance**. |  |  |
| b | What **documents should be 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). |  |  |
| c | **Type of review** (e.g., full board vs. expedited review) **and the range of possible actions the IRB may take, if any**. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **25** | **How does the IRB consider 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?** [[34]](#footnote-34)  Operation details should include: | **Written Material** | **Notes** *(as needed)* |
| a | Under what circumstances it might be **appropriate to suspend or terminate IRB approval**. |  |  |
| b | Consideration of **what happens to subjects already enrolled** (e.g., informing subjects about the suspension or termination). |  |  |
| c | **Process of orderly termination of the study, or transfer of the study or study subjects**, if applicable. |  |  |
| d | **Communicating the reasons for the IRB’s decision** to suspend or terminate approval of the research. |  |  |

# V. Additional Topics the Institution/IRB May Consider

*Each IRB must follow written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, 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 non-compliance with the applicable HHS and/or FDA regulations, or the requirements or determinations of the IRB and any suspension or termination of IRB approval.*[[35]](#footnote-35)

|  |  |  |  |
| --- | --- | --- | --- |
| **A** | **Scope & Authority** |  |  |
| **26** | **Who is responsible for preparing, revising, maintaining, and approving written procedures?**  Address how often they are reviewed and updated, to whom they apply, and what happens if they are not followed. | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **27** | **Identify the institutional authority under which the IRB is established and empowered, and the independence afforded the IRB to carry out its duties.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **28** | **Identify the ethical principles which govern the IRB in assuring that the rights and welfare of human subjects are protected.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **29** | **Provide important regulatory definitions that guide the IRB’s review processes and procedures** (e.g., the definition of research, clinical investigation, human subject, minimal risk). | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **30** | **Identify other relevant federal regulations that may apply to human subject research at your institution** (e.g., Health Insurance Portability and Accountability Act regulations; Department of Defense regulations). | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **31** | **Which institutional offices or officials, if any, are responsible for further review and approval, or disapproval of research that is approved by the IRB?** [[36]](#footnote-36) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **32** | **Describe 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.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **B** | **IRB Membership** |  |  |
| **33** | The **number of members** on the IRB.[[37]](#footnote-37) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **34** | **How is the diversity in the IB membership ensured** (e.g., representation by both genders, multiple professions, scientific and nonscientific members, nonaffiliated members)**?** [[38]](#footnote-38) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **35** | **Describe the process for selecting and appointing the IRB chairperson, the members and alternate members (if any), including:** | **Written Material** | **Notes** *(as needed)* |
| a | The length of term or service, general description of duties, attendance requirements and performance evaluation, including removal if necessary. |  |  |
| b | The qualifications of the IRB chairperson, members and any alternate members. [[39]](#footnote-39) |  |  |
| c | The criteria used to categorize members and alternates as scientist, nonscientist and nonaffiliated members. [[40]](#footnote-40) |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **36** | **Define what constitutes a conflicting interest for the IRB chairperson, members and/or alternates, and describe how the IRB manages any such conflicting interest (including recusal from meetings) to ensure that that person does not vote or count towards the quorum.** [[41]](#footnote-41) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **37** | **Describe the training and education provided the IRB chairperson, IRB members, alternates, administrative support staff and investigators** (including any orientation, continuing education and a list of reference materials provided as a resource). | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **C** | **IRB Functions & Operations** |  |  |
| **38** | **How is it determined whether a study is subject to IRB review?**  For example, what types of studies must be reviewed, which regulations apply and who makes the determination? | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **39** | **Which HHS-conducted or –supported research studies qualify as Exempt from the HHS regulations?**  **Who makes this determination?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **40** | **How are cooperative IRB review arrangements implemented (when applicable), such as joint review, reliance on the review of another qualified IRB, or similar arrangements aimed at avoiding duplication of effort?**  Address procedures used to determine which studies qualify for cooperative review, the role of the institution and the institution’s IRB in this type of review process, and the documentation of these arrangements in written agreements. [[42]](#footnote-42)  NOTE |*FDA has guidance specific to using a centralized IRB review process in multicenter clinical trials.* [[43]](#footnote-43) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **41** | **What is the process for reporting the emergency use of an FDA-regulated test article to the IRB?** [[44]](#footnote-44) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **42** | **Address the use of consultants by the IRB,**[[45]](#footnote-45) **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.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **43** | **How does the IRB identify and manage an investigator with a conflicting interest?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **44** | **How does the IRB determine the applicability of state and local laws?** [[46]](#footnote-46) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **45** | **Address how the IRB tracks study approvals and schedules continuing review to prevent lapses in IRB approval.**  **Include procedures to be followed if IRB approval lapses.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **46** | **How does the IRB handle subject complaints, problems, concerns and questions about rights as a research subject?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **47** | **Summarize duties of administrative support staff.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **48** | **How is the IRB kept informed of study completion and close-out to ensure record retention is in compliance with 45 CFR 46.115(b) and/or 21 CFR 56.115(b)?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **49** | **Who is responsible for registering the IRB and maintaining IRB registration** [[47]](#footnote-47) **via the HHS internet-based registration system?** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **50** | **How is the research community informed of the IRB requirements and procedures** (e.g., posting the information on a website accessible to the investigators, sponsors and others)? | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **51** | **What are the contingency plans for transferring oversight of one or more studies to another institution or IRB in the event that the IRB is unable to continue oversight of the study** (e.g., the IRB closes, suffers loss due to fire, natural disaster)**?**  NOTE | *FDA has guidance on considerations when transferring clinical investigation oversight to another IRB*. [[48]](#footnote-48) | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **D** | **IRB Records** |  |  |
| **52** | **List the records maintained by the IRB.**[[49]](#footnote-49)  This may include:   * research proposals reviewed * scientific evaluations * approved sample consent documents * progress reports submitted by the investigators * reports of injuries to subjects * minutes of meetings * records of continuing review activities * copies of all correspondence between the IRB and the investigators * IRB membership rosters * IRB written procedures * statements of significant new findings provided to subjects * IRB member training records   NOTE | *This includes studies that never enrolled participants.* | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **53** | **Describe where records are stored** (e.g., on-site/off-site archives)**, and the format for record storage** (e.g., hard copy, electronic or both)**.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **54** | **Address how minutes of IRB meetings are prepared and maintained. [[50]](#footnote-50)‑[[51]](#footnote-51)**   * Include documentation of attendance at the meeting, actions taken by the IRB, the vote on these actions including the number of members voting for, against and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution.[[52]](#footnote-52) * Also include documentation of the approval period, the names of the members who left the meeting because of a conflicting interest, and protocol-specific findings supporting the determinations for research involving children, prisoners, and women, fetuses, and neonates. | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **54** | **Address how the IRB ensures that records are retained for at least 3 years after completion of the research and are accessible for inspection. [[53]](#footnote-53)**  NOTE | *This includes studies that never enrolled participants.* | **Written Material** | **Notes** *(as needed)* |
|  |  |

# Appendix II. *OPTIONAL: International Council for Harmonisation – Good Clinical Practice (E6)[[54]](#footnote-54)*

|  |  |  |  |
| --- | --- | --- | --- |
| **1** | **The IRB should consider the qualifications of the investigator for the proposed study, as documented by a current curriculum vitae and/or by any other relevant documentation the IRB requests.** | **Written Material** | **Notes** *(as needed)* |
|  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **2** | **The informed consent discussion and written informed consent form and any other written information to be provided to subjects should include explanations of the following:** | **Written Material** | **Notes** *(as needed)* |
| a | The probability for random assignment to each treatment. |  |  |
| b | The subject’s responsibilities. |  |  |
| c | The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks. |  |  |
| d | That the monitor, the auditor, the IRB, and the regulatory authority will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access. |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **3** | **The investigator should promptly report to the IRB/IEC:** | **Written Material** | **Notes** *(as needed)* |
| a | Any changes significantly affecting the conduct of the trial, and/or increasing the risk to subjects. |  |  |
| b | New information that may adversely affect the safety of the subjects or the conduct of the trial. |  |  |

1. Based on: Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs ([May 2018](https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm512761.pdf)) [↑](#footnote-ref-1)
2. 45 CFR 46.103(b)(4)(i), 45 CFR 46.108(a)(3)(i), 21 CFR 56.108(a)(1) [↑](#footnote-ref-2)
3. 45 CFR 46.108(b), 21 CFR 56.108(c) [↑](#footnote-ref-3)
4. 45 CFR 46.108(b), 21 CFR 56.108(c) [↑](#footnote-ref-4)
5. 45 CFR 46.110, 21 CFR 56.110 [↑](#footnote-ref-5)
6. 45 CFR 46.111, 21 CFR 56.111 [↑](#footnote-ref-6)
7. 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 [↑](#footnote-ref-7)
8. [FDA Informed Consent Information Sheet](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf) (July 2014 draft guidance pp.30-33) [↑](#footnote-ref-8)
9. [FDA Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects](https://www.fda.gov/RegulatoryInformation/Guidances/ucm566474.htm) (July 2017) [↑](#footnote-ref-9)
10. [FDA Informed Consent Information Sheet](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf) (July 2014 draft guidance) [↑](#footnote-ref-10)
11. [FDA Informed Consent Information Sheet](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf) (July 2014 draft guidance) [↑](#footnote-ref-11)
12. 45 CFR 46.111(b), 21 CFR 56.111(b) [↑](#footnote-ref-12)
13. [FDA Informed Consent Information Sheet](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf) (July 2014 draft guidance, pp 34-35) [↑](#footnote-ref-13)
14. [Secretarial Waiver for OHRP](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html), and 21 CFR 50.24 for FDA-regulated studies [↑](#footnote-ref-14)
15. 21 CFR 312.2, 812.2 [↑](#footnote-ref-15)
16. 21 CFR 56.108(a)(1), 56.115(a)(6), 812.2, 812.66 [↑](#footnote-ref-16)
17. 45 CFR 46 Subparts B and C [↑](#footnote-ref-17)
18. 45 CFR 46 Subpart D, 21 CFR 50 Subpart D, 45 CFR 46.111(b), 21 CFR 56.111(c) [↑](#footnote-ref-18)
19. 45 CFR 46.103(b)(4)(i), 45 CFR 46.108(a)(3)(i), 21 CFR 56.108(a)(1), 45 CFR 46.109(d), 21 CFR 56.109(e) [↑](#footnote-ref-19)
20. 21 CFR 312.305(c)(4), 812.36 [↑](#footnote-ref-20)
21. 21 CFR 50.23, 56.102(d), 56.104(c) [↑](#footnote-ref-21)
22. 21 CFR 814.124 [↑](#footnote-ref-22)
23. 45 CFR 46.103(b)(4)(ii), 45 CFR 46.108(a)(3)(ii), 21 CFR 56.108(a)(2) [↑](#footnote-ref-23)
24. 45 CFR 46.103(b)(4)(ii), 45 CFR 46.108(a)(3)(ii), 21 CFR 56.108(a)(2) [↑](#footnote-ref-24)
25. 45 CFR 46.103(b)(4)(ii), 45 CFR 46.108(a)(3)(ii), 21 CFR 56.108(a)(2) [↑](#footnote-ref-25)
26. 45 CFR 46.103(b)(4)(iii), 45 CFR 46.108(a)(3)(iii), 21 CFR 56.108(a)(3) and (4) [↑](#footnote-ref-26)
27. 45 CFR 46.103(b)(4)(iii), 45 CFR 46.108(a)(3)(iii), 21 CFR 56.108(a)(3) and (4) [↑](#footnote-ref-27)
28. 45 CFR 46.109(d), 21 CFR 56.109(e) [↑](#footnote-ref-28)
29. 45 CFR 46.103(b)(5)(i) and (ii), 45 CFR 46.108(a)(4)(i) and (ii), 21 CFR 56.108(b)(1)(2) and (3) [↑](#footnote-ref-29)
30. 45 CFR 46.103(a) and (b)(5), 45 CFR 46.108(a)(4), 21 CFR 56.108(b) [↑](#footnote-ref-30)
31. 45 CFR 46.103(b)(5)(i) and (ii), 45 CFR 46.108(a)(4)(i) and (ii),21 CFR 56.108(b)(1)(2) and (3) [↑](#footnote-ref-31)
32. 45 CFR 46.103(b)(5)(i), 45 CFR 46.108(a)(4)(i), 21 CFR 56.108(b)(1) [↑](#footnote-ref-32)
33. 45 CFR 46.103(b)(5)(i), 45 CFR 46.108(a)(4)(i), 21 CFR 56.108(b)(2) [↑](#footnote-ref-33)
34. 45 CFR 46.113, 21 CFR 56.113 [↑](#footnote-ref-34)
35. 45 CFR 46.103(b)(5)(i) and (ii), 45 CFR 46.108(a)(4)(i) and (ii), 21 CFR 56.108(b)(1)(2) and (3) [↑](#footnote-ref-35)
36. 45 CFR 46.112, 21 CFR 56.112 [↑](#footnote-ref-36)
37. 45 CFR 46.107(a), 21 CFR 56.107(a) [↑](#footnote-ref-37)
38. 45 CFR 46.107, 21 CFR 56.107 [↑](#footnote-ref-38)
39. 45 CFR 46.107(a), 21 CFR 56.107(a) [↑](#footnote-ref-39)
40. 45 CFR 46.107(c) and(d), 21 CFR 56.107(c) and (d) [↑](#footnote-ref-40)
41. 45 CFR 46.107(e), 21 CFR 56.107(e) [↑](#footnote-ref-41)
42. 45 CFR 46.114, 21 CFR 56.114 [↑](#footnote-ref-42)
43. FDA Guidance for Using a Centralized IRB Review Process in Multicenter Clinical Trials [↑](#footnote-ref-43)
44. 21 CFR 50.23, 21 CFR 56.102(d), 21 CFR 56.104(c) [↑](#footnote-ref-44)
45. 45 CFR 46.107(f), 21 CFR 56.107(f) [↑](#footnote-ref-45)
46. 45 CFR 46.101(f), 21 CFR 56.103(c) [↑](#footnote-ref-46)
47. 45 CFR 46 Subpart E, 21 CFR 56.106 [↑](#footnote-ref-47)
48. FDA Guidance for Considerations When Transferring Clinical Investigation Oversight to Another IRB [↑](#footnote-ref-48)
49. 45 CFR 46.115, 21 CFR 56.115 [↑](#footnote-ref-49)
50. 45 CFR 46.115(a)(2), 21 CFR 56.115(a)(2) [↑](#footnote-ref-50)
51. [OHRP-FDA Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM470154.pdf) (November 2015 draft guidance) [↑](#footnote-ref-51)
52. 45 CFR 46.115(a)(2), 21 CFR 56.115(a)(2) [↑](#footnote-ref-52)
53. 45 CFR 46.115(b), 21 CFR 56.115(b) [↑](#footnote-ref-53)
54. Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance (IRB/IEC) [<http://www.fda.gov/downloads/Drugs/.../Guidances/ucm073122.pdf>] [↑](#footnote-ref-54)