Minutes of Institutional Review Board (IRB) Meetings

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)

September 2017

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Contains Nonbinding Recommendations

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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), and is consistent with the goals of section 3023 of the 21st Century Cures Act (Cures Act) (Pub. L. 114-255). This guidance is intended for institutions and institutional review boards (IRBs) responsible for oversight of human subject research under HHS and FDA regulations.

This guidance is intended to assist institutions and IRBs responsible for preparing and maintaining minutes of IRB meetings (also referred to in this guidance as minutes). This guidance document describes requirements for minutes and provides recommendations for meeting the regulatory requirements for minutes.

OHRP's and FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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 joint OHRP and FDA 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 joint OHRP and FDA guidance means that something is recommended or suggested, but not required.

Note: References in this guidance to HHS regulations at 45 CFR part 46 are to this part in effect at the time this guidance is published, and not to the part as amended by a final rule published January 19, 2017, that has not yet gone into effect (82 Fed. Reg. 7149).

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 46.115(a)(2) and the FDA regulations at 21 CFR 56.115(a)(2) specifically require that an institution, or when appropriate, an IRB, prepare and maintain adequate documentation of IRB activities, including minutes in sufficient detail to show:

1. Attendance at the meetings;

2. Actions taken by the IRB;

3. The vote on these actions, including the number of members voting for, against, and abstaining;

4. The basis for requiring changes in or disapproving research; and

5. A written summary of the discussion of controverted issues and their resolution.

These five items must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

III. DISCUSSION

IRBs have been cited in OHRP Determination Letters[1] and FDA Warning Letters[2] for failing to prepare and maintain adequate minutes. For this reason, OHRP and FDA believe providing recommendations on the type and amount of information to include in minutes will help IRBs meet the regulatory requirements for minutes.

Examples of noncompliance related to minutes include:

- Minutes are missing.
- Minutes reflect an inaccurate account of meeting attendance.
- Minutes lack sufficient detail to show the vote on actions taken by the IRB, including the number of members voting for, against, and abstaining.
- Minutes are incomplete and only describe voting actions as "passed unanimously."
- Minutes do not clearly indicate, or contain discrepancies about, what the IRB approved.
- Minutes fail to include a summary of the discussion of controverted issues.

Minutes are intended to provide a summary of what occurred during a convened meeting and provide information to persons not present at the meeting (e.g., investigators, institutional officials, regulators, IRB members who could not attend) about what the IRB reviewed and the actions taken by the IRB.

[1] OHRP Determination Letters are posted at https://www.hhs.gov/ohrp/compliance-and-reporting/determination-letters/index.html and can be viewed by the date issued.
[2] FDA Warning Letters are posted at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm and can be viewed via multiple browsing options (e.g., by date, by company, by subject).

When reviewing proposed research, the IRB must document the information required by 45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2) in the minutes. However, there are other findings and determinations the IRB must make to fulfill other regulatory requirements (e.g., the IRB must review research involving children as subjects that is covered by 45 CFR part 46, subpart D and/or 21 CFR part 50, subpart D, and approve such research only if it satisfies the conditions of all applicable sections of those subparts). While we recommend that IRBs document these additional findings and determinations in the minutes, these can be documented elsewhere in the IRB records to avoid redundancy (e.g., IRB reviewer form/checklist, database entries, other forms of physical or electronic records). Documentation should include relevant summary information when such information contributes to an understanding of the IRB's findings and determinations (e.g., a brief rationale for the IRB's pediatric risk determination).

The regulations for meeting minutes at 45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2) provide institutions and IRBs with flexibility in choosing how to prepare minutes. Institutions and IRBs should adopt written procedures for preparation and maintenance of minutes that best suit their particular organization and allow the IRB to efficiently accomplish its tasks.

A. Attendance at the IRB Meeting

Minutes of IRB meetings must be in sufficient detail to show attendance at the convened meetings of the IRB (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). In addition, except when an expedited review procedure is used, the IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas (nonscientist). In order for the research to be approved, it must receive the approval of a majority of those members present at the meeting (45 CFR 46.108(b); 21 CFR 56.108(c)).

1. Members, Alternates, Consultants, and Guests

The minutes must be in sufficient detail to show attendance at the convened meeting (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). For ease of review, OHRP and FDA recommend that attendance information be listed at the beginning of the minutes and include the full name and representative capacity (e.g., scientist, nonscientist, unaffiliated) of each IRB member present at the convened meeting. Some IRBs may choose to append a current IRB membership roster to the minutes to avoid having to repeat certain information (e.g., representative capacity for each IRB member). However, the minutes must clearly document which IRB members were present at any given convened meeting (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

IRB members may participate in a convened meeting of the IRB via telephone or video conferencing when those members have received in advance of the meeting a copy of the documents for research proposals that are to be reviewed at the meeting. The minutes should make clear which members, if any, participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing.

An IRB may choose to appoint alternate members who may substitute for primary members for an entire meeting (e.g., when the primary member is not able to attend the meeting), or at any time during a meeting (e.g., when the primary member is not able to attend the whole meeting, or when the primary member has a conflicting interest and is recused from review of a particular study). When an alternate member replaces a primary member at a convened meeting, the minutes must include the name of the alternate member in attendance (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). When an alternate member substitutes for a primary member due to a conflicting interest, the minutes should identify the name of the primary member for whom the alternate member is substituting, and state that this is the reason for the substitution.

IRBs may invite consultants to assist in the review of a particular study when expertise is required beyond or in addition to that available on the IRB (45 CFR 46.107(f); 21 CFR 56.107(f)). If the IRB uses a consultant and the consultant is present at the convened meeting, the minutes must include the name of the consultant (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)), and should include a brief description of the consultant's expertise. In accordance with 45 CFR 46.107(f) and 21 CFR 56.107(f), the consultant may not vote with the IRB on the study.

If the IRB permits non-members and guests to attend a convened meeting (e.g., IRB support staff, the investigator whose study is being reviewed, study coordinator), then the minutes must record the name(s) of all such attendees (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

The institution and the IRB may establish written procedures covering the use of alternate members, the use of consultants, and attendance of non-members and guests at a convened meeting. Such written procedures may help to ensure that those who attend an IRB meeting understand their role, and to promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects.

2. Quorum

A quorum is the minimum number and type of IRB members that must be present at a convened meeting. In order to review proposed research at a convened meeting, a majority of the members of the IRB must be present, including at least one member whose primary concerns are in nonscientific areas (45 CFR 46.108(b); 21 CFR 56.108(c)). If a majority of the IRB membership is not present, or if a nonscientist is not present, then quorum has not been met.

The attendance information in the minutes assists in determining whether enough IRB members were present to constitute a quorum, whether the nonscientist was present, and whether proposed research received enough votes (i.e., a majority of those present) to be approved.

IRBs often calculate majority by using the "half-plus-one" technique. This technique works well for IRBs with an even number of IRB members. For example, if the total IRB membership is 10, then the majority is 6 (half of 10 is 5, plus 1 equals 6). However, if the IRB has an odd number of members, then the majority should be calculated by taking half of the total number of IRB

members, and rounding up to the next whole number. For example, if the IRB membership is 15, then majority is 8 (half of 15 is 7.5, and rounding up to the next whole number is 8).[3]

A quorum must be maintained throughout the meeting. If quorum is lost during a meeting, then the IRB may not vote on proposed research (45 CFR 46.108(b); 21 CFR 56.108(c)). Because IRB members may occasionally enter or leave the room at various times during a convened meeting (e.g., arrive late, depart early, or leave the meeting temporarily), we recommend that the minutes provide sufficient information to indicate that a quorum is maintained.

B. Actions Taken by the IRB

The minutes of IRB meetings must be in sufficient detail to show the actions taken by the IRB at the convened meeting (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). OHRP and FDA interpret "actions taken by the IRB" (also called "IRB actions") to refer to any vote taken by the IRB related to a proposed research activity. Accordingly, to be in sufficient detail to show actions taken by the IRB, the minutes must provide sufficient information to identify the research activities being reviewed and voted on by the IRB at that meeting (e.g., initial review of protocol title/protocol number). The minutes should serve as a central repository for IRB actions on proposed research activities.

1. Approve, Require Modifications to Secure Approval, Disapprove

OHRP and FDA regulations require that an IRB review and have the authority to approve, require modifications in (to secure approval), or disapprove all proposed research activities covered by the regulations (45 CFR 46.109(a); 21 CFR 56.109(a)). Any IRB action to approve, require modifications in (to secure approval), or disapprove proposed research activities that occurs at a convened meeting must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). Additionally, the IRB or institution may develop a range of other allowable actions the IRB may take when reviewing proposed research activities (e.g., approve with conditions[4], defer a decision until additional information can be obtained). The IRB's written procedures should describe the range of possible actions the IRB can take.

The minutes must be in sufficient detail to show the actions taken by the IRB at the convened meeting (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). In order to approve research covered by the regulations in 45 CFR part 46 and/or 21 CFR part 56, the IRB must determine that all of the criteria for IRB approval of research are satisfied (45 CFR 46.111; 21 CFR 56.111). We recommend that the minutes, or other IRB record (e.g., correspondence with the investigator), identify the effective date of approval and the approval period (continuing review interval) for any research approved by the IRB. IRBs must determine which projects require review more often than annually (45 CFR 46.103(b)(4)(ii); 21 CFR 56.108(a)(2)). Both OHRP and FDA have

[3] Note that the regulations do not prohibit IRBs from having more stringent requirements for quorum.
[4] OHRP's Guidance on IRB Approval of Research with Conditions can be found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-irb-approval-of-research-with-conditions-2010/index.html; FDA's Guidance on IRB Continuing Review after Clinical Investigation Approval can be found at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf.

issued guidance on continuing review of research to assist the IRB in determining the effective date of the initial approval and the subsequent date of continuing review.[5]

If the IRB takes an action to require modifications in the proposed research to secure approval, or disapproves the proposed research, the minutes must be in sufficient detail to show the action taken by the IRB, and the basis for requiring changes in, or for disapproving the proposed research (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

2. Suspension or Termination of IRB Approval

Both OHRP and FDA regulations authorize an IRB to suspend or terminate 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 (45 CFR 46.113; 21 CFR 56.113). Any IRB action to suspend or terminate IRB approval that occurs at a convened meeting must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). Any suspension or termination of approval must include a statement of the reasons for the IRB's action (45 CFR 46.113; 21 CFR 56.113). Any decision to suspend or terminate the study that occurs outside of a convened IRB meeting (e.g., as determined by the IRB Chair or Institutional Official for subject safety reasons) should be reported to the convened IRB and the discussion summarized in the minutes. Any subsequent action taken by the convened IRB (e.g., to lift the suspension or to terminate the study) must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

3. Other IRB Regulatory Determinations and Review Responsibilities

As previously mentioned, in addition to the findings and determinations the IRB must make and document in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)), there are other findings and determinations the IRB must make to fulfill other regulatory requirements. While we recommend that IRBs document these additional findings and determinations in the minutes, these can be documented elsewhere in the IRB records to avoid redundancy (e.g., IRB reviewer form/checklist, database entries, other forms of physical or electronic records). Again, we recommend that documentation include relevant summary information when such information contributes to an understanding of the IRB's findings and determinations.

- **Criteria for IRB Approval of Research**

  In order to approve research, the IRB must determine that all of the criteria for IRB approval of research are satisfied (45 CFR 46.111; 21 CFR 56.111). The process the IRB follows for considering the approval criteria should be addressed in the IRB's written procedures. The IRB's consideration of these criteria applies to both initial review and continuing review of research and provides the framework for the IRB's evaluation of

[5] OHRP's Guidance on Continuing Review can be found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html; FDA's Guidance on IRB Continuing Review after Clinical Investigation Approval can be found at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf.

research. The minutes must document actions taken by the IRB (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

- **Informed Consent**

  In order to approve a study, the IRB must determine that informed consent will be sought from each prospective subject or the subject's legally authorized representative (LAR) in accordance with the regulations (45 CFR 46.111(a)(4); 21 CFR 56.111(a)(4)). The IRB must also determine that informed consent will be appropriately documented in accordance with the regulations (45 CFR 46.111(a)(5); 21 CFR 56.111(a)(5)). The minutes should indicate that, as part of its review and approval of a study, the IRB reviewed the informed consent form(s) and determined that the form(s) meet the applicable regulatory requirements.[6]

  The IRB may require changes to the informed consent form(s). The minutes of IRB meetings must be in sufficient detail to show the basis for requiring changes in (to secure approval) or disapproving research (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). The IRB may summarize any changes to the informed consent form(s) required by the IRB in the minutes, or other IRB record (e.g., an annotated informed consent form that includes IRB-required changes that gets appended to the minutes).

  Both OHRP and FDA regulations permit an IRB to waive the requirement that the subject or the subject's LAR sign a written consent form if the IRB determines that certain criteria are met (45 CFR 46.117(c); 21 CFR 56.109(c) and (d)). We recommend that any such waiver of documentation of informed consent be documented in the minutes or other IRB record.

  In addition, for HHS-conducted or -supported research, the regulations at 45 CFR 46.116(c) and (d) permit an IRB to approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that certain criteria are met.[7] When an IRB approves a waiver or alteration of consent for research reviewed by the convened IRB, these findings must be documented (45 CFR 46.116(c) and (d)). OHRP recommends that IRB decisions for waiver or alteration of consent be documented in the minutes or other IRB record.

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[6] See 45 CFR 46.116, 45 CFR 46.117, 21 CFR 50.20, 21 CFR 50.25 and 21 CFR 50.27.

[7] On December 13, 2016, the President signed the 21st 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.

- **Studies Involving Children**

  Each IRB that reviews studies involving children as subjects covered by 45 CFR part 46 subpart D and/or 21 CFR part 50 subpart D may approve only those studies that satisfy the conditions of all applicable sections of those subparts (45 CFR 46.403; 21 CFR 50.50).

  In its review of proposed research involving children, the IRB must find that the research meets the conditions of 45 CFR 46.404 and/or 21 CFR 50.51 (research/clinical investigations not involving greater than minimal risk); 45 CFR 46.405 and/or 21 CFR 50.52 (research/clinical investigations involving greater than minimal risk but presenting the prospect of direct benefit to individual subjects); or 45 CFR 46.406 and/or 21 CFR 50.53 (research/clinical investigations involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition). If the IRB determines that the proposed research cannot be approved under these categories, then additional regulatory requirements under 45 CFR 46.407 and/or 21 CFR 50.54 (research/clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children) must be met. Both OHRP and FDA have issued guidance to assist IRBs with handling clinical investigations that include children as subjects and that have been referred under 45 CFR 46.407 or 21 CFR 50.54.[8]

  In addition to the findings and determinations described above, the IRB must also determine that requirements for permission by parents or guardians and for assent by children are met (45 CFR 46.408; 21 CFR 50.55). If the proposed research involves children who are wards of the State or other agency, institution or entity, then the IRB must ensure that additional requirements are met (45 CFR 46.409; 21 CFR 50.56).

  OHRP and FDA recommend that the IRB's findings and determinations for studies involving children be documented in the minutes.

- **Emergency Research**

  If the IRB reviews a proposal for research involving an exception from informed consent requirements for emergency research, the IRB must find and document that the proposed research satisfies the criteria found in OHRP's Secretarial Waiver[9] and/or FDA's regulations at 21 CFR 50.24.

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[8] OHRP's guidance on Children as Research Subjects and the HHS "407" Process can be found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-407-review-process/index.html; FDA's guidance on the Process for Handling Referrals to FDA Under 21 CFR 50.54, Additional Safeguards for Children in Clinical Investigations can be found at https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm127605.pdf.

[9] Information about OHRP's Informed Consent Requirements in Emergency Research can be found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html.

FDA has issued guidance on the exception from informed consent requirements for emergency research.[10] As outlined in FDA's guidance, FDA anticipates that an emergency research study in which informed consent is not obtained for all subjects is, by its very nature, controversial. Therefore, IRBs must summarize their discussions and decisions about the required elements for these studies in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

- **FDA-Regulated Medical Device Studies**

  Unless FDA has already made a risk determination for a device study (e.g., significant risk (SR), or nonsignificant risk (NSR)), or the study is exempt in accordance with 21 CFR 812.2(c), sponsors are responsible for making the initial risk determination and presenting it to the IRB. In that case, the IRB must then make its own SR/NSR determination about the study, and either agree or disagree with the sponsor's determination by reviewing relevant information provided by the sponsor at a convened meeting (21 CFR 56.108(a)(1); 21 CFR 812.66). FDA considers this determination to be part of the IRB's responsibilities for conducting its initial review of a study. FDA recommends that the IRB document each SR/NSR determination, along with the reason for the determination, in the minutes.

- **Studies Involving Pregnant Women, Human Fetuses, and Neonates**

  The regulations for research conducted or supported by HHS require specific findings for research involving pregnant women, human fetuses, and neonates as subjects (45 CFR part 46, subpart B). OHRP recommends that when such research is approved by the convened IRB, all required findings should be documented in the minutes or other IRB record.

  IRBs should be aware that FDA regulations do not require specific findings for research involving pregnant women, human fetuses, and neonates as subjects. If an IRB reviews an FDA-regulated study that is not HHS-conducted or -supported research, and the study is expected to involve pregnant women, fetuses, or neonates as subjects, IRBs may find 45 CFR part 46, subpart B to be helpful.

- **Studies Involving Prisoners**

  The regulations for research conducted or supported by HHS require specific findings for research involving prisoners as subjects (45 CFR part 46, subpart C). OHRP recommends that when such research is approved by the convened IRB, all required findings should be documented in the minutes or other IRB record.

[10] FDA's guidance on the Exception from Informed Consent Requirements for Emergency Research can be found at https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf.

IRBs should be aware that FDA regulations do not require specific findings for research involving prisoners as subjects. If an IRB reviews an FDA-regulated study that is not HHS-conducted or -supported research, and the study is expected to involve prisoners as subjects, IRBs may find 45 CFR part 46, subpart C, and OHRP's guidance on prisoners in research[11] to be helpful.

- **Reporting of Expedited Review Activities**

  Each IRB that uses an expedited review procedure must adopt a method for keeping all members advised of research proposals which have been approved under the expedited review procedure (45 CFR 46.110(c); 21 CFR 56.110(c)). There are various methods IRBs can use to keep the IRB members apprised of expedited actions. One method that may be used is to present a report of expedited actions during a convened meeting. If this method is used and the IRB reviews a report summarizing expedited review actions at a convened meeting, the minutes should describe what was presented to the IRB, indicate that the IRB members had an opportunity to ask questions or raise concerns, and summarize questions or concerns, if any, raised by the IRB members. The report of expedited actions may also be appended to the minutes for reference.

- **Unanticipated Problems, Serious or Continuing Noncompliance, Suspension or Termination of IRB Approval**

  If at a convened meeting, the IRB reviews an issue that requires prompt reporting to the IRB under 45 CFR 46.103(b)(5) or 21 CFR 56.108(b) (e.g., an unanticipated problem involving risk to human subjects or others), the minutes should summarize the report and must document the IRB's action, if any, resulting from that review (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). Any review of such information and any decisions made outside of a convened meeting (e.g., as determined by the IRB Chair or Institutional Official for subject safety reasons) should be reported to the convened IRB and the discussion summarized in the minutes. Any subsequent action taken by the convened IRB (e.g., to lift suspension or to terminate the study) must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

C. The Vote on IRB Actions

The minutes of IRB meetings must be in sufficient detail to show the vote on IRB actions as determined during the convened meeting, including the number of members voting for, against, and abstaining (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). Individual voting records by name are not required. The following are examples of acceptable formats for documenting the votes on actions taken by the IRB in the minutes. Each example assumes that 15 members are attending the meeting:

[11] OHRP's guidance on Prisoner Involvement in Research can be found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/prisoner-research-ohrp-guidance-2003/index.html, and the Prisoner Research FAQs can be found at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html.

- Total Voting = 15; Vote: For = 14, Opposed = 0, Abstained = 1.

OR

- Total Voting = 14 [1 member was recused and did not vote]; Vote: For = 12, Against = 1, Abstained = 1.

The minutes should identify any member who has a conflicting interest in a research study, and as such, is excluded (recused) from participation in the IRB's review of that particular research including the reason for the recusal. As shown in the examples above, the minutes of the meeting must reflect a vote count (i.e., for, against, and abstaining) that is consistent with the number of non-conflicted IRB members present (45 CFR 46.107(e); 21 CFR 56.107(e); 45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

Members who are recused from voting on a specific study because of conflicting interests may not be counted toward the quorum. That is, their recusal may not be recorded as an abstention.

IRB members who participate in a convened meeting via telephone or video conferencing may vote and be counted towards the quorum. The IRB must ensure that the votes of such members are recorded in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

IRB members may not vote on proposed research outside of the convened meeting (e.g., via email prior to the convened meeting). IRB members who cannot attend a convened meeting may not send someone (e.g., from their department or office) to vote in their place. Opinions of absent members that are transmitted prior to the convened meeting by mail, telephone, telefax, or email may be considered by the attending IRB members but must not be counted as votes or towards the quorum for convened meetings (45 CFR 46.108(b); 21 CFR 56.108(c)).

D. Requiring Changes or Disapproving Research

The minutes of IRB meetings must be in sufficient detail to show the basis for requiring changes in (to secure approval) or disapproving research (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

If the IRB requires that the investigator make specified changes to the research protocol or informed consent document(s) and resubmit such documents to the convened IRB for subsequent review, the IRB's action, along with the basis for requiring changes must be documented in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

If the IRB disapproves a research activity, the IRB must include a statement of the reasons for its decision in the written notification to the investigator and the institution, and provide the investigator an opportunity to respond in person or in writing (45 CFR 46.109(d); 21 CFR 56.109(e)). The minutes must document the IRB's action along with the basis for disapproving the research (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

E. Controverted Issues and Their Resolution

The minutes of IRB meetings must be in sufficient detail to show a written summary of the discussion of controverted issues and their resolution (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). Many IRBs struggle with the amount of detail that is necessary to satisfy this regulatory requirement.

Controverted issues are those that cause controversy and dispute among the IRB membership during a convened meeting. Controverted issues that arise during the convened meeting usually are the result of opposition to some aspect of the proposed research. During the review of proposed research, IRB members may express a difference of opinion, or raise issues, questions or concerns that cause debate among the IRB members, or even result in disagreement. Some research, by its very nature, is considered to be controversial (e.g., emergency research where informed consent may not be obtained for all subjects or some research involving vulnerable populations).

IRB members may resolve controverted issues and concerns with continued discussion and deliberation, decide to seek further clarification from the investigator or sponsor of the proposed research, or decide to settle the issue by vote. The minutes must summarize the IRB's discussion and resolution of any controverted issues (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

IV. ADDITIONAL CONSIDERATIONS

We recommend that institutions and IRBs decide who is responsible for preparing and maintaining minutes at their institutions and outline the process in the IRB's written procedures. While there is no regulatory requirement for IRBs to approve or accept minutes of IRB meetings, if the institution and IRB choose to adopt a process for review and approval/acceptance of minutes, this process should be covered in the IRB's written procedures. Institutions and IRBs may consider creating a standard template to assist in the preparation of their minutes.

OHRP and FDA recognize that in addition to documenting the IRB's findings and determinations in the minutes, or elsewhere in the IRB records, IRBs may also choose to document other activities that occur during the meeting. For example, some IRBs provide continuing education and training to the IRB members at a convened meeting and document such training in the minutes. IRBs may also communicate announcements or other information to the IRB members and attendees at the meeting and document this in the minutes (e.g., upcoming meeting schedule, staff or membership changes). This practice is acceptable to OHRP and FDA.

IRBs may choose to record IRB meetings (e.g., video, audio tape) and use the recording as a tool to assist in the preparation of written minutes.[12] However, retention of complete recordings of meetings is not required nor does it relieve an IRB of its obligation to keep written minutes in accordance with the requirements of 45 CFR 46.115(a)(2) and 21 CFR 56.115(a)(2). We do not

[12] Institutions and IRBs should ensure recording is permitted by institutional policy and, if applicable, state law. All members, and any others attending the meeting, should be informed that the meeting is being recorded and how the recording(s) will be used.

expect the minutes to include a verbatim transcription of what each member said during the course of the meeting.

IRB records required by the regulations, including meeting minutes, must be retained for at least 3 years after completion of the research that is the subject of the review and must be accessible for inspection and copying by authorized representatives from OHRP and/or FDA at reasonable times and in a reasonable manner (45 CFR 46.115(b); 21 CFR 56.115(b)). Many sets of minutes will have records of review of multiple studies. Relevant portions of the minutes must be retained until the regulatory retention period for each study is satisfied. Institutions and IRBs can expect that representatives of OHRP conducting a compliance oversight assessment, or representatives of FDA conducting a Bioresearch Monitoring inspection, will review minutes and other appropriate IRB records to assess compliance with the regulations.