Minutes of Institutional Review Board (IRB) Meetings: Guidance for Institutions and IRBs

DRAFT GUIDANCE

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U.S. Department of Health and Human Services

Office for Human Research Protections **Food and Drug Administration**

November 2015

Contains Nonbinding Recommendations

Draft – Not for Implementation

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U.S. Department of Health and Human Services

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This draft guidance, when finalized, will represent the Office for Human Research Protections' (OHRP's) and the Food and Drug Administration's (FDA's) current thinking on this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This draft guidance has been prepared jointly by the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and the Food and Drug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). This guidance is intended for institutions and institutional review boards (IRBs) responsible for oversight of human subject research under HHS and FDA regulations.

This draft guidance is intended to assist institutions and IRBs responsible for preparing and maintaining minutes of IRB meetings (also referred to in this guidance as minutes). This draft guidance document describes requirements for minutes and provides recommendations for meeting the regulatory requirements for minutes.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 *should* in OHRP and FDA guidances means that something is recommended or suggested, but not required.

II. BACKGROUND

The institution, or where appropriate an IRB, must prepare and maintain adequate documentation of IRB activities, including minutes of IRB meetings (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). 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.

[1] OHRP Determination Letters are posted at http://www.hhs.gov/ohrp/compliance/letters/index.html and can be viewed by the date issued.

[2] FDA Warning Letters are posted at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm and can be viewed via multiple browsing options (e.g., by date, by company, by subject).

Examples of noncompliance related to minutes include:

- Minutes are missing.
- 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.
- The IRB maintains multiple sets of minutes with different information for the same meeting.
- 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 document the IRB's findings and determinations. Minutes provide information to persons not present at the meeting (e.g., institutional officials, regulators, IRB members who could not attend) about the IRB's decisions and provide documentation of the IRB's compliance with regulatory requirements. Minutes should be detailed enough for OHRP and FDA to be able to determine compliance with the applicable regulations.

When reviewing proposed research, IRBs must make certain findings and determinations to fulfill specific regulatory requirements (e.g., that the study meets the approval criteria found in the regulations at 45 CFR 46.111 and 21 CFR 56.111). We recommend that IRBs document their findings and determinations in the minutes, or elsewhere in the IRB records (e.g., IRB reviewer form/checklist, database entries, or other forms of physical or electronic records).

The regulations for IRB records 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 may adopt procedures for preparation and maintenance of minutes that best suit their particular organization.

III. DISCUSSION

IRBs that review research subject to HHS and FDA regulations (45 CFR part 46 and 21 CFR parts 50 and 56, respectively) must comply with the requirements in 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 institutions, or where appropriate, an IRB, prepare and maintain adequate documentation of IRB activities, including minutes in sufficient detail to show:

- Attendance at the meetings;

- 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.

A. Attendance at the IRB Meeting

Minutes of IRB meetings must be in sufficient detail to show attendance at the convened meeting 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. 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

It is important for IRBs to keep an accurate record of who attended each convened meeting of the IRB. OHRP and FDA recommend that the minutes include the full names of the IRB members present and participating in the convened meeting and the representative status for each member (e.g., scientist, nonscientist, unaffiliated). We recommend that attendance information be listed at the beginning of the minutes so it is clear who was present at the meeting.

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.

If the IRB has appointed alternate members who may substitute for primary members at a convened meeting, the minutes should document any circumstance in which an alternate member is replacing a primary member. An alternate may substitute for a primary IRB member for an entire meeting (e.g., when the primary member is not able to participate in the meeting), or at any time during a meeting for the review of particular research proposals (e.g., when the primary member has a conflict of interest and is recused from review of a particular study). In any situation in which an alternate member replaces a primary member at a convened meeting, the minutes must provide the alternate's name and representative status, the name of the primary member for whom the alternate is substituting, and the reason for the substitution (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). Even if an alternate substitutes for a primary member for only a portion of the meeting, we recommend that the reason for the substitution be documented in the minutes.

IRBs may invite consultants to assist in the review of a particular study. If the IRB uses a consultant, the minutes should include the name of the consultant and a brief description of the consultant's expertise. Because a consultant is prohibited from voting (45 CFR 46.107(f); 21 CFR 56.107(f)), we recommend that IRBs document in the minutes that the consultant did not vote 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 minutes should be clear that the non-member or guest did not participate in the deliberation and voting. The institution and the IRB may consider having a written policy covering the attendance of non-members and guests at a convened meeting. This policy may help to ensure that those who attend an IRB meeting understand the confidential nature of the information being reviewed and promote respect for the IRB's advice and counsel in safeguarding the rights and welfare of human subjects.

2. Quorum

The attendance information documented in the minutes assists in determining which and how many IRB members must be present to convene a meeting (i.e., quorum) and whether proposed research receives enough votes (i.e., a majority of those present) to be approved.

A quorum is the minimum number and type of IRB member that must be present at a convened meeting for the IRB to conduct business. 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.

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 majority is 6 (half of 10 is 5, plus 1 equals 6). However, if the IRB has an odd number of members, then 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 in order for the IRB to conduct business (45 CFR 46.108(b); 21 CFR 56.108(c)). If quorum is lost during a meeting, then the IRB may not take any further action or vote on proposed research. Because IRB members may occasionally enter or leave the room at various times during a convened meeting (e.g., arrive

[3] Note that the regulations do not prohibit IRBs from having more stringent requirements for quorum.

late, depart early, or leave the meeting temporarily), we recommend that the minutes provide sufficient information to indicate that a quorum is present throughout the meeting.

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. The minutes must summarize all research activities being reviewed by the IRB at that meeting, and must document actions taken by the IRB (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). The minutes should serve as a central repository for IRB decisions 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)). 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, table the proposed research until additional information can be obtained, or defer a decision).

The minutes, or other IRB record, should show that the IRB made all of the findings and determinations required for approval under the regulations. If a proposed research activity is approved with conditions, the minutes should state the process to be followed to ensure the conditions are met (e.g., the IRB Chair, or other individual(s) designated by the IRB, will review and determine whether the changes, clarifications, and/or additional documents submitted by the investigator are satisfactory). Both OHRP and FDA have issued guidance that addresses the authority of IRBs to approve research with conditions.[4]

The minutes should identify the effective date of approval and the approval period (continuing review interval) for any study approved by the IRB. IRBs must determine which protocols require continuing review more often than annually (at intervals appropriate to the degree of risk) (45 CFR 46.103(b)(4)(ii); 21 CFR 56.108(a)(2); 45 CFR 46.109(e); 21 CFR 56.109(f)). Both OHRP and FDA have 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]

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[4] OHRP's Guidance on IRB Approval of Research with Conditions can be found at http://www.hhs.gov/ohrp/policy/conditionalapproval2010.html; FDA's Guidance on IRB Continuing Review after Clinical Investigation Approval can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf.

[5] OHRP's Guidance on IRB Continuing Review of Research can be found at http://www.hhs.gov/ohrp/policy/continuingreview2010.html; FDA's Guidance on IRB Continuing Review after

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 summarized in the minutes (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). The summary should include the reason(s) for the IRB's action(s) and any follow-up action items. Any decision to suspend or terminate IRB approval that occurs 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.

3. Other IRB Regulatory Determinations and Review Responsibilities

IRBs must make certain regulatory findings and determinations in order to approve research (e.g., that research involving children satisfies the additional protections provided for children at 45 CFR part 46, subpart D and 21 CFR part 50, subpart D). Because these findings and determinations are made during IRB meetings, many IRBs document them in the minutes. OHRP and FDA recommend that IRBs document all required findings and determinations in the minutes or elsewhere in the IRB records (e.g., IRB reviewer form/checklist, database entries, or other forms of physical or electronic records), and include protocol-specific information justifying the 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). These criteria apply to both initial review and continuing review of research and provide the framework for the IRB's evaluation of research. The minutes, or other IRB record, should summarize the IRB's consideration of the approval criteria and should include a determination as to whether the criteria were met, as applicable.

- **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 informed consent 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)).

Clinical Investigation Approval can be found at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294558.pdf.

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 minutes, or other IRB record, must also summarize any changes to the informed consent form(s) required by the IRB (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

Both OHRP and FDA regulations permit an IRB to waive the requirement that the subject or the subject's LAR sign a written consent 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 with protocol-specific information justifying the IRB's decision(s).

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 requirements to obtain informed consent provided the IRB finds and documents that certain criteria are met. When an IRB approves a waiver 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 of consent be documented in the minutes and that the minutes include protocol-specific information justifying each IRB finding.

IRBs should be aware that FDA does not have similar regulatory provisions permitting an IRB to waive elements of consent, or to waive informed consent altogether.

- **Studies Involving Children**

  Each IRB that reviews studies involving children as subjects covered by 45 CFR part 46 subpart D and 21 CFR part 50 subpart D may approve only those studies that satisfy the criteria described in subpart D (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 or 21 CFR 50.51 (research/clinical investigations not involving greater than minimal risk); 45 CFR 46.405 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 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 or 21 CFR 50.54 (research/clinical investigations not otherwise approvable that present an opportunity to understand, prevent, or alleviate a serious problem

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

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.[7]

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 protections 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[8] and/or FDA's regulations at 21 CFR 50.24.

  FDA has issued guidance on the exception from informed consent requirements for emergency research.[9] 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**

  For FDA-regulated research involving an investigational medical device, sponsors are responsible for determining whether the device study is significant risk (SR) or nonsignificant risk (NSR) and presenting this information to the IRB.[10] The IRB must then make its own SR or NSR determination about the study, and either agree or disagree with the sponsor, by reviewing relevant information provided by the sponsor at a

[7] OHRP's guidance on Children Involved as Subjects in Research: Guidance on the HHS 45 CFR 46.407 ("407") Review Process can be found at http://www.hhs.gov/ohrp/policy/populations/guidance_407process.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 http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm127605.pdf.

[8] Information about OHRP's Informed Consent Requirements in Emergency Research can be found at http://www.hhs.gov/ohrp/policy/hsdc97-01.html.

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

[10] See FDA's Information Sheet Guidance on Significant Risk and Nonsignificant Risk Medical Device Studies at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf.

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 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 46 subpart B). OHRP recommends that when such research is approved by the convened IRB, all required findings should be documented in the minutes, including protocol-specific information justifying the IRB's findings.

  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, and neonates as subjects, IRBs may find 45 CFR 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 46 subpart C). OHRP recommends that when such research is approved by the convened IRB, all required findings should be documented in the minutes, including protocol-specific information justifying the IRB's findings.

  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 46 subpart C, and OHRP's guidance on research in prisoners[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 appraised of expedited actions. One method that may be used is to present a report of expedited actions during a convened meeting. If this

[11] OHRP's guidance on the Involvement of Prisoners in Research can be found at http://www.hhs.gov/ohrp/policy/prisoner.html, and the Prisoner Research FAQs can be found at http://answers.hhs.gov/ohrp/categories/1568.

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.

- **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), 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 documented.

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 were present for the vote:

- 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.

OHRP and FDA recommend that minutes 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 (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

IRB members may not vote 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 to resubmit such documents to the convened IRB for subsequent review, these IRB decisions 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 should summarize the IRB's discussion and deliberations for its decision to disapprove proposed research, and clearly indicate the IRB's reasons for its decision.

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. If resolution was not reached about a controverted issue and the IRB seeks additional information, the minutes must summarize the IRB's discussion and plans for seeking resolution (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)).

Similarly, when resolution of controverted issues is reached, the minutes must summarize the IRB's discussion and how they were resolved (45 CFR 46.115(a)(2); 21 CFR 56.115(a)(2)). If there were no controverted issues, this should also be noted in the minutes.

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. If the institution and IRB have a process for review and either acceptance or approval 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. This process, if used, should be described in the IRB's written procedures.[12] However, retention of complete recordings of meetings does not 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 expect the minutes to include a verbatim transcription of what each member said during the course of the meeting.

Records required by the regulations, including meeting minutes, must be retained for at least 3 years after completion of the research subject of the review and must be accessible for inspection and copying by authorized representatives from OHRP and 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; those minutes must be retained until all of the studies that were reviewed at that meeting have been completed for at least 3 years. 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.

[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.