The Importance of IRB Meeting Minutes, Review Guides, and Other Documentation

As Scrutiny Continues, Community Hospitals and Other Institutions with IRBs Need to Ensure Proper Documentation

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In recent months, the accuracy and completeness of human participant protection program documentation has received increased attention from the Office for Human Subjects Research Protection (OHRP)[1] and the Department of Veterans Affairs Office of Inspector General (VA OIG).[2] The recent scrutiny reminds community hospitals, universities, academic medical centers, and other institutions with institutional review boards (IRBs) to engage in the possibly long overdue evaluation of whether the actions of IRB members are properly documented in meeting minutes, review guides, and other supporting materials.

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Introduction: Identifying IRB Documentation

The term "meeting minutes" generally encompasses a set of documents that arise from a convened IRB meeting, including an attendance record, the protocol voting record, and other panel composition documentation, such as a log of the IRB members who recuse themselves during a protocol review due to a conflict of interest. A review guide is used both in convened IRB review, where it may or may not be filed with the protocol, and to document expedited review findings, where it is the only documentation of the review.

The review guide may contain all the requirements that the reviewer must consider before making a determination, such as the regulations and elements of consent in detail, or it may be very general and refer the reviewer to supplemental materials, often in the form of

laminate sheets, that detail the specific regulations, laws, and other requirements that the reviewer must consider before making a determination on the review guide.

For institutions acting as the IRB of record for a VA medical center, the institutions should note that attendance sign-in sheets and other documentation that record requirements in the table within this article also should be delivered to the VA Research and Development (R&D) Committee to demonstrate appropriate IRB composition, particularly as to quorum, the presence of a physician member for Food and Drug Administration (FDA) regulated research, *ad hoc* consultant materials, and the presence of an appropriate representative for vulnerable populations as defined by the VA.

The Importance of Conducting an Assessment

The meeting minutes or review guides are the only indication that the review has integrated the factual circumstances of the protocol with the applicable requirements. As with other health care compliance areas, if a thoughtful consideration of the application of requirements is not documented, it is as though it did not happen. The documentation of a thoughtful consideration that applies both the legal and regulatory framework to the factual circumstances on a protocol-by-protocol basis is far more favorable from a compliance perspective than having no record of the decision making process.

Getting Started with an Assessment of IRB Meeting Minutes, Review Guides, and Other Documentation

To assess human participant program compliance with applicable documentation requirements, an institution can utilize the table of compiled requirements as a self-assessment tool in the following manner:

- Gather relevant review guides, checklists, IRB rosters, protocol voting records, standard operating procedures, and policies and procedures.
- Review whether the review guides, checklists, and internal policies and procedures:
  - accurately state requirements; and
  - are consistent among all documents and policies and procedures.
- Remove unnecessarily duplicative instructions from the documents and incorporate the checklists and review guides by references in the policies and procedures.
- Assess whether the extensive rewriting of policies and procedures and other related materials is required and whether the development of new materials is necessary.
- Obtain a sample of meeting minutes from several recent IRB meetings from all boards and review against the table in this article (see page 18 - 19) for compliance with the applicable requirements.
- Obtain a sample of review guides for expedited review to determine whether the review was appropriate and whether the reviewer properly documented required findings on the review guide.
- If an institution has created an IRB meeting minute template, review the IRB template for compliance with requirements and ease of use on a regular basis, particularly when policies and procedures are updated.
- If an institution does not have a meeting minute template, consider creating an IRB meeting minute template to increase accuracy and efficiency. (Refer to "Evaluating and Developing Meeting Minute Template Tools" on page 19.)

IRB Documentation as a Component of the Quality Assurance/ Quality Improvement Program

Human participant protection programs with quality assurance/quality improvement programs in different stages can benefit equally from the use of the meeting minutes as a tool to evaluate, and provide feedback to, the IRB chair, IRB members, and human par-

ticipant protection program staff, from programs that are in their infancy to more developed programs.[3] Educational materials and policies and procedures can be developed in response to findings, as well as the implementation of different processes.

Meeting minutes are often seen as an afterthought in human subject protection programs because the productivity of the office is often benchmarked to a certain rate of protocol processing. Yet, meeting minutes and review guides serve a vital function for internal audit, assessment, and evaluation purposes.

For example, for noncompliance activities, including but not limited to subject complaints, lapses in IRB approval, expired investigator or research personnel training, or the use of improper informed consent forms, an individual in the human participant protection program, with the possible assistance of the IRB Chair, should first review the matter for factual basis as noncompliance in nonemergency situations and, if so, recommend the matter to the convened IRB for a determination of whether the noncompliance is serious or continuing noncompliance. The individual's determination and reasoning for this matter must be documented and filed in the protocol file so that a record exists of the disposition of the matter, particularly if the matter is not recommended to the convened IRB. For matters that are recommended to the convened IRB, the meeting minutes must capture that the matter was reviewed, whether or not the noncompliance presented serious and continuing noncompliance, the reasoning, and any controverted points.

Institutions that are the IRB of record for VA medical centers are responsible for a more timely turnaround time because the IRB of record at the affiliate institution must make the draft IRB meeting minutes available to the VA medical center R&D Committee within three weeks of the IRB of record meeting date.[4] As a subcommittee of the VA medical center R&D Committee, the affiliate IRB has a responsibility to communicate through meeting minutes that it considered each requirement in making each protocol determination as the meeting minutes are the primary means of communicating the rationale of the IRB determinations.

If the minimum documentation requirements are not met, the human participant protection program staff would not have any objective indication as to whether and on what basis the key determinations of a protocol have been made. Fortunately, the documentation requirements for meeting minutes and related records are very much in step with the information that an IRB or human participant protection program needs to operate as an IRB of record. Once meeting minutes become a priority, the overall efficiency and accuracy of an office can improve.

Commonly, institutions discover that meeting minutes are lacking only when an IRB determination needs further explanation long after the panel met. For example, a principal investigator might request the underlying reasoning behind the determination in response to a modification request letter. An internal audit may uncover irregularities with the determination, and the auditor might want to refer to the meeting minutes to understand how the IRB came to its determination to identify the source of the problem.

Complete and accurate minutes also reduce redundancy and improve efficiency in running IRB meetings, a significant benefit to IRB members who are either volunteers or receive a minor compensation. Most frequently, IRB members may question whether certain points were raised and resolved at the previous convened continuing review or at initial review and, if so, inquire as to how the issue was resolved. The meeting minutes serve as an important tool that can be used to make the IRB more efficient to ensure that previously discussed matters are not repeated without a reason.

A wide range of institutions can make meeting minute preparation more timely and efficient by considering the following:

- Create meeting minute templates with exact regulatory, policy, and directive

Library of IRB Documentation Requirements

General Topic	Citation	Documentation
Convened IRB Composition and Documentation of Activity: Including but not limited to: Licensed physician included in quorum for FDA-regulated research; recusal due to COI; capturing detailed IRB discussion of controverted issues and resolution; rationale for requiring changes; rationale for disapproval; voting; actions taken by IRB; documentation of unresolved matters	45 C.F.R. §115(a)(2); 45 C.F.R. §46.107(a)-(f); VHA Handbook 1200.05, Section 7.i.(a)-(b), pp. 16; AAHRPP Elements: II.3.A, II.3.C; VHA Handbook 1200.05, Section 7.f.(1); OHRP Guidance on Written Procedures, dated January 15, 2007; 38 C.F.R. §115(a)(2); 38 C.F.R. §16.107(e); 21 C.F.R. §56.107(e); 38 C.F.R. §115(a)(2); 21 C.F.R. §56.116(a)(2)	IRB Roster; Protocol Voting record; Meeting Minutes
Waiver or Alteration of HIPAA Authorization	45 C.F.R. §46.107(a)-(f); VHA Handbook 1200.05, Section 7.i.(a)-(b), pp. 16; AAHRPP Elements: II.3.A, II.3.C; VHA Handbook 1200.05, Section 7.f.(1); OHRP Guidance on Written Procedures, dated January 15, 2007; 38 C.F.R. §115(a)(2); 45 C.F.R. §164.512(i)(2); VHA Handbook 1200.05, Appendix E, Section 2; AAHRPP Elements II.6.A; II.6.B	Meeting Minutes
Initial Review: Minimization of risks to subjects; risks to subjects are reasonable related to the benefits; equitable selection of subjects; informed consent from prospective subject or legally authorized representative; protections for privacy of participant and confidentiality of data, as applicable; protocol has provisions for data safety monitoring, if applicable; assessment of risk and review period	21 C.F.R. §56.111(a)(1)-(a)(5); 38 C.F.R. §16.111(a)(1)-(a)(5); AAHRPP Elements: II.3.A & C; II.4.A & B; II.5.A & B. II.6.A & B	Meeting Minutes (convened review); Review Guide (expedited review); support in protocol file (application)
Expedited review: IRB Chair or his or her designee who is an experienced reviewer conduct expedited review; research is minimal risk; exped ted review category: justification; IRB member notice that the research is expedited	45 C.F.R. §110; 38 C.F.R. §16.110(b); 21 C.F.R. §56.110(b); 38 C.F.R. §16.110(c); 21 C.F.R. §56.110(c)	Review Guide; Agenda
Short Form Consent: Must be reviewed; review of summary of information verablly provided to prospective participants	45 C.F.R. §109; 45 C.F.R. §46.116-117, generally	Meeting Minutes (convened review); Review Guide (expedited review); support in protocol file
Continuing Review: Minimization of risks to subjects; risks to subjects are reasonable related to the benefits; equitable selection of subjects; informed consent from prospective subject or legally authorized representative; protections for privacy of participant and confidentiality of data, as applicable; protocol has provisions for data safety monitoring, if applicable; assessment of risk and review period	45 C.F.R. §115(a)(2); 38 C.F.R. §16.111(a)(1)-(a)(7); 21 C.F.R. §56.111(a)(1)-(a)(7); AAHRPP Elements: II.3.A & C; II.4.A, B, D; II.5.A & B; II.6.A & B; OHRP Guidance; FDA Info Sheets	Meeting Minutes (convened review); Review Guide (expedited review); support in protocol file (application)
Unanticipated Problems/Events Requiring Prompt Reporting: reasons for terminating or suspending research	45 C.F.R. §113; 38 C.F.R. §16.113; 21 C.F.R. §56.113; AAHRPP Element: II.4.D	Meeting Minutes

General Topic	Citation	Documentation
Review of Investigational Devices	21 C.F.R. §812(b); AAHRPP Element: 1.5.A; FDA Info Sheets	Meeting Minutes
Tissue Banking	VHA Tissue Banking Requirements: http://www.research.va.gov/programs/tissue_banking/ For NIH GWAS funded: http://grants.nih.gov/grants/gwas/	Meeting Minutes (convened review); Review Guide (initial review); support in protocol file (application); support in Informed Consent Template
Informed Consent Process: Waiver of Informed Consent Alteration of Elements of Informed Consent Waiver of Documentation of Informed Consent	45 C.F.R. §109; 45 C.F.R. §46.116-117, generally; 38 C.F.R. §16.117(c)(1); AAHRPP Elements II.3.A; II.3.C; II.7.E; OHRP Guidance; note FDA limitations; VHA Handbook 1200.05, Appendix C, Section 3(f); AAHRPP Elements: II.6.A, II.6.B	Meeting Minutes
Vulernable Populations: additional protections vulnerable populations, decisionally and cognitively impaired, prisoners, children, women and fetuses	OHRP Guidance; 38 C.F.R. §16.107(a); 21 C.F.R. §56.17(a); 45 C.F.R. §46.107(a); VHA Handbook 1200.05: Appendix D, Section 6 b(1)-(2); c(1)-c(3), 6(e), Section 11(b), Appendix C; AAHRPP Elements: II.1.D; II.4.C, II.5.A, 11.7.A & B, III.1.F; 21 C.F.R. §50.27; 21 C.F.R. §50.27(a; 38 C.F.R. §16.107(a); 21 C.F.R. §56.107(a); 45 C.F.R. §46.304(a)-(b); 45 C.F.R. §46 Subpart D; VHA Directive 2001-028; 45 C.F.R. §46.204; Various VA memos; Office of Research Oversight Guidance, dated May 10, 2007	Meeting Minutes (convened review); Limited Circumstances: Review Guide (expedited); support in protocol file

Note: This table is intended to be a tool for compiling a library of documents and IRB documentation and is not intended to be inclusive of all requirements that might apply to the factual circumstances of each individual research protocol.

language that can be tailored to the protocol for the most part in real time during the IRB meeting;

- Use templates in running IRB meetings to ensure that the required points are covered and to assist in a more efficient process;
- Provide training for staff who document meeting minutes on meeting minute requirements and explain their application through case studies to ensure efficiency in both documentation and running the IRB meeting; and
- Create a flow diagram that shows how meeting minutes are compiled, including a representation of whether letters are generated first and then the letter language is pasted into the meeting minutes or vice versa. Based on these findings, consider whether this order is necessary and whether the organization can develop a more efficient process. Document the process in a standard operating procedure so that human participant program staff is using the same work flow process.

The meeting minutes, review guides, and supporting documentation are essential for institutions to demonstrate an ongoing attempt to comply with applicable regulations, policies, and directives when undergoing site audits from various government agencies, as well as site visits from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) for research accreditation and reaccreditation purposes.

IRB Documentation as a Component of AAHRPP Research Accreditation

AAHRPP research accreditation sometimes imposes requirements beyond regulations, laws, handbooks, and directives in many areas, including in the area of meeting minutes and documentation. Complete and timely meeting minutes are essential for the following AAHRPP elements:

- Documentation of IRB findings is evaluated by AAHRPP site visitors to determine whether certain elements related to documentation are met.[5]
- Having a checklist format that clearly states regulatory, policy, handbook, and directive requirements assists IRB members in recalling, remembering, and applying the requirements, which assists when IRB members undergo the AAHRPP interview process.[6]
- AAHRPP requires the evaluation and feedback of the IRB chair, IRB members for accreditation or reaccreditation.[7]

Due to highly technical and specific matters that the IRB must consider in the convened and expedited review process, creating an appropriate meeting minute template tool is key.

Evaluating and Developing Meeting Minute Template Tools

The Department of Health and Human Services, the Food and Drug Administration, OHRP, the Office of Research Oversight (for VA research), and AAHRPP each have precise and easily identifiable IRB determination documentation standards, with many standards overlapping or restating a requirement in a more detailed manner. Yet, because these elements are being applied to varied factual circumstances, and to both social and behavioral and biomedical research, a variety of different results are possible.

In many cases, IRB determination requirements originate from ethical considerations that may be subjective and dependent on local research context judgments. As evidence of this, IRBs around the country apply many of these requirements on the same protocols and often diverge on their determinations. The requirements should be viewed as topics that must be considered but are not so specific as to render the review framework unworkable.

Precise Review Requirements

Due to the precise points that need to be considered by an IRB panel or designated reviewer during an expedited review, government agency audits quickly find gaps in the review process. OHRP has consistently emphasized the importance of creating a written record[8] of IRB findings in its determination letters to institutions, including those dating back to 2000.

For example, in 2007, OHRP noted in a determination letter to the University of California (UC) at Berkeley that a lack of written documentation of the IRB determination as to which of the four categories of subpart D[9] apply to children's research existed in a trial within OHRP jurisdiction: "OHRP finds no evidence that the institution's IRB [the institution's IRB] made subpart D findings when reviewing study #2004-3-6 in 2001, 2002, 2003, 2004, and 2005." OHRP determined that UC Berkeley was required to submit a corrective action plan as to the above finding of noncompliance:

> Please provide OHRP with a corrective action plan outlining how UC Berkeley will ensure that [the institution's IRB] makes the required findings under subpart D when reviewing research involving children. In addition, please review all currently active research studies involving children and receiving HHS support to determine whether subpart D findings were appropriately made for those studies.[10] If subpart D findings were not made, [the institution's IRB] must re-review all such studies for compliance with subpart D.

Similarly, the VA OIG's recent increased scrutiny of VA affiliate IRBs of record[11] also underscores that quantifiable elements must be thoughtfully considered by the IRB and applied on a protocol-by-protocol basis. In *Comparison of VA and University Affiliated IRB Compliance with VHA Handbook 1200.5*, the VA Office of Inspector General examined "whether IRB minutes contained eight necessary elements described in VHA Handbook

[1200.05]" among VA IRBs and university affiliate IRBs, finding that the university affiliate IRBs lagged VA IRBs in percentage of compliance performance.[12]

Creating a Meeting Minute Template, Checklist, and Review Guide

Certain determinations must be made by the IRB and, therefore, a checklist format is favorable for developing meeting minute template tools. Templates, checklists, and review guides should be created using the following core guidelines:

- Regulatory, policy, and directive language should never be restated or paraphrased. Ensure that all requirements have been added to the template.[13] Quote the exact language in the aid to avoid changing the meaning of the language or having inconsistent documentation requirements.
- Include points that the IRB can consider that can help explain, or place in context, the primary regulatory, policy, or directive requirement.
- Clearly distinguish requirements from points to consider under each requirement.
- Avoid inadvertently providing a "not applicable" option for regulatory, policy, and directive requirements by carefully reviewing the format of the checklist.
- Introduce a sign-in sheet to capture IRB members at each meeting and show that sufficient IRB staff are present to document attendance.[14]
- Template language should be used only to reflect the discussion at an IRB meeting and should never be included simply to fulfill a regulatory element.[15]

Conclusion

A regular, systematic evaluation of IRB meeting minutes and supporting documentation must be a part of all human participant protection programs. Meeting minutes, review guides, and other supporting documents demonstrate that the IRB properly met composition requirements and thoughtfully considered applicable federal and state regulations and laws, VHA directives and handbooks, and institutional policies and procedures in making its determination as to a research protocol.

Endnotes:

1. OHRP Determination Letter to the University of California at Berkeley, dated June 29, 2007; OHRP Guidance on Written IRB Procedures, dated Jan. 15, 2007.
2. *Comparison of VA and University Affiliated IRB Compliance with VHA Handbook [1200.05]*, VA Office of Inspector General, dated Sept. 28, 2007, *available at* www.va.gov/oig/54/reports/VAOIG-06-00980-217.pdf.
3. An institution should follow applicable regulations and its own policies and procedures, and the appropriate parties should determine whether a quality assurance/quality improvement assessment qualifies as human participant research prior to engaging in such activities.
4. Requirements for the Protection of Human Subjects in Research, VHA Handbook 1200.05, dated July 31, 2008, p. 16.
5. AAHRPP Evaluation Instrument for Accreditation, Element II.3.C, p. 46, available at http://www.aahrpp.org/Documents/D000043.PDF; AAHRPP Evaluation Instrument for Accreditation- For VA Facilities and Academic Affiliates and AAHRPP Evaluation Instrument for Accreditations, updated June 1, 2007, Element II.3.C, pp. 47-48, available at www.aahrpp.org/Documents/D000103.PDF.
6. AAHRPP Evaluation Instrument for Accreditation, Standard I-4, p. 30, available at http://www.aahrpp.org/Documents/D000043.PDF: AAHRPP Evaluation Instrument for Accreditation for VA Facilities and Academic Affiliate, updated June 1, 2007, Standard I-4, pp. 30-31, *available at* www.aahrpp.org/Documents/D000103.PDF.
7. AAHRPP Evaluation Instrument for Accreditation, Element I.3.L, p. 29; Element II.1.D, p. 38, available at http://www.aahrpp.org/Documents/D000043.PDF; AAHRPP Evaluation Instrument for Accreditation for VA Facilities and Academic Affiliate, updated June 1, 2007, Element I.3.L, p. 29; Element II.1.D, p. 38, *available at* www.aahrpp.org/Documents/D000103.PDF.
8. OHRP Determination Letter to the University of Chicago, dated Aug. 9, 2002, p. 3, provides that "HHS regulations at 45 C.F.R. §46.115(a)(2) require that minutes of IRB meetings provide a written summary of the discussion of controverted issues and their resolution"…"tape recording of UC IRB meetings did not fulfill these requirements."
9. 45 C.F.R. §46, subpart D (Additional Protections for Children Involved as Subjects in Research).
10. The UC Berkeley asserted that its federal wide assurance does not state that the university will apply 45 C.F.R. 46 to research funded by "non-federal monies." OHRP Determination Letter to the University of California at Berkeley, dated June 29, 2007, p. 11, *available at* www.hhs.gov/ohrp/detrm_letrs/YR07/jun07c.pdf.

11. VA Office of Inspector General, *supra* note 2.
12. *Id.*, at 13.
13. OHRP Determination Letter addressed to the University of Washington, dated Sept. 9, 2005, noted that a template did not contain sufficient detail and did not "contain an entry for the documentation of specific IRB findings or any indication of how findings will be documented."
14. OHRP Determination Letter addressed to St. Joseph's Hospital, dated May 19, 2005, provided that a sign-in sheet for IRB members and sufficient IRB staffing was sufficient to meet regulatory documentation requirements as to IRB meeting attendance.
15. OHRP Determination Letter addressed to Cook County Bureau of Health Services, dated June 19, 2006, cautions, "It is not appropriate to insert template language in the minutes unless that language reflects actual consideration of a specific regulatory issue that occurred during the IRB meeting."

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