**AAHRPP ELEMENT II.5.B.**

***ELEMENT II.5.B.: The IRB or EC documents discussions and decisions on research studies and activities in accordance with legal and regulatory requirements, sponsor requirements (if any), and organizational policies and procedures.***

The IRB or EC must document discussions, decisions, and findings. This can be accomplished either through the minutes (defined to include primary documents plus any supplemental documents such as checklists or notes) or, when the expedited procedure for review is used, through documentation in the protocol file or other records. Records may be maintained in printed form or electronically.

Minutes of IRB or EC meetings should be clear about the actions the IRB or EC takes and exactly what the IRB or EC approved, including documenting that the IRB or EC has considered an approved research in accordance with criteria based on applicable laws, regulations, codes, and guidance. Minutes should specify the modifications required to secure approval and the reason the IRB or EC is requesting the modifications. Minutes should indicate proposals or motions voted upon by the IRB or EC, and the results of each vote. When conducting initial or continuing review, minutes should document the IRB’s determination of the approval period.

**Regulatory and guidance references**

* **DHHS**: 42 USC 498A(b)(1), 42 USC 498A(b)(2), 42 USC 498A(c), 45 CFR 46.115(a)(2), 45 CFR 46.116(c)-(d), 45 CFR 46.117(c), 45 CFR 46.204, 45 CFR 46.205, 45 CFR 46.206, 45 CFR 46.207, 45 CFR 46.305, 45 CFR 46.306, 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, 45 CFR 46.407, 45 CFR 46.408, 45 CFR 46.408, Appendix D, 45 CFR 46 Waiver of the Applicability of Certain Provisions of Department of Health and Human Services Regulations for Protection of Human Research Subjects for Department of Health and Human Services Conducted or Supported Epidemiologic Research Involving Prisoners as Subjects (Federal Register, Vol. 68, No. 119, pp. 36929-36931, Friday, June 20, 2003), 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research (Federal Register, Vol. 61, No. 192, pp. 51531-51533, October 2, 1996), OHRP Guidance on Written Institutional Review Board (IRB) Procedures, OHRP and FDA Guidance on Minutes of Institutional Review Board (IRB) Meetings (2017)
* **DOD**: Instruction 3216.02 15.d
* **FDA**: 21 CFR 50.51, 21 CFR 50.52, 21 CFR 50.53, 21 CFR 50.54, 21 CFR 50.55, 21 CFR 50.56, 21 CFR 56.109(c), 21 CFR 56.115(a)(2)
* **VA**: 38 CFR 16.115(a)(2), 38 CFR 16.116(c)-(d), 38 CFR 16.117(c),  VHA Handbook 1200.05, 24, 28
* [AAHRPP Tip Sheet: Documenting Discussions and Decisions on Research Studies and Activities](https://www.aahrpp.org/resources/for-accreditation/tipsheets/documenting-discussions-and-decisions-on-research-studies-and-activities)

**Required written materials**

1. **Essential requirements:** 
   1. Written materials have IRB or EC minutes document attendance at the meeting, including:
      1. Each member’s full name.
      2. Each member’s representative capacity (scientist, non-scientist, member who represents the general perspective of research participants, unaffiliated).
      3. The names of members who participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing.
      4. If a consultant is present at the convened meeting, the name of the consultant, and a brief description of the consultant’s expertise, and documentation that the consultant did not vote with the IRB or EC on the study.
      5. The names of non-members and guests, such as IRB or EC support staff, researchers, and study coordinators.
      6. When an alternate member replaces a primary member, including the name of the alternate member.
      7. The names of IRB or EC members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.
   2. Minutes include actions taken by the IRB or EC with sufficient information to identify the research activities being reviewed and voted on by the IRB or EC at that meeting, including:
      1. Initial review of a protocol.
      2. Review of a request to modify a protocol.
      3. Continuing review of a protocol.
   3. Minutes record separate deliberations for each action.
   4. Minutes record votes for each protocol as numbers for, against, or abstaining.
   5. Minutes include basis for requiring changes in research.
   6. Minutes include the basis for disapproving research.
   7. Minutes include a written summary of the discussion of controverted issues and their resolution.
   8. For initial and continuing review, minutes include the approval period.
   9. Minutes include required determinations and protocol-specific findings justifying those determinations for:
      1. Waiver or alteration of the consent process.
      2. Research involving pregnant women, fetuses, and neonates.
      3. Research involving prisoners.
      4. Research involving children.
      5. Research involving participants with diminished capacity to consent.
2. **When following DHHS regulations:** 
   1. Records must include the rationale for conducting continuing review on research that otherwise would not require continuing review. (See Elements II.2.E. and II.2.F.)
   2. Records must include the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk. (See Element II.2.F.)
   3. Records must include documentation specifying the responsibilities that a relying organization and an organization operating an IRB or EC each will undertake to ensure compliance with the requirements of the Common Rule. (See Standard I-9)
3. **When following DoD requirements:** 
   1. Records maintained by non-DoD organizations that document compliance or noncompliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD.
4. **When following FDA regulations or guidance** 
   1. Policies and procedures have IRB or EC minutes document the rationale for significant risk/non-significant risk device determinations.
5. **When following VA requirements:** 
   1. When the IRB of Record for a VA facility is the IRB of a non-VA entity (e.g., IRB of another federal entity, IRB of an academic affiliate), the non-VA entity must either:
      1. Provide VA with, or access to, unredacted copies of meeting minutes in a timely manner that allows the R&D Committee to review the IRB’s deliberations on VA protocols, or
      2. Provide VA with, or access to, redacted minutes in a timely manner that allows the R&D Committee to review the IRB’s deliberations on VA protocols. The non-VA entity must permit relevant VA personnel (including, but not limited to, ORO staff, local VA research office staff, local research compliance officers, and members of the research and development committee) to review unredacted minutes within two business days of a written request.
         1. Redacted copies of meeting minutes should include the parts of the minutes related to the IRB’s review of VA protocols.
   2. When the IRB approves a consent procedure which does not include, or which alters, any of the elements of informed consent, or waives the requirement to obtain a signed informed consent document, it must find and document that all criteria for the waiver have been satisfied
   3. The IRB must document its determination on the level of risk either in the IRB minutes or the written communication to the researcher.

Common types of materials that may be used to meet the element

* Minutes
* Other records, including documentations

Outcomes

* IRB or EC records reflect the actions of IRB or EC members.