**Human Research Ethics Training Tips**

**Documenting IRB Actions & Discussions**

1. **Federal Regulations & Guidance**

**45 CFR §46.115 IRB Records.**

(a) ***An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities***, including the following:

(2) Minutes of IRB meetings which shall be 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.

(b) The records required by this policy shall ***be retained for at least 3 years***, and records relating to research that is conducted shall be retained for ***at least 3 years after completion of the research***. The institution or IRB may maintain the records in printed form, or electronically***. All records shall be accessible for inspection and copying*** by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner. (Approved by the Office of Management and Budget under Control Number 0990-0260.)

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

IRBs have been cited in *OHRP Determination Letters*[*[1]*](https://www.hhs.gov/ohrp/minutes-institutional-review-board-irb-meetings-guidance-institutions-and-irbs.html-0#_ftn1) *and FDA Warning Letters*[*[2]*](https://www.hhs.gov/ohrp/minutes-institutional-review-board-irb-meetings-guidance-institutions-and-irbs.html-0#_ftn2) 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 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.*

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. <https://www.hhs.gov/ohrp/minutes-institutional-review-board-irb-meetings-guidance-institutions-and-irbs.html-0#_Toc491772342>

1. **AAHRPP Tip Sheet:**

**Documenting Discussions and Decisions on Research Studies and Activities**

* **IRB or EC minutes should document:**
* Actions taken by the IRB or EC.
* Separate deliberations for each action.
* The basis for requiring changes in research.
* The basis for disapproving research.
* A written summary of the discussion of controverted issues and their resolution.
* For initial and continuing review, the approval period.
* Required determinations and protocol-specific findings justifying those determinations for:
  + Waiver or alteration of the consent process.
  + Research involving pregnant women, fetuses, and neonates.
  + Research involving prisoners.
  + Research involving children.
  + The rationale for determining that risk associated with using a medical device in a study is significant or non-significant (referred to as significant risk/non-significant risk device determinations)

1. **Summary & Key Points:**

* Regulator mantra: If it’s not written, it didn’t happen.
* Documentation includes: ***Essential that we have these documents!***
  + **Minutes:** Are they stand alone documents? Staff records only what is said, be sure to speak up.
  + **Checklists:** All necessary ones for each study uploaded into IRBIS?
  + **Stipulations, waivers, Cat 9 and notes**: Additional discussions complete on why or why not?

Remember: If you don’t remember what you ate for dinner last Tuesday, then how will you remember your comments on a protocol reviewed 3 months ago or in 4 years when the FDA audits the file?