Jefferson
Philadelphia University +
Thomas Jefferson University

June 2018 FDA Inspection of IRB

6/25 - 6/28

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CE Background

The 2 Main Goals of IRB Member Continuing Education

1. It is a requirement for AAHRPP accreditation.

2. To provide the IRB members with information that is helpful for the review and approval process.

- Jacquie Wright is now the facilitator.
- Please let her know if you have any presentation ideas.

The Inspection in General – June 25 – 28, 2018

Why were there few observations? 2 Main Reasons

1. We do our jobs well and maintain the right documentation

The Inspection in General – June 25 – 28, 2018

2. Luck

Inspector (Very Accomplished):

- Member of the uniformed services (Public Health Service)
- Air Force
- ER Nurse
- Indian Health Service
- FDA Inspector (Processing Plants, Animals, Pharma)

FDA Inspection of IRB – June 25 – 28, 2018

Main Items Reviewed by the Inspector:

- IRB Study Files
- IRB Meeting Minutes

IRB Study Files

Inspector found Memo: Saline Used May Not be FDA Approved

Other Documentation in IRB Study File:

- OHR-12 (amendment): Done in case unapproved saline had to be used
- OHR-8 (consent): Info on saline and its risks
- IRB Meeting Minutes: Showing that IRB agreed that re-consent would be required
- Letter from Sponsor: Indicating they were getting approval from FDA

IRB Study Files

This was not an FDA Observation because the IRB:

- Did an amendment to ensure subject safety.
- Reviewed all the required documents.
- *Saved all the required documentation, including the letter from the sponsor.

If it's not documented, it didn't happen.

- Don't save every scrap, but when in doubt, file it.
- Make sure important discussion points are included in the minutes.

IRB Meeting Minutes

In the IRB Meeting Minutes the Inspector Concentrated on:

- Were a non-scientist and unaffiliated member present?
- Was Quorum met?
- Did members present match the vote?
- Was an IRB member present who is an expert?
- IRB Member CITI Training
- Should late arrivals abstain from voting?
- Were minutes accurate and complete?

IRB Meeting Minutes

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Order of Review		☐ Vote Not Taken (Reason Below)
☐ Not Reviewed	☐ Incomplete Submission	☐ Loss of Quorum
Other:		
Conflict of Interest: ☐ No COI		
-OR- Name was not present for the discussion, deliberation and vote. This individual ☐ was ☐ was not asked to answer a question(s) for the Board. Note: If COI, vote must reflect this individual's absence.		
Risk		☐ Minimal ☐ Greater than Minimal
Vulnerable Populations ☐ NA -OR- Check Applicable Boxes		
☐ Study involves pregnant women, fetuses and/or newborns. The criteria in 45 CFR 46 Subpart B have been met. The risks to and safety of both the woman and the fetus/newborn were discussed by the IRB. See the OHR-27 in the IRB file.		
☐ Study involves prisoners. The criteria in 45 CFR 46 Subpart C have been met.		
☐ Study involves children. The criteria in 45 CFR 46 Subpart D have been met. See the OHR-26 in the IRB file.		
☐ Study involves another vulnerable population. The criteria in 45 CFR 46.111(b) have been met.		
Device Studies – Risk Determination ☐ No Device		
Documentation for the risk determination can be found in the OHR-25 and any related materials.		
☐ The device is FDA approved. ☐ The device has an IDE/HDE number. ☐ The device is exempt from the requirements to have an IDE (21 CFR 812.2(c)). ☐ The device is non-significant risk and meets the requirements for an abbreviated IDE.		
- OR - If none of the conditions above apply, the IRB must make the risk determination to be recorded below.		
☐ Significant Risk (study may not begin until FDA approves the IDE/HDE application) ☐ Non-Significant Risk		
Recommendation		
	☐ **Approved** ☐ **Not Approved**	

Number of Members Needed for a Quorum (From Roster)	Number of Members Present for Discussion and Vote	For	Against	Abstain

Member Arrives/Departs	Time

Comments
☐ There were no comments for the investigator. -OR- There were the following comments, which include the controverted issues discussed by IRB members:

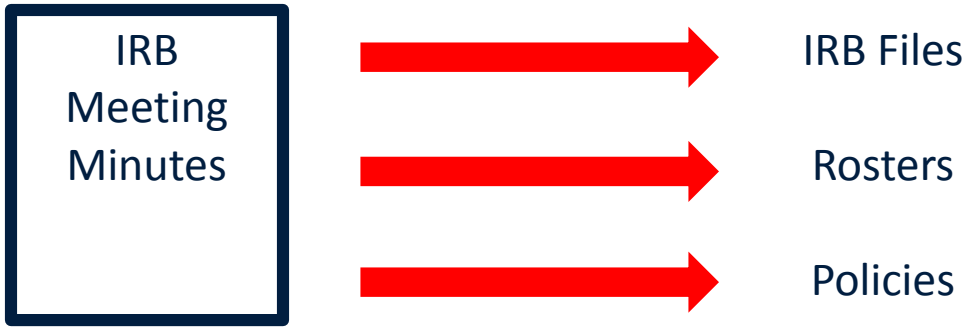
IRB Meeting Minutes

The minutes are the main documents reviewed by the inspector. The inspector starts with the minutes and work out from there. The minutes document:

The studies reviewed by the IRB → IRB Files

That quorum was met → Rosters

That the appropriate regulations were considered → Policies



IRB Meeting Minutes

- There were few FDA observations because:
  - The IRB Members and OHR Personnel do their jobs well
  - The minutes are accurate and complete

- The minutes document all important decisions made by the IRB. They are the record of everything we do.

- *Crystal and Jenn's jobs don't end when the meeting is over. Their attention to detail resulted in fewer FDA observations. Great Job Crystal and Jenn !!!

- Please assist Crystal and Jenn in completing the minutes when clarifications are needed.

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As reviewers, what do you need to do?

- Ensure all appropriate documentation is provided to Secretaries to save in the IRB file.
- Support Crystal and Jenn in creating complete and accurate minutes.

Questions? Comments?

Uniformed Services

The seven uniformed services are:

- United States Army
- United States Marine Corps
- United States Navy
- United States Air Force
- United States Coast Guard
- United States Public Health Service Commissioned Corps
- National Oceanic and Atmospheric Administration Commissioned Officer Corps