Articulating Satisfaction of the IRB Review Criteria

UNC OHRE Full Board Education Session

November 2021

IRB Review Criteria (.111 Criteria)

- 1) Risks to subjects are minimized
- 2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result
- 3) Selection of subjects is equitable.
- 4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative
- 5) Informed consent will be appropriately documented, in accordance with, and to the extent required by the Federal Regulations [45 CFR 46.117].
- 6) The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 7) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- 8) Additional safeguards for vulnerable subjects have been included in the study to protect the rights and welfare of these subjects.

Please note this is an abbreviated representation of the criteria. For full regulatory text please see

§46.111 Criteria for IRB approval of research

Scope and Focus

- This education session is to aid full board reviewers in communicating during the convened meeting in such a way that the meeting minutes analyst can document the satisfaction of the regulatory requirements for §46.115 IRB Records

- The IRB has a regulatory requirement to document 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.*"

Translation:

- You do a lot of really good work to protect human subjects- we want that to be showing up in the meeting documentation.

We want to show off your hard work!

Things to consider:

- Remember: not everyone is an expert on the application and protocol the way you are. Avoid relying on your in-depth familiarity with the materials when presenting.
- Remember: Anyone should be able to do a “cold read” on the meeting minutes and know why the study was reviewed that way without digging for additional supporting information elsewhere in the IRB records (resolved rounds of stipulations, reviewer summaries, reviewer worksheets, etc).

A.R.E

Primary and Secondary Reviewer presentations made to the convened committee should cover what your conclusions are+ how you came to that conclusion, and + evidence from the proposal to back up your statement.

- Discussion that follows should follow the same format until an agreed upon course of action results (findings, motion, vote)

A simple formula to use: Tell us what your thoughts on the review of the study **A.R.E.**

A- Assertion (statement or claim)
R- Reasoning (elaboration and explanation)
E- Evidence (support and used to help prove and show)

When Conversation at Board Incompletely Represents Work of the Reviewer: A Look at the Results

- Initial (reconsideration)

Internal Meeting Notes:

The primary reviewer presented the study and noted that most of previous concerns have been resolved before this meeting. The secondary reviewer concurred with the primary reviewer. With the changes as outlined in the directive stipulations, the Board agreed that the study meets 45 CFR 46.111 criteria for approval and approved the study with minor stipulations for 12 months.

After reading the minutes, discuss:

- What is the study purpose? Study Population? Proposed Procedures?
- Why was this study deferred? Issues were resolved- what were they, and what were the solutions? Why were those solutions deemed appropriate?
- How much of the chart can you complete?

Statement (Assertion)	Reasoning	Evidence
Risks are minimized		
Risks reasonable in relation to benefits		
Equitable subject selection		
Informed consent OK		
Consent documented		
Safety plan appropriate		
Privacy & confidentiality protected		
Vulnerable Subjects protected		
Risk level: 405/406/407		
Regulatory Finding Example: Child Finding 405/406/407		

Putting It All Together

Statement (Assertion)	Instead of:	Consider saying:
Risks reasonable in relation to benefits	"The risks to participants include {list risks}, considering the potential for direct benefit receiving treatment, the risk: benefit ratio is reasonable.	**The risks to participants include {list risks}, considering the potential for direct benefit receiving treatment, the risk: benefit ratio is reasonable.**
Equitable subject selection	Instead of "subject selection is equitable"	**Subject selection is equitable because they are recruiting only from the disease group which may potentially benefit from the drug being studied, and as stated in the protocol and consent forms status of insurance is not required to participate- all costs or co-costs are covered by the study regardless of the individual subject's reducing likelihood of socioeconomic status as a barrier to participation.**
Vulnerable Subjects protected	'risks are mitigated for child population"	**Additional protections are adequate for child subjects in this study; primary risk to subjects is potential emotional distress which may lead to self-injurious behavior. Specialty support staff is available at each session and is experienced working with this population as well as trained monthly in safe restraint and intervention techniques to lower subject risk of harm.**