

To Table or Not to Table? That is the Question

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Goals

- Discuss when and why a protocol should be tabled by an IRB.
- Discuss what qualifies as a "minor modification" and what does not.
- Describe application of the ethical principles to the federal regulations relevant to a decision to table a protocol.

Voting options

- Approve
- Approve pending *minor* modifications
- Table
- Rejected
- Disapproved
- Not approved

Approved Pending Minor Modifications

- The most abused phrase in IRB-dom?
- This means that the modifications will be reviewed by the chair or his or her designee
 - This means those modifications must be "expeditable"
 - OHRP states that the modifications must require "simple concurrence" by the investigators

Expeditable?

- Since the modifications will be reviewed by the chair or the chair's designee, the modifications must meet the requirements for expedited review
- Additionally, the modifications cannot contain elements that would need to be reviewed by the full IRB

What requires full IRB review?

- 45 CFR.111 and 21 CFR 56.111

Who cares???

- The Belmont Report
 - Respect for Persons
 - Treat individuals as autonomous persons
 - Protect those with diminished autonomy
 - Beneficence
 - Maximize benefit
 - Minimize harm
 - Justice
 - Fairly distribute benefits and burdens of research

Ethics and Regulations

- Respect for persons
 - Informed consent will be sought
 - Informed consent will be documented
 - Privacy and confidentiality
 - Vulnerable populations

Ethics and Regulations

- Beneficence
 - Risks are minimized
 - Risks are reasonable in relation to benefits
 - Monitoring safety data
- Justice
 - Selection of subjects is equitable

Simple Concurrence?

- The modification must be spelled out such that the investigator need only concur

Table

- The study will be reviewed again at the next meeting because the IRB lacks sufficient information to approve the study
- Similar to not approved

Bad Reasons to Table

- Spite
- Sending a message
- Random tabling to “keep investigators and staff on their toes”
- Poor preparation on your part
 - Contact investigators or study staff with questions *before* the meeting

Good Reasons to Table

- The elements of 45 CFR 46.111 and 21 CFR 56.111 cannot be decided upon by the IRB
 - If you cannot answer these questions, the study cannot be approved, even with modifications
- The requested modifications or lacking information is such that more than simple concurrence is required
 - What is the plan for protecting privacy?
 - How will blood be stored?

More Good Reasons to Table

- The modifications, even if they only require simple concurrence, are extensive and lengthy

Conclusion

- IRBs should be careful when deciding to conditionally approve a study pending minor modifications
- The regulations have solid ethical underpinnings
- Don't be afraid to table a study...if it is for a good reason
