

Completing a First-Rate Review:

**Your Responsibilities
as an
IRB Reviewer**

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The IRB Mission

To protect the rights and welfare of research participants.

- The IRB is charged with the responsibility of reviewing and overseeing human subject research.
- The IRB review process is designed to **protect the rights and welfare of human subjects** by ensuring
 - equitable subject selection
 - assuring adequate informed consent
 - assessing and minimizing risks
 - maintaining privacy and confidentiality

The Office for Human Research Protections

OHRP is an office within the Dept. of Health & Human Services (DHHS) that deals with the ethical oversight of research.

OHRP Guidance Translation ("Know the Lingo"):

- "Must" = Required
- "Should" = Recommended or Suggested

<http://www.hhs.gov/ohrp>

Title 45 Code of Federal Regulations, Part 46

- **45 CFR 46** consists of Sub-Parts A – D:
 - **Sub-Part A** = “The Common Rule”
 - **Sub-Part B** = Additional protections related to research involving *fetuses/neonates & pregnant women*
 - **Sub-Part C** = Additional protections related to research involving *prisoners*
 - **Sub-Part D** = Additional protections related to research involving *children*

Key Points to Consider

- **Risk:** Is the risk minimized?
- **Validity:** Will the study yield results that matter?
 - » *This doesn't necessarily mean the results matter to you personally...*
- **Consent:** Is the consent document clear & easy to understand?
 - Is it appropriate for the population being studied?

Minimizing Risk

45 CFR 46.111

- How do we ensure the risks to participants are minimized?
 1. Use procedures consistent with sound research design & which do not unnecessarily expose subjects to risk
 2. Whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes

“The job of the IRB is to evaluate
ethics...

...It has no business commenting on
the *science* of a research study.”

What do you think?

Criteria for Approval

- 45 CFR 46.111:
 - In order to approve research, risks to subjects are minimized by using procedures which are consistent with **sound research design**

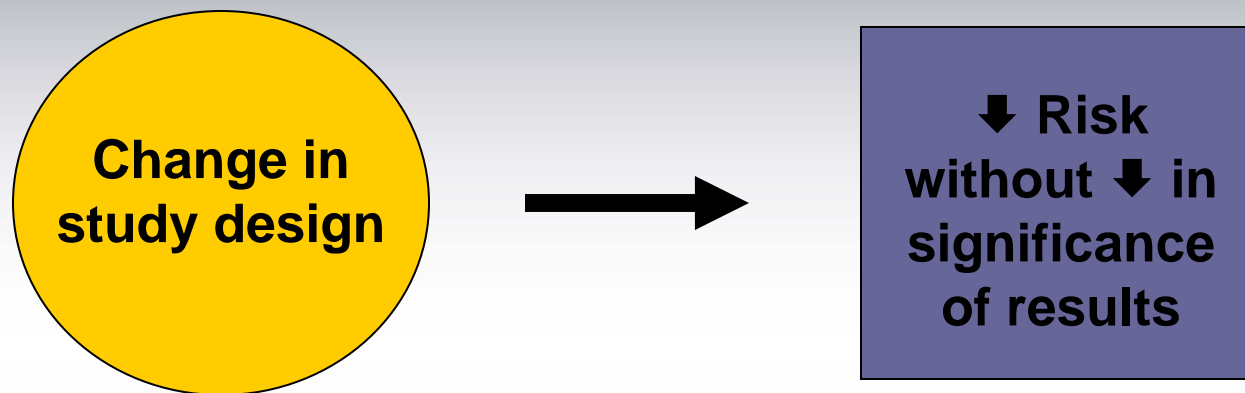
Ethical Science = Good Science

- Declaration of Helsinki (2000):
 - Human research must conform to **accepted scientific principles** and be **based on thorough knowledge** of literature
 - And should only be done if the **importance of the objective** outweighs risks and burdens to participants

Criteria for Approval

- Risks are minimized
- Risk-benefit ratio is reasonable
 - **Risk-benefit ratio:** *The comparison of the risk to its related benefits. "Benefit" includes direct benefit to the participant, and anticipated benefit to society.*
- Selection of participants is equitable
- Informed consent obtained as needed
- Consent documented as required
- Data is monitored to ensure safety
- Participant privacy/confidentiality is protected
- Vulnerable populations are protected

Changing the Study Design



Appropriate to table the study until the design is revised.

👉 If the study is less than minimal risk and the design is flawed (but not fatally), there is no real ethical justification for IRB to recommend mandatory revisions to the study design (e.g. minimal risk student research).

Privacy vs. Confidentiality

- **Privacy:**

- o Refers to persons and their interest in controlling access of others to themselves
- o Controlling the access, extent, timing and circumstances of sharing oneself

- **Confidentiality:**

- o Refers to participant's understanding of ways that their identifiable information will be stored and shared
- o Control circumstances of sharing information

❖ **Privacy** = refers to people

❖ **Confidentiality** = refers to data about people

Examples

- **Privacy:** Conducting interviews in a closed office



- **Confidentiality:** Storing data on a password-protected computer



Assessing Risk

- **Minimal Risk:**

- o The probability and magnitude of harm and discomfort anticipated in research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests

- **Greater than Minimal Risk**

Requesting Revisions

- Will a change in the protocol be likely to improve the welfare of research subjects to a **meaningful degree**?
 - **If “No”**: Approve the study without the change
 - **If “Yes”**: Request the change be made prior to approval



Presenting Your New Study Review

- **Primary Reviewer:**

- Limit the summary of the study to 1-2 minutes
 - » Don't make the other board members relive your review experience...
- Be precise about required changes to the study
 - » The IRB Staff will be requesting your revisions; they need to know what to ask for
- End your presentation with a recommendation for the vote
 - » Approve as submitted, Approve with changes, Tabled, Disapproved

Presenting Your Review

- **Secondary Reviewer:**
 - Focus on any areas of disagreement with the primary reviewer
 - Discuss the Consent Document and Consent Process
 - Be precise about required changes to the study
 - » Any significant changes to the consent document **must** be approved by the full board.
 - » If you do not provide exact wording for a meaningful change, the study will have to be tabled
 - End your presentation with a recommendation for the vote
 - » Approve as submitted, Approve with changes, Tabled, Disapproved

Systematic Review

1. Skim the Consent Document
2. Read the Protocol Summary
3. Read the supporting documents (e.g. company protocol, recruitment materials, investigator brochure, etc.)
4. Re-read the Consent Document carefully



Continuing Reviews

- Revisions must be “substantive” and “meaningful”
- Same criteria to approve the initial research must still be in effect
- **Primary Questions:**
 1. Has any new information emerged that **changes the risk** to participants?
 2. Have there been any **unanticipated problems**?
 3. Is the Consent Document still **accurate and appropriate**?
 4. Does the Consent Document reflect any **new findings** that might affect a participant’s willingness to participate?

Don't sweat the small stuff!



- 👉 Don't worry about correcting typos (unless significant), formatting, etc. on Continuing Reviews

Presenting Your Continuing Review

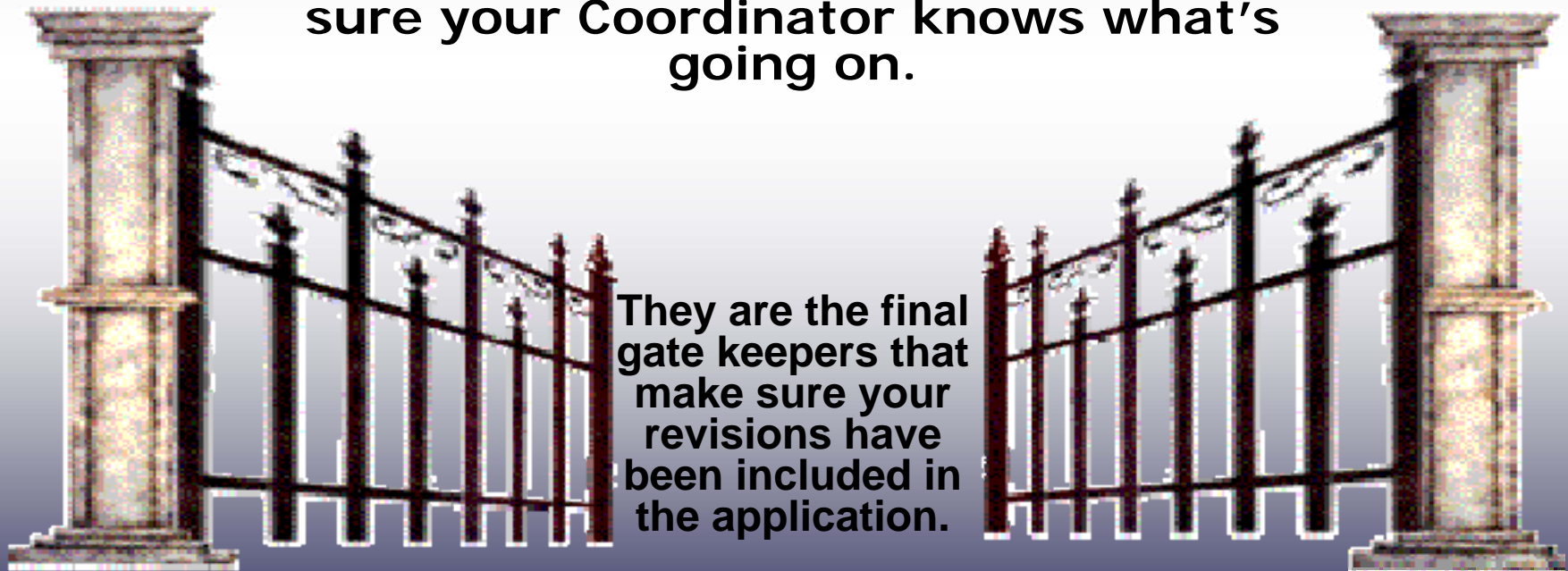
- **Summarize** the study (1-3 sentences)
 - o Progress of the study
 - o Enrollment: open, closed, suspended, over/under accrued
 - o Number of participants accrued
- **Adverse Event (AE)/Unanticipated Problem (UP)** reports
 - o DSMB findings, if applicable
 - o Withdrawals, complaints, multi-site reports
- **Amendments** since last review
- Current **Consent Document**

The Board Meeting

- A place to make decisions, not gather information
- Prepare, prepare, prepare!
 - o Ask questions before the meeting
 - o Discuss issues with the Principal Investigator (PI) as needed
 - » Collegial interactions facilitate review process and promote respect for IRB
 - o Decide if the PI should attend the meeting
 - o Come with your required revisions in writing
 - » Discuss major changes with the study team in advance
 - » Respect for IRB process is compromised when IRB tables proposal for minor “word-smithing”

Keep your IRB Coordinator in the loop!

✋ If you are communicating revisions to the study team before the meeting, make sure your Coordinator knows what's going on.



They are the final gate keepers that make sure your revisions have been included in the application.

Points to Discuss

- Additional discussion is required at the board meeting for studies involving:
 - o Vulnerable populations
 - o Waivers
 - o Placebo

Placebo Guidelines

1. No established effective therapies
2. Substantial doubt about effectiveness of available therapies
3. Refractory to, or response suboptimal, to available therapies
4. Refuses available therapies
5. Study ADDS a new therapy to an established therapy (so comparing established + new vs. established + placebo)
6. Health problem is minor and treatment is reasonably not done
7. Placebo cross-over designs evaluated on case by case basis.
8. Proposed placebo exposure is of specified duration such that evidence supports the exposure as no more than minimal risk. Reviewed by IRB on case-by-case basis.

The Vote

- Approve as submitted
- Approve with changes
- Table
 - » Psychologically “better” for a PI than a straight disapproval
 - o IRB must clearly articulate what information it requires to reconsider the study
 - o The reviewer should plan on being present at the next board meeting (the following month) to re-present the study and recommend another vote
- Disapproved
- Abstain
 - o Enter the room after the discussion but before the vote
 - o Insufficient information to make an informed decision
 - o Counts as a “No” in close votes



Expedited Reviews

- In general, a study is eligible for Expedited review if:
 - o The research is **minimal risk**; and
 - o The research falls into one of more of the **Expedited categories**; and
 - o The research will not place participants at **risk for civil liability or damage** to their financial standing, employability, reputation, etc.; and
 - o The research is not **classified**

Questions? Contact Us!

The IRB Staff and your fellow board members are here to help you!

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