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The Seven Habits of Highly Effective IRBs

Tips for Increasing Ethical Review Efficiency

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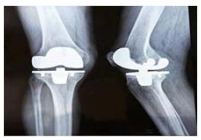

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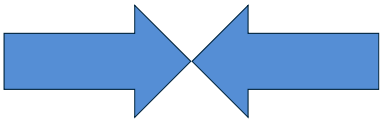
Objective

- List ways that your IRB can become more effective at protecting subjects while also becoming more efficient

What are some of the biggest challenges for IRBs?

- Decreasing turn around times
- Keeping staff challenged and avoiding burnout
- Adequate resources (staff, IRB members)

Regulatory pressure: Ensure compliance



Institutional pressure: Minimize bureaucracy Maximize efficiency

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The Seven Habits of Highly Effective IRBs

1. Use flexibility for non-regulated research
2. Review all research at the least restrictive level of review
3. Evaluate risk probability and use the minimal risk standard
4. Use full-time, professional IRB members
5. Rely on AAHRPP-accredited IRBs
6. Use the regulatory criteria for approval
7. Use smaller IRBs with more frequent IRB meetings

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1. Use the flexibility for non-regulated research

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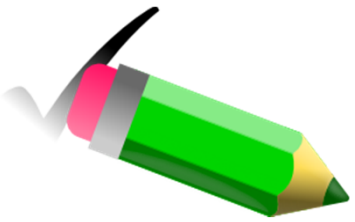
Use the flexibility for non-regulated research



- Don't "check the box" (but consult with legal counsel)
- Be legal only to the extent required
- Always be ethical
- Don't impose legal requirements just to be ethical

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Ways to be flexible

- Credential faculty to make exemption determinations.
- Allow continuing review intervals to exceed one year.
- Allow non-IRB members to conduct expedited review.
- Exempt #4:
  - Define "existing" to mean exist at the time the research is proposed or will exist in the future for non-research reasons
- Do not apply Subpart B to minimal risk research.
- Do not apply Subpart C to unexpected incarcerations.
- Do not apply Subpart C to exempt category #4.
- Do not apply Subpart D to exemptions.

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Advantages

- Focuses on ethics
- Focuses on approval
- Reduces investigator focus on mechanism of approval
- Reduces focus on legal bureaucracy
- Reduces burden
- Speeds approval

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2. Review all research at the least restrictive level of regulatory review

Review all research at the least restrictive level of regulatory review

- Even within the existing regulations, one can establish a policy to aggressively review all activities for the least restrictive level of the following categories:
  - Not human research
  - Human research, but the institution is not engaged
  - Exempt
  - Expedited
  - Convened IRB review
- Provide advice for how to lower the level of review

Not human research determinations

- Ask in order:
  - Is this research? Stop if no.
    - Common issue is "generalizable" – use right definition
    - Ignore publishing and intent
  - Does this research involve human subjects?
    - Common issues are "about whom," "conducting research," "private," and "identifiable."
- Not all ethical issues belong to the IRB
- Ask yourself:
  - If outside the academic context would this require IRB review?
  - If this is human research, what else is research?

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Engagement determinations

- Employees or agents refers to individuals who:
  1. Act on behalf of the institution;
  2. Exercise institutional authority or responsibility; or
  3. Perform institutionally designated activities.
- Decision of whether someone is doing 1-3 is policy
- Subjects, location, or ownership of information is irrelevant

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Exemption

- Approve all exemptions according to ethical criteria
- Exempt does not prevent IRB from requiring:
  - Consent
  - Parental permission
  - Procedures to ensure minimal risk
- What counts is what you approve, not the regulatory level
- If you take an exempt research study, make it expedited, and approve it without any changes, you created regulatory burden without improving the protection of subjects.

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Expedited review

- Approve all expedited reviews according to regulatory criteria
- Expedited review does not prevent IRB from obtaining:
  - Consultation
  - Input from other IRB members
- What counts is what you approve, not the regulatory level
- If you take an expedited research study, take it to full board, and approve it without any changes, you created regulatory burden without improving the protection of subjects.

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3. Evaluate risk in terms of probability and magnitude and use the minimal risk standard

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What is a risk?

- Two factors
  - Probability
  - Magnitude

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Minimal risk

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

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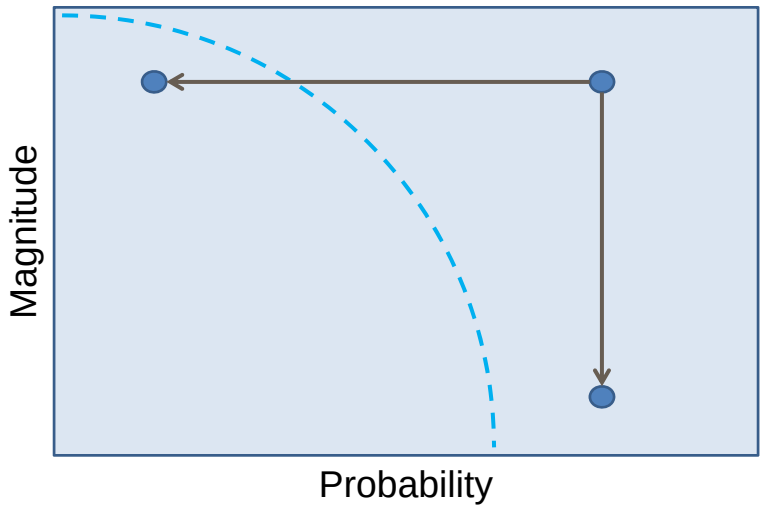
Minimizing risk



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What is the probability?

- A research laptop is stolen and you experience identity theft
- You use your credit card and you experience identity theft
- You become embarrassed during a research interview
- You become embarrassed in daily life
- You experience severe pain in a research study
- You break a bone while playing sports
- A child becomes terrified during a research MRI
- A child becomes terrified at school

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What do you think about?

- Living next to a nuclear power plant?
- Swimming in shark infested waters?
- Flying Aeroflot?
- Cooking?
- Driving a car?
- Driving a car while talking on a cell phone?

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Risk: Probability and magnitude of harm

- Humans are really good at magnitude assessment
- Humans are notoriously bad at probability assessment
- Be quantitative and get consultation
- Use the rigor you expect of your investigators

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Regulatory criteria for minimal risk research

- Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk,
- 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.
- Selection of subjects is equitable.

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Wavier of written documentation of consent

- The research presents no more than minimal risk of harm to subjects
- The research involves no procedures for which written consent is normally required outside of the research context.

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Advantages

- Focuses on ethics
- Reduces focus on legal bureaucracy
- Reduces burden
- Speeds approval

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4. Use full-time, professional IRB members

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Use full-time, professional IRB members

- Assign IRB staff members to be IRB members
- Train IRB staff members to:
  - Grant non-human research determinations
  - Grant non-engagement determinations
  - Approve exempt research
  - Conduct expedited review
- Designate IRB staff members as experienced IRB members

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Key advantages

- Compared to "part time" IRB members with a primary job, full time IRB staff members:
  - Spend more time per review
  - Pay better attention to regulatory detail
  - Can do more actions per day
  - Better understands all levels of review
- IRB staff who do "pre-review" for the chairs are the real reviewers
- IRB staff members given this responsibility feel more valued as a research professional

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Advantages

- Focuses on ethics
- Better attention to regulatory detail
- Better, more detailed reviews
- Allows IRB members to focus on meetings
- Speeds approval

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5. Rely on AAHRPP-accredited IRBs

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IRB review of multicenter studies

- What is the benefit of review of a single multicenter research study by multiple IRBs?
- What is the downside of review of a single multicenter research study by multiple IRBs?

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No one does as good a review as our IRB!

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IRB review of multicenter studies

- Additional reviews by multiple IRBs have no benefit.
- AAHRPP accreditation is an indication of adequacy of review (if not excellence)
- If one IRB is responsible for ALL sites, review is better!
  - Leverage with sponsor
  - Coordinated review of all problems
  - IRB can see the big picture

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What about liability?

- You liability is in your investigator and research staff
- Accredited IRBs tend to stay out of trouble and quickly respond to trouble

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Other benefits

- 70-80% of commercially sponsored research studies are reviewed by one IRB (almost always AAHRPP accredited)
- Sites that rely on their own IRB are not offered these studies
- National funding agencies are following suit
- Rely on the AAHRPP accredited IRB selected by the sponsor and get more studies

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Advantages

- Focuses on ethics
- Allows IRB to focus on local research
- Speeds approval

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6. Use the regulatory criteria for approval

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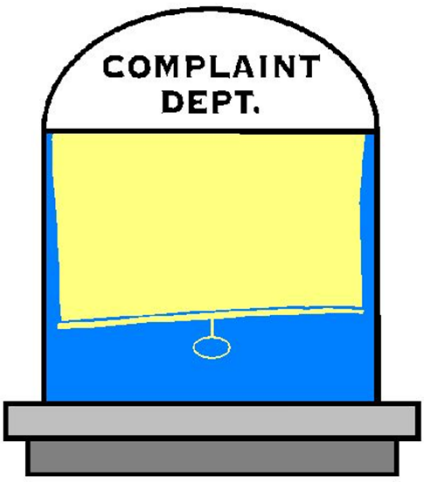
Common IRB problems



- Inconsistency
- Focus on scientific review
- Non-scientists feel left out
- Scope creep
- Picking on nits
- Lack of focus on important issues

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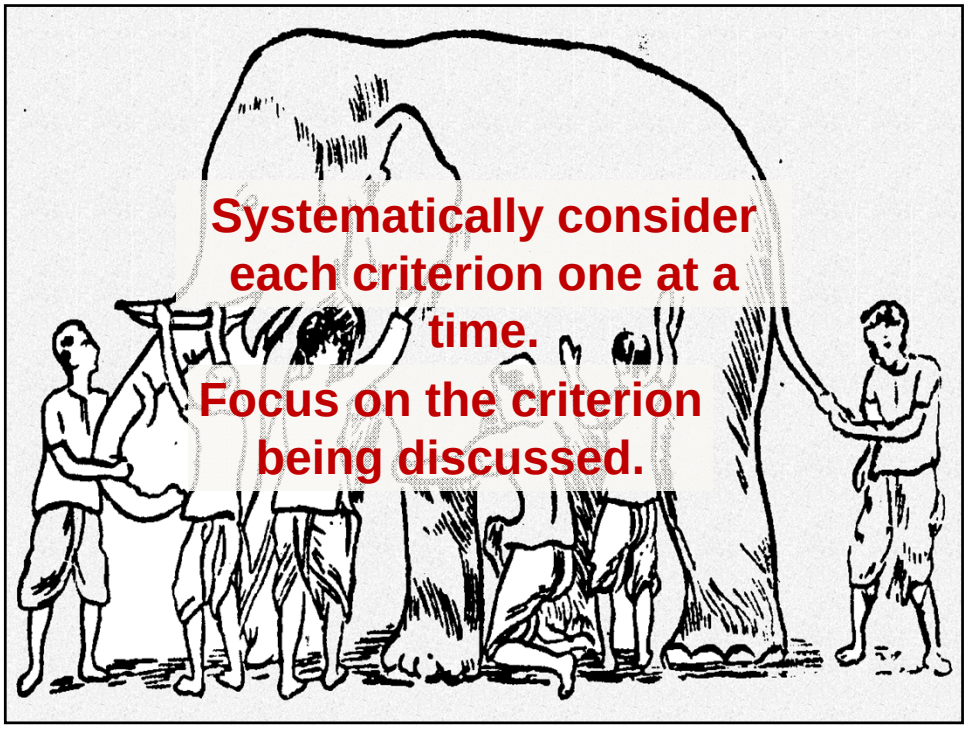

Solution: Focus on the regulatory criteria for approval at meetings

- Discuss science before discussion of criteria for approval
- Consider each regulatory criterion for approval in order
  - Separate discussion of consent process from consent documentation
- Justify each change/problem by the criterion not met
  - Items unrelated to a criterion are "off the table"
- When addressing changes to the consent document, first explain whether the document affects the process

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Advantages

- Consistency
- Separation of scientific and ethical review
- Non-scientists feel included
- Prevents scope creep
- Attention to real issues
- Complete discussion of issues

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7. Use smaller IRBs with more frequent IRB meetings

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Common problems

- HUGE agenda packets
- Long meetings
- Problems getting and maintaining quorum
- Reviews consist of a discussion between the primary reviewer and chair
- The later the meeting the faster the review

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Regulatory issues

- IRBs can be as small as five members
- Consultation can be obtained for every protocol to obtain scientific expertise
- Consultants do not have to be IRB members
- Consultants do not have to attend the entire meeting

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What is the optimal meeting size?

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Cooper's Rule of IRB Attendance

- No matter how many members are in the meeting room, no more than 5 are really present for the meeting

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Solution

- Have one IRB with 5 or 7 members
- Make everyone else alternates
- Whether someone is an alternate or regular member is arbitrary
- Could have one IRB with 7 members and 25 alternates
- Assign a consultant to every protocol
- Have more frequent meetings with few items per agenda

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Observation

- When five people review and discuss a protocol in depth, the review is much better than when 21 people get together in a room an two people review and discuss a protocol in depth.

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Advantages

- Focuses on ethics
- Better attention to regulatory detail
- Better, more detailed reviews
- Less IRB workload
- Better attention spans at meetings
- Faster approval

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Questions

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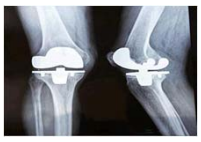

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