

What In the World Do We Do with Exempt Protocols?

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Objectives

- At the end of this program the participant will be able to:
 - Describe federal regulations pertaining to exempt protocols
 - Appreciate the diversity of approaches used by IRBs when they review exempt protocols
 - Implement policies on exempt protocols that most effectively protect human subjects and foster valuable human subject research at their institutions

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Resources

- *Code of Federal Regulations*, Title 45, Part 46: "Protection of Human Subjects"
- *Federal Register*, Vol. 63, No. 216, pp. 60353-56, 64-67: NIH and FDA "Categories of Research That May Be Reviewed by the IRB Through an Expedited Review Procedure"
- OHRP Guidance Document: "Guidance on the Use of Expedited Review Procedures," August 11, 2003. Available at www.hhs.gov/ohrp/policy.
- *IRB Advisor*, April 2006: "How Much Oversight for Quality Improvement Activities?"
- *IRB Advisor*, July 2006: "Over Regulating Can Put Subjects at Risk"

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Resources 2

- Kathleen Dziak, Roger Anderson, et al. "Variations among IRB Reviews in a Multisite Health Services Study." *Health Services Research* 40, No. 1 (Feb. 2005): 279-290.
- Ivor A. Pritchard. "Searching for 'Research Involving Human Subjects': What Is Examined? What Is Exempt? What is Exasperating?" *IRB* 23, No. 3 (May – June 2001): 5-13.
- AAHRPP Tip Sheets: "Determining Whether an Activity is Research Involving Human Participants and Covered by the Federal Regulations," "Exemptions: Criteria for Making Determinations," and "Exemptions: Determinations and Review." Available at www.aahrpp.org.

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How IRBs Deal with Exempt Protocols

- Minimal review—determination of exempt status only
- Full board review—scrutiny on the level of a protocol with greater than minimal risk
- Expedited review—even though not required by federal regulations

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Two Questions IRBs Need to Ask

- Is this project human subject research?
- If yes, what category of human subject research does this protocol fall under?

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What is a Human Subject?

- Living individual(s) about whom an investigator (whether professional or student) conducting research obtains:
 - Data through intervention or interaction with the individual, or
 - Identifiable private information.

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What is Research?

"A systematic investigation, including research development and testing and evaluation, designed to develop or contribute to generalizable knowledge."

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Categories of Research Protocols Reviewed by IRBs

- **Exempt**
 - CFR 46.101(b): "Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy"
 - IRBs often designated to determine study category
- **Expedited Review**—for research involving no more than minimal risk and for minor changes in approved research (specific list published in Federal Register)
- **Full Board Review ("Convened")**—studies involving at least minimal risk (ordinarily encountered in daily life or during routine physical or psychological exams or tests)

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Which Studies are Exempt?

- Studies of standard educational interventions
- Surveys/Interviews
- Observation of public behavior (adults)
- Collection or study of existing data, documents, records, pathological specimens
- Taste and food quality evaluation and consumer acceptance studies
- Studies of federal benefit programs

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Exempt Unless...

- Human subject can be identified AND disclosure could place subjects at risk
- Minors in Survey/Interview Research
- Prisoners
- Other categories of protected populations
 - Pregnant women
 - Human embryo research
 - Fetuses
 - Observation of public behaviors when investigator participates in activities being observed

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Expedited Review

- “Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research” (CFR 46.110(b)).

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Expedited Review Categories (9 listed)

- Some clinical studies of drugs and medical devices
- Collection of bloods samples by finger, heel, or ear sticks, or limited blood draws
- Collection of biological specimens through noninvasive means
- Collection of data through procedures routinely employed in clinical practice
- Research on data collected solely for nonresearch purposes

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Expedited Review Categories (9 listed) [Continued]

- Collection of data from voice, video, digital, or image recordings made for research purposes
- Social science or behavioral research on individuals or groups which is not exempt research
- Continuing review of research
 - Previously approved by full board
 - In closed, completed, follow-up, or data analysis stages
- Continuing review of research not covered by other categories and involves no greater than minimal risk

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Regulations Concerning Exempt Protocols Are Not Easy to Follow

- “The regulations, commonly called ‘the Common Rule,’ sometimes lack the capacity to promote common understanding”—Pritchard
- Study on IRB approval for a multisite health services research protocol showed great variations in:
 - Type of IRB review conducted (exempt, expedited, full)
 - Turnaround time (5-172 days)
 - Requirements imposed on research team by IRBs
 - Subject participation rates because of individual IRB requirements

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Conclusion of IRB Study

- “Variations in IRB requirements can affect response rates and sample generalizability”



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Understanding the Regs?

- “The exemption at §46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed (46.401(b)). [Underline added.]”

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Concerns Shared by Exempt Protocol Researchers

- Patricia Keith-Spiegel: An IRB's overzealousness or uncooperative attitude could drive some social-behavioral research underground
 - Researchers collect data as "regular educational assignments"
 - Submit elaborate protocols to bore readers
 - Not seek IRB approval for protocols at all
- A survey of researchers indicated that the most important qualities they looked for in an IRB included fairness, respect, and full explanations of the decision-making process (protecting research participants was No. 7 on the list)

Concerns Shared by IRBs about Exempt Protocols

- Protect the rights and welfare of research participants
- Protect researchers and institution
- Review in an expeditious a manner as possible
- Abide by federal and state regulations
- Not discourage exempt research

Thesis of This Presentation

- "Participants in research outside the scope of Common Rule's authority deserve equal protection."
- "Research institutions may choose to implement IRB review policies and procedures on their own initiative, purely out of respect for the research participants, or for reasons related to protecting the interests of their institutions and their staffs."
 - From Pritchard, pages 5 and 6

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Ethical Guidelines

- Nuremberg Code
- Principles
 - Beneficence: "Doing good"
 - Justice: "Fairness"
 - Respect for persons
- Golden Rule: "Do unto others as you would have them do unto you"

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Suggestions for IRBs Concerning Exempt Protocols

- Survey researchers about your performance (IRB-Researcher Assessment Tool)
- See where you can improve on:
 - Transparency
 - Avoiding bias
 - Being pleasant and respectful
 - Providing full explanations
 - Giving researchers a voice

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Suggestions for IRBs Concerning Exempt Protocols 2

- Establish clear procedures for deciding which activities are human subjects research
- Establish clear procedures for deciding which research protocols require exempt, expedited, or full board review
- [IMHO] Take exempt protocols seriously, use expedited review procedures for all of them

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AAHRPP Recommendations for Review of Exempt Protocols

- Cite federal regulations verbatim to determine exempt category
- Note federal exemptions don't apply to prisoners!
- Note situations in which research on children may be exempt and when not

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AAHRPP Recommendations for Review of Exempt Protocols 2

- Describe criteria used to determine that participants are protected in exempt research, such as:
 - Research involves no more than minimal risk
 - Selection of subjects equitable
 - If recording identifiable information, provisions to protect confidentiality
 - If there are interactions with participants, insisting on an adequate consenting process
 - Privacy concerns addressed

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Concluding Thoughts

- “There is more flexibility in the human subjects protection system than is sometimes recognized in the field, and OHRP encourages IRBs to specialize in the kinds of research they mostly see”
 - Mary Ann Baily, Ph.D., Associate for Ethics and Health Policy at the Hastings Center, Garrison, NY

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Concluding Thought 2

- “The concept of **exempt** research and the practice of **expedited review** of research can come together, as some institutions choose to provide an additional measure of protection for human subjects by reviewing what would be exempt research under 46.101(b) in an expedited manner. This is acceptable, since expedited review of that which is exempt exceeds the minimum requirement for both in 45 CFR Part 46” (Gary Ellis, Ph.D.).

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Discussion



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