IRB Review of Minimal Risk Research

September 17, 2014

Presented by:
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IRB Vice Chairperson
Schulman Associates IRB
About Schulman Associates IRB

- Established in 1983
- US and Canadian boards fully accredited by the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
- Superior audit history with FDA—five consecutive audits with no findings
- 21 CFR Part 11 compliant electronic systems
- Compliant with FDA, OHRP and Health Canada requirements
About Schulman Associates IRB

- Full board meetings **five days a week**
- Dedicated **daily expedited review** of qualifying minimal risk protocols
- **Phase I Board** with streamlined processes tailored to Phase I timelines
- **Oncology Review Board** for all phases of oncology research
- Customized services for **institutions and AMCs**
- Experienced primary points of contact for sponsors, CROs, institutions and sites
Clinical Quality Assurance (CQA) and Human Research Protection (HRP) consulting services provided by Provision Research Compliance Services

Provision is a joint venture between Schulman Associates IRB and Falcon Consulting Group

www.provisionrcs.com
Michelle Coughlin, M.S.
IRB Vice Chairperson
- Masters degree in Medical Genetics
- 9 years experience working for IRBs
- Developed and implemented Schulman’s Minimal Risk Review service line
Presentation Goals

- Examine the regulations that define minimal risk research
- Describe how IRBs view minimal risk research
- Summarize how to prepare minimal risk study submissions
- Discuss how to anticipate IRB decisions/questions
What Is Minimal Risk Research?

- **Research** involving human subjects that presents minimal risk to subjects and may be approved by expedited review.

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

**FDA:** Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA, or is not subject to requirements for prior submission to the FDA under these sections of the Federal Food, Drug, and Cosmetic Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
What Is Minimal Risk Research?

- Research involving **human subjects** that presents minimal risk to subjects and may be approved by expedited review.

**DHHS:** A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**FDA:** An individual who is a participant in research, either as a recipient of a test article or as a control.
What Is Minimal Risk Research?

- Research involving human subjects that presents **minimal risk** to subjects and may be approved by expedited review.

Minimal risk means that 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.

[21 CFR 56.102(i) and 45 CFR 102(i)]

- "Minimal risk" is the level of risk an average healthy person would be expected to encounter during typical daily experiences.
What Is Minimal Risk Research?

- Research involving human subjects that presents minimal risk to subjects and may be approved by **expedited review**

- Review performed by one or more IRB members rather than the full board
- “Expedited” does not describe the review timeline
- The reviewing board member applies the same criteria for approval as the full board
- Federal regulations specifically define the procedures approvable by expedited review
Issues of Confidentiality

Expedited review procedure may not be used when identification of the subjects and/or their responses would:

- reasonably place them at risk of criminal or civil liability
- be damaging to the subjects’ financial standing, employability, insurability, or reputation
- be stigmatizing

UNLESS reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

[63 FR 60364-60367, November 9, 1998]
Confidentiality – Examples

1. Discussion of a survey regarding opioid abuse in a private interview setting

2. Discussion of a survey regarding opioid abuse in a focus group setting
Expedited Review Categories

45 CFR 46.110 and 21 CFR 56.110
1. Research on drugs for which an IND application is not required
   OR
2. Research on medical devices for which an IDE is not required
   OR
3. The device is cleared/approved for marketing and is used in accordance with its label

   • For research on medical devices for which an IDE is not required, needs to be ONE of the following:
     • Not a safety or effectiveness study
     • Exempt under 21 CFR 812.2(c)
Expedited Review Categories – #2
45 CFR 46.110 and 21 CFR 56.110

- Blood collection from healthy, non pregnant adults who weigh at least 110 pounds (may not exceed 550 ml in 8 weeks and no more than 2 draws per week)
  OR
- From other adults and children (may not exceed the lesser of 50 ml or 3 ml/kg in 8 weeks and no more than 2 draws per week)
Prospective collection of biological specimens for research purposes by noninvasive means

For example:
- Hair and nail clippings in a nondisfiguring manner
- Urine or sweat samples
- Placenta removed at delivery
- Mucosal and skin cells collected by swab
Collection of data through noninvasive procedures (not involving anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves

For example:

- weighing or testing sensory acuity
- magnetic resonance imaging (no sedation or contrast)
- Physical examination
- Some types of blood or specimen testing (non-sensitive in nature)
Expedited Review Categories – #5
45 CFR 46.110 and 21 CFR 56.110

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)
Collection of data from voice, video, digital, or image recordings made for research purposes.
Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, or program evaluation.
Case Study

Collection of a 10 mL blood sample from individuals experiencing an active lupus flare for measurement of magnesium levels
Case Study

Collection of a 10 mL blood sample from individuals with lupus for identification of genetic factors associated with kidney involvement

No—Requires Full Board Review
Case Study

Retrospective review and analysis of normal pediatric growth data collected from clinical medical charts

Yes—Expedited Review
Retrospective review and analysis of normal pediatric growth data collected in previous clinical study.
Preparing Your IRB Submission
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Preparing your protocol:

- Include all basic protocol elements
- Specify procedures to be performed in enough detail to allow expedited review categories to be considered
- Specifically define inclusion/exclusion criteria
- Describe specific data to be collected
- Describe measures to protect confidentiality
Preparing Your IRB Submission

Obtaining informed consent

- Content requirements same for studies involving more risk, except where regulations indicate (compensation for injury)
- Risks may include loss of confidentiality (accidental disclosure of data)
- Waivers of consent or documentation of consent may be approved when impracticable to do study without the waiver of consent
Minor details in a study may determine whether a study may qualify for expedited review.

Even though the regulations outline the criteria for expedited review, interpretation remains subjective.

If you’re not sure whether your study may qualify for expedited review, speak with your IRB.
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