Expedited Review Revisited

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IRB Review

One of the 4 ways to categorize the review process necessary for each protocol

- **Non human subject**
- **Exempt**
- **Regular review**
- **Expedited**

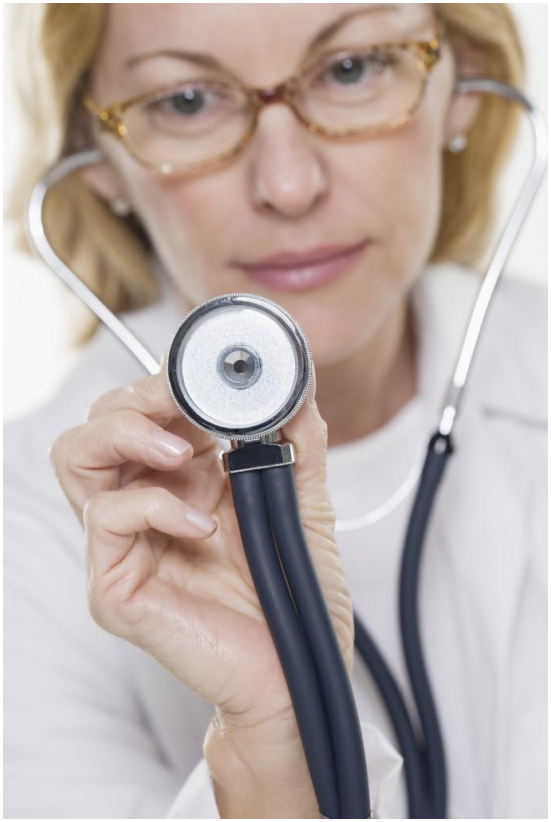
Expedited Review Categories

1. 5..
2. 6.
3. 7.
4. 8.
9.

Determinations revolve around:

- risk to subjects
- involvement/interaction with human subjects

Definitions of Minimal Risk



"the probability and magnitude of **harm or discomfort**…

not greater …than those ordinarily **encountered in daily life**

or during the performance of **routine** physical or psychological **examinations** or tests"

45 CFR §46.102(i)

Expedited review procedures may be used when…

- Minimal risk to subjects
- Research is not classified (considered secret)
- Identification of subjects (or their responses) doesn't put them at greater than minimal risk of:

Invasion of Privacy Breach of Confidentiality

Damages To Financial Standing

Criminal or civil liability

Employability and Insurability

Being Stigmatized and Damage to Reputation

9 Expedited Review Categories

1. Clinical studies of drugs or devices ONLY WHEN:

(a) an IND is not required

NOTE : marketed drugs that significantly increase the risks or decrease the acceptability of risks associated w/the use of the product are not eligible for expedited review

(b) device study where:

- an IDE is not required

OR

- is cleared/approved for market AND is being used according to label

IND : Investigational New Drug

IDE: Investigational Device Exemption

2. Collection of blood samples

- by finger, ear or heel stick, or venipuncture

3. Prospective collection of biological samples

- for research purposes
- by non-invasive means

4. Collection of data

- through non-invasive procedures routinely employed in clinical practice
- excludes procedures using X-rays and microwaves
- using devices that are approved/cleared for marketing

5. **Involves materials (data, documents, recordings or specimens) that were collected, or will be collected for non-research purposes**

6. **Collection of data from voice, video, digital or image recordings made for research purposes**

7. Research on individual or group characteristics or behavior

- Including but not limited to research involving perception, cultural beliefs and social behavior

…OR research employing methods such as surveys, interviews, and oral histories

Category 8: Continuing review

a. i. Closed to enrollment
ii. no more research related interventions
iii. only open for long-term follow-up

or

b. Where no subjects have been enrolled, and no additional risks have been identified

or

c. Data analysis only

Category 9 – Continuing Review

If the research is:

- not being done under an IND or IDE, **and**
- categories 2-8 do not apply **but**
- the IRB has determined and documented at a convened meeting:

the research involves no greater than minimal risk

and

no additional risks have been identified

IRB Related Matters

- Rodney Reviewer looks over a protocol via expedited review, and does not feel that all the criteria for approval have been met. He has exchanges with the PD regarding his questions, but is not satisfied that the study warrants approval.

- Can he make the determination to disapprove the study?

IRB Related Matters

- Although one member can approve a protocol through expedited review, the regulations prohibit disapproval of any research unless it is reviewed by the full board for a final determination.

IRB Related Matters

A protocol that is presented at panel is approved and the determination is made that it can be moved to expedited review.

The next year, the reviewer notes that there have been problems indicating additional risks. Can it be reviewed by the one panel member?