



Expedited Review

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

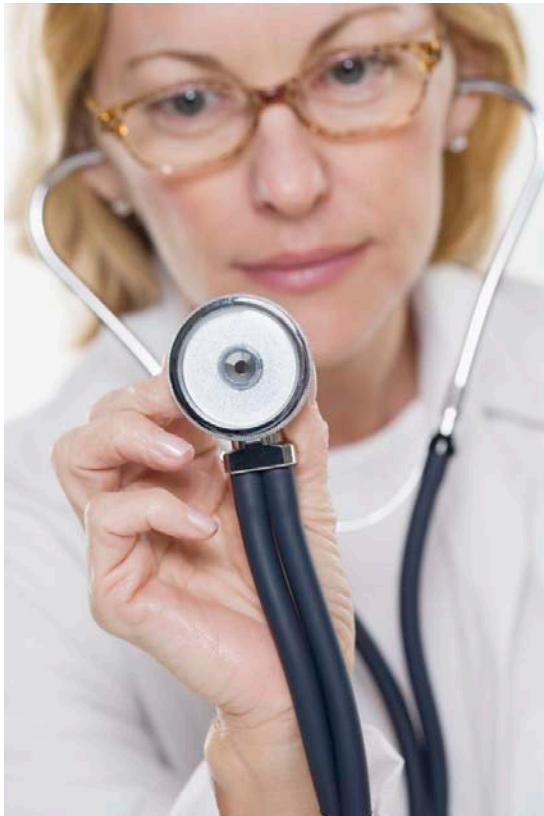
Determinations revolve around:

- risk to subjects
- involvement/interaction
with human subjects



Definitions of Minimal Risk

- **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**

**Criminal or
civil liability**

**Employability
and
Insurability**

**Damages
To Financial
Standing**

**Being
Stigmatized**

**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

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2. Collection of blood samples

- by finger, ear or heel stick, or venipuncture

- if healthy and 110 lbs or more, cannot exceed 550 mL in 8 weeks and not more than 2X/week

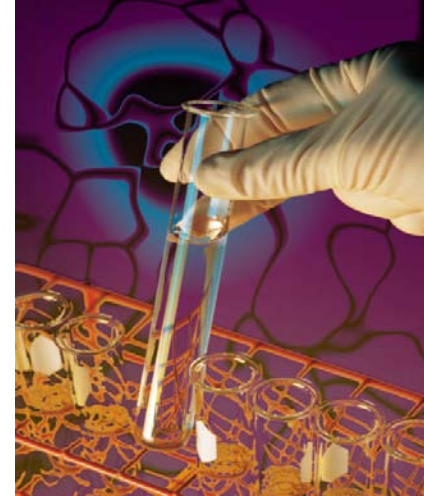
- if not healthy or if subject is a child, then it cannot exceed:



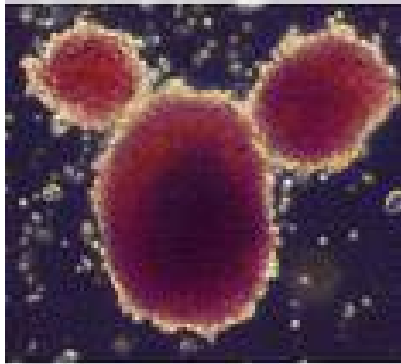
- 50 mL or
- 3 mL per kg in 8 weeks
(whichever is less)
- **and** not more than 2X/week

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**



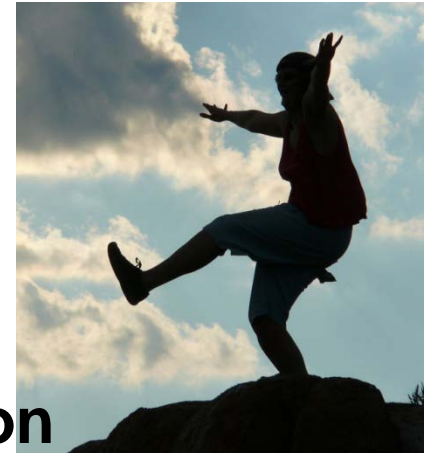
6. Collection of data from voice, video, digital or image recordings made for **research purposes**

7. Research on individual or group characteristics or behavior

Including but not limited to research involving:



Perception
Cognition
Motivation
Identity
Language
Communication
Cultural beliefs or practices
Social behavior



Research on individual or group characteristics, cont.

7. ...OR research employing:

- surveys
- interviews
- oral history
- focus group
- program evaluations
- human factors evaluation
- quality assurance methodologies



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:**

the research involves
no greater than minimal risk

and

no additional risks have
been identified

