Exempt or Expedited: What’s the difference?

Remember, as with so much else when working with the IRB, these are regulatory terms of art.

An Exempt classification means the study is “human subjects research” but it meets certain federally mandated criteria that don’t require the review by a voting member of the IRB. The IRB Program Coordinator reviews the file and makes the determination about whether the study meets one of the exempt criteria. Exempt studies receive a three year determination (rather than one year) and only require an amendment submission for review if the protocol change increases the level of risk to the research subjects.

Exempt review studies require IRB review, but meet federally defined categories that allow one experienced voting board member to approve the study rather than the convened full board. The entire board is informed of these decisions at its monthly meeting. The review of these studies does not require the investigator to provide paper copies of the submission; they are handled electronically.

For more information about Exempt or Expedited categories, contact your IRB Program Coordinator for a consultation or to request an education presentation to your group!

Tip of the Month

In the IRB application form, choose “Exempt” or “Expedited” on Step 1, Question 2.

- Please indicate the level of review your application requires
  - Full Board
  - Expedited (see expedited category numbers) 45 CFR 46.116
  - *Exempt (see exempt category numbers) 45 CFR 46.101 (6)

The next IRB Full Board meeting is June 27, 2011
The deadline to submit paper copies is June 10, 2011.

Frequently Used “Exempt” Categories

Remember – “Exempt” studies must meet the same ethical principles as “Expedited” studies; they are not “exempt” from obtaining informed consent!

Category 1 Exemption studies involve research in:
- Commonly accepted educational settings
  - AND
- ONLY normal educational practice.

Category 2 Exemption studies involve:
Interacting with subjects using educational tests, surveys, interviews or observation of public behavior UNLESS
- Information is recorded in such a manner that subjects can be identified
  - AND
- Any disclosure outside the research setting will not damage their reputation or put them at legal risk.

Category 4 Exemption studies involve:
- Using existing data that is publicly available OR
- Using existing data but recording the information in such a manner that subjects cannot be identified.

For either Exempt or Expedited studies, you will need to complete:
- The online application (a faculty member must be listed as the PI of Exempt studies)
- A proposal in the IRB-required format
- A template consent form