Exempt or Expedited?

What’s the difference?

How do I apply?

Carrie McDaniel, CIP
Senior Regulatory Analyst
Human Subjects Committee
Yale University’s HRPP
What’s the difference?

- Exemptions

- 6 specific categories defined in federal regulations as not requiring IRB oversight
  - Educational research falls into one of those
    - [45 CFR 46.101(b)(1)]

- IRB grants the exemption

- Have no expiration date
What’s the difference?

- Do not fit into any exemption categories
- Meet ‘minimal risk’ requirement as defined in the regs
- IRB issues ‘approval’ which expires in one year
- Investigator must apply each year to renew research
- Requires review of all amendments

Expedited reviews
Apply for an Exemption if ALL of the following are true:

- The research will be conducted in an educational setting.
- The research involves normal educational practices such as:
  - Research on regular or special education strategies or research on the effectiveness of, or the comparison among instructional techniques.
The goal of the research is to improve aspects of education such as:

- Improvement of student understanding
- Educational performance
- Ability to function productively in the class, etc.

The research is not regulated by the FDA and does not involve prisoners.
If the project does **NOT** meet all of the previous criteria, then you may need to apply for an expedited review...
All of the HSC forms can be found on the HRPP website:

http://www.yale.edu/hrpp/forms-templates/behavioral.html

To apply for exemption:

“Request for HSC Determination of Exempt Status”

To apply for expedited review:

“Application Form”
“I submitted my application two days ago—how long does this take?”

- Depends on the volume of submissions
- Wait times average 2-4 weeks
- Make sure to note intended start date on cover of application
Questions?

- **Call or email**
  - 203-785-4688
  - human.subjects@yale.edu

- **Set up a consultation if you have more detailed and/or specific questions**