Navigating the IRB for Educational Research

February 6, 2012
The process
Required On-line Modules

- Research Integrity
- Human Subject Protection
  A – Biomedical
- HIPAA Researchers Privacy Requirements
- Conflict of Interest
Recommended Modules

- Responsible Literature Searching
- Research with Children

Internet-based Studies on Education and Research  <www.health.pitt.edu>
Types of IRB Review

- Exempt: minimal risk for subjects; falls into specified categories
- Expedited: minimal risk for subjects but not exempt
- Full board: greater than minimal risk; often involves invasive procedure or clinical trial
Exempt Projects

- Tests, surveys, interviews, observation
- Existing data
- Retrospective unidentifiable medical record research (honest broker or physician)
- Research with unidentifiable biological specimens (honest broker or physician)
Exempt Projects

- Educational strategies, curricula, or classroom management methods
- Always low risk projects
- Often, data collected anonymously
Exempt Projects

- Private identifiable information cannot be recorded by the investigator or members of the research team
Exempt Projects

- Private identifiable information cannot be recorded by the investigator or members of the research team if the possibility exists that release of that information could affect the individual’s reputation, employability, or financial status.
The Exempt Review

- Still has to go under IRB review.
- There are no annual reviews.
- No written informed consent.
- You still have to obtain oral informed consent by using a script that has been approved by the IRB.
Research or QI?
- Be careful with Question 3d.
- How will subjects be evaluated?
- Subjects are not evaluated; the curriculum is.
Expedited Projects

- Low risk studies, not involving significant invasive procedures
- Subject identifiers can be linked to data.
- Written informed consent is required.
Expedited Projects

- Must address methods of recruitment
- No cold calling
- Contact initiated by member of health care team
- Advertisements and recruitment materials must be approved
- Must address statistical issues (e.g., sample size, analysis plan)
HIPAA

- Requires investigators to obtain authorization prior to collecting PHI
- HIPAA authorization can be combined with the informed consent document to minimize respondent burden (they don’t have to sign twice)
- Does not usually apply to educational projects (no PHI being collected)
HIPAA WAIVER

- Attest to usual access to data or honest broker
- Research could not practically be done without data
- Research could not practically be done without waiver
- Applies even to exempt projects
Elements of Informed Consent

- Description of the research being conducted
- Description of potential risks
- Description of benefits to the subject
- Statement re: how confidentiality will be safeguarded
Elements of Informed Consent

- Statement of voluntary nature of research
- Contact information for the IRB and the Principal Investigator
The principal investigator is the individual with the responsibility of carrying out a research project.

A principle is a tenet, a core belief, a rule.

You cannot, should not, must not have a principle investigator.

(although a principled principal investigator is a good thing)
Studies involving only GIM residents

- Don’t require IRB review
- Fall under Educational Innovations Project (EIP)
- Blanket approval for all research/education projects
- Although it may feel like it sometimes.

- Generally, IRB staff are happy to answer questions and work with you to resolve problems.
A Case Study: Working with the IRB
What if…?

What if you gave a test to see if the students understand the issue around cardiac disease in the elderly. When you review the answers, you find that all the females reported that women were most inclined to get the disease and all the males reported that it was the elderly men who were most likely to get the disease.

Now, this is an interesting outcome! You might want to write this up for publication!
My first response and second...

- My first response was to tell you that if you want to publish this, you can publish it as an interesting case study or vignette and not worry about the IRB.

- Then I thought, why don’t I call the IRB and ask what they think about giving approval for research retroactively.
The IRB Response

“Wow! That’s a really good question; I have no idea how to answer that!”

Not quite the answer I was looking for.
You can still publish it as a case study or vignette, providing the journal does not require IRB approval.
If you are just publishing the results of the test and not collecting or using any additional data, you can apply for an exempt review using the IRB criterion, “Existing Data.” You will still need to interact with the class to explain what you plan to do and obtain verbal informed consent.
The Answer: Version 3

- If you want to look at test results in conjunction with other previously collected data or collect prospective data, you will need to apply for an expedited review, obtain written informed consent for new data and retrospective data (test results) and you’ll be fine.
The Point

- We actually can work with the IRB productively, and we can even find ways to publish data not previously reviewed by the IRB!

- CAVEAT
The IRB is by nature conservative and will sometimes make demands that don’t make sense.

Example: Asking for consent forms for studies not involving human subjects

I can’t change things if I don’t know.
Multi site studies
When in doubt...

- Let me know ASAP so we can resolve issues before they become BIG ISSUES.
- I work closely with the Director of the IRB, Chris Ryan, and we can often resolve problems more easily than you can on your own.
What to keep in mind about IRB Protocols

- It take longer than you think to...
- Prepare the IRB protocol
- Receive the final approval
- If you are not sure what kind of protocol to prepare, talk with me, someone in your Division, or the IRB.
The Dreaded OSIRIS

- Electronic system for submitting protocols
- Takes longer to put together because you have to cut and paste each section
- It’s brutal for the scientific reviewer so be kind to him/her
Finally

- Keep your project simple but make sure you don’t limit yourself by what you include in the protocol (analyses, numbers).
- Plan ahead, taking into consideration the time needed to design and review and approve your protocol.
- Work with your mentor.
I’m happy to answer any questions at any time.

My contact info:  

seltzer@pitt.edu
seltzerdl@upmc.edu
412.692.4848