Educational Research and the IRB: When is Research really Research?

January 14, 2013
The process
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 reviewers, so be kind to him/her
Required Training: citi.pitt.edu

- Collaborative Institutional Training Initiative
- Important to get on through Pitt using your email address and hsconnect password. Don't go to CITI site directly. YOU WON'T GET CREDIT.

Three user group choices:

- Biomedical Researcher (including all Health Science students)
- Social & Behavioral Researcher
- Undergraduate Student Researcher
Important deadline

After March 31, 2013, no individual can be listed on an IRB protocol or obtain access to OSIRIS unless the required CITI modules are completed.

Keep in mind that Investigators from other institutions must complete the modules as well.
According to the federal regulations, which of the following studies meets the definition of research with human subjects?

- A researcher sets up a meeting with the superintendent of a large and diverse public school system to get data about the ethnic composition of the school system and the number of students receiving free lunches.

- Undergraduate students in a field methods class are assigned a research question and asked to interview another classmate, to be followed by a class discussion on interview techniques.

- A researcher conducts a comparison of the comments made in a publicly available blog and the blogger's comments on a similar topic in a weekly magazine.

- A cognitive psychologist enrolls undergraduate students for a computer-based study about the effect of mood on problem solving behaviors.
 Responsible Conduct of Research

- CTSI Workshops throughout the year
- Ethics and the Responsible Conduct of Research (CLRES 2050)
  (online or in-person)
- Various events around the university
**Types of IRB Review + 1**

- **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
- **Determination that study is not research or does not involve human subjects**
Study does not involve human subjects or is not research (according to 45 CFR part 46)

To involve human subjects, researcher-subject interaction is required OR identifiable private information is collected

To involve research, the systematic collection of information leading to generalizable knowledge must occur
Determining that a study is not generalizable research

- Not an insult—Your work is research
- Just not according to The Code of Federal Regulations, Title 45 CFR Part 46
- We think other schools should, and we hope they do, adopt our curricula—not
- In the US, just over 10% of youth between 5 and 17 years old have asthma—generalizable
Not generalizable research

- In your protocol, avoid 'researchy' words (e.g., controlled, hypothesis, randomized)

- Use educational terms (e.g., curriculum evaluation, assessment of teaching methods)

- Getting this determination is useful for publishing (must be obtained before study is started)

- So why do we still have to write a brief protocol?
Exempt Categories

- Educational strategies, curricula, or classroom management methods
- Tests, surveys, interviews, or observations of public behavior
- Existing data or research records
- Retrospective medical record review (honest broker or physician)
- Research with unidentifiable biological specimens (honest broker or physician)
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.
If IRB Doesn’t Get It, It’s Our Mistake

- Be careful with Question 3d.
- How will subjects be evaluated?
- Trainees are not evaluated; the curriculum is being evaluated.
Expedit ed 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)
Elements of Informed Consent

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

- Statement of voluntary nature of research
- Contact information for the IRB and the Principal Investigator
Time Out

- 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)
Multi-site studies
Research or QI?
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
Working with the IRB at the VA
Working WITHOUT the VA IRB
Let the VA Site Serve as Control Site

- Usual practice at the VA compared to modified practice here
- Key is not using VA resources
- Key is not to change current activities
I just wanted to document the particulars of our conversation:

The following conditions were met therefore VAPHS does not have oversight responsibility of the proposed research activity as no VAPHS resources will be utilized and thus does not constitute VA research:

1. The noon conferences at VAPHS will be presented as usual (without any changes as a result of the conduct of the study) and thus no VA resources are being utilized for this component of the project.

2. The assessments (i.e., surveys) will be administered/completed by participants in a Web-based approach outside of the VA setting (e.g., no VA computers will be used) therefore no VA resources are being utilized for this component of the project.

The group concurred that this is consistent with the University of Pittsburgh-VAPHS MOU and the University of Pittsburgh IRB will have sole oversight responsibility for the proposed activity.
Although it may feel like it sometimes.

Generally, IRB staff are happy to answer questions and work with you to resolve problems.
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.
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.
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.

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