IRB Considerations in Medical Education Research

John Mahoney, MD
Associate Dean for Medical Education

University of Pittsburgh
School of Medicine
What is known?

Spectrum of Med Ed research

Why are there human subject concerns?

Common challenges & questions

School of Medicine concerns
Stakeholders

- Investigators
- The Faculty & Administration
- Students / Residents AKA subjects
- IRB, University & the Public
Stakeholders’ concerns

- Data, answers to questions, promotion
- Develop new knowledge, gather essential data
- An education, be left alone
- Protect subjects from harm
Spectrum of HS research

- Existing data
- Surveys – anonymous, not anonymous
- Sensitive data
- Experiments outside of curriculum
- Whole class interventions, curriculum change
- Pilot programs
Why are there HS concerns?

It’s not as if we’re doing surgery on them…

Are students and faculty Human Subjects?

Example: A report on a curricular innovation
Common challenges
A simple survey

I’ll just ask them to fill it out in class
Do I need approval?
A retrospective, I think

I’m just using evaluation data
Is it Research, is it Exempt?

Research vs. program evaluation

Consent
The Questions

SOM concerns

- Cannot interfere with curriculum
- No coercion
- Fair, equal treatment for all
- Protect students from being over-surveyed
The Questions

ROMS RC

Overall burden on students, survey fatigue

Confidentiality

Cannot compete with vital SOM studies, such as seniors completing the Graduation Questionnaire
Examples

A curious question

I have a friend at University of....

Too much information

Daily special
IRB form tips

- Be precise
- Avoid too much information
- Call for advice, before submitting
- If it is simple, keep it simple
Clear explanation of student activity

Call for advice, before submitting

Engage with appropriate curriculum leaders
Thank you