THE OHIO STATE UNIVERSITY

A Faculty Member's Perspective: Considerations and Suggestions for Navigating the Consent Process

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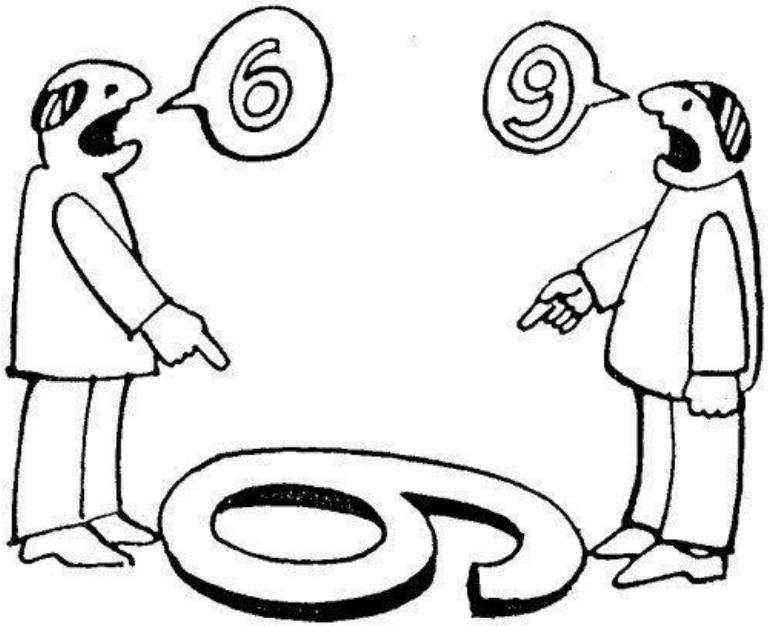
IRB Issues: Compliance, Quality, and Consent

My lens

- IRB is responsible for "ensur[ing] that research is designed and conducted in an ethical manner that protects the rights, dignity, welfare, and privacy of research subjects"
- I am responsible for protecting participants involved in my research studies and IRB compliance
- I am responsible for advocating for my research and my research team, in successfully addressing research goals and deliverables (esp for funded projects)



- IRB's role is to **SUPPORT** researchers in protecting human subjects
- **Knowledge, planning, communication, 'negotiation'** is key
- Particularly for complex projects

My research: Context and populations

Process

- Getting educators/administrators on board
  - MOU/consent
- Getting parents on board
  - Consent
- Getting children on board
  - Assent ("required whenever the child is capable of providing assent, based on the age, maturity, condition, and psychological/emotional state of the child.")

Across all -

Clear, consistent communication is essential

- Both with stakeholders/participants AND in how you communicate your plan to IRB

Schools as research sites

- "Approved Research Performance Sites"
- Include/add non-approved sites to IRB
- Requires formal agreement (MOU)

Educators/administrators as key research personnel, participants, or neither

- Important implications for IRB protocol, CITI training, etc.!
- Depends on involvement, esp recruitment and consent

Educators as key personnel

Educators as means of access

Educators as distributors/collectors of consent forms

- Should NOT have bearing on consent response (i.e., not recruitment or coercion)
- No explanation of consent from educators – simply distributor
- Collect in a way that minimizes coercion and maintains privacy
  - Centrally-located drop box
  - Self-addressed, stamped envelopes
  - Consent forms collected regardless of response

Increasing consent rates

- Make personal contact and provide ways for ongoing communication
  - Teacher lunch, staff meetings
  - Parent nights, dropoff/pickup
- Multiple contact attempts (without being overbearing)
- Teacher/school letter
- Incentives
- Carefully attend to consent form language and length

Consent form (and other communications)

- Keep it simple and brief

Consent form (and other communications)

- Keep it simple and brief
- Plan for full project duration (and beyond)
- Consider your audience
  - 8th grade readability
  - Minimize technical terms/legalese
  - Need to read orally or translate?
- Language is important!
- Clearly state benefits and obligations
- Adhere to/include any requirements stipulated by IRB

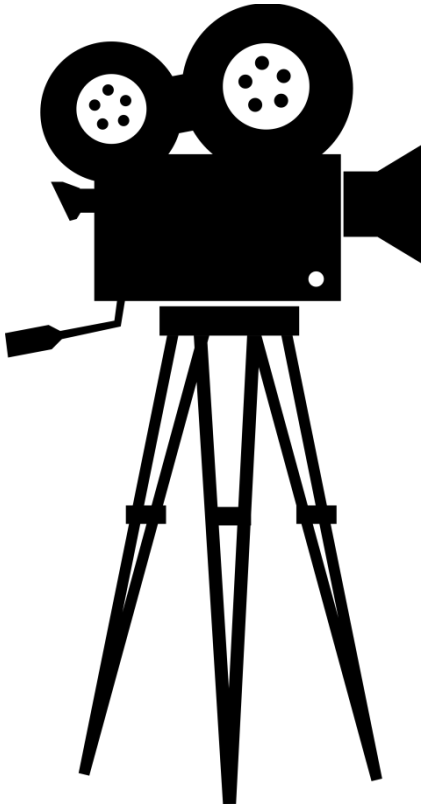
http://orrp.osu.edu/irb/investigator-guidance/consent/

Waiver or alteration of informed consent

- Only in compelling circumstances under very specific criteria
  - Research on public benefit or service programs with cooperation of state/federal government
  - Research that involves minimal risk and could not practically be carried out without waiver/alteration
  - Research to study conditions in children when parent permission is not a reasonable requirement to protect the child subjects

Minor providing consent for both child and self

Classroom observations



Additional suggestions

- Be informed about IRB policies/regulations
- Be your own biggest advocate with respect to balancing responsibilities as a researcher
  - Pick your battles
- Be open and creative in solutions
- Seek permission, not forgiveness
- Communicate with IRB staff and use them as supports

Additional suggestions

- Remember that IRB staff and IRB members may not conduct field-based/educational research
  - Structure your IRB proposal/protocol to make your research plan as clear as possible
  - Try to head off any potential pitfalls
- Be courteous, professional, and responsive

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