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

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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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