Tips from the Trenches:
Ten Tips from an IRB Reviewer for a Successful IRB Application

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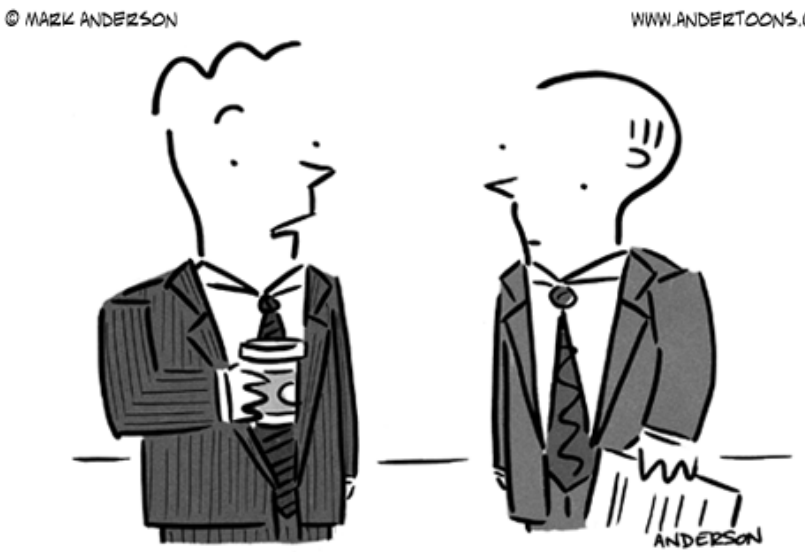
1 – Alignment

Alignment among:

- Online application
- Consent forms
- Proposal
- Appendices

Common Errors

- # of participants
- Duration
- Who gets what instrument or procedure



"You ever have one of those days where you just don't feel like aligning?"

2 – Precise Methods

- Research methods need to be detailed enough that it is clear what is going on
- Be clear about what is going on in the setting without a research study & what the research study is layering on top of the setting.
- Alignment among documents
- Break into phases if relevant
- Make it easy to understand & read

"You are completely free to carry out whatever research you want, so long as you come to these conclusions."

– underline, bullet & sub-head to help ease of reading.

- Be precise: What? How many times? When? Where is it taking place? Who is getting it? Who is giving it?

3 – Consent Process

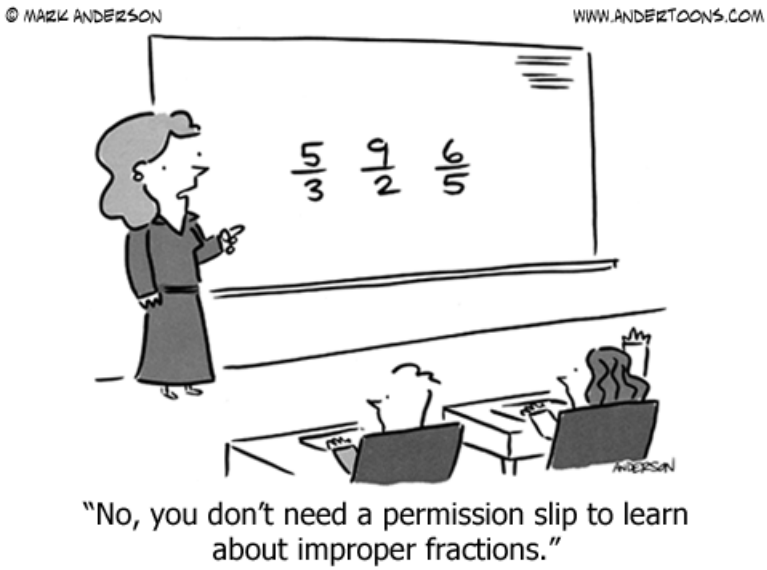
- CONSENT – adults only
- ASSENT – under 18
- PARENTAL PERMISSION– consent for child
- Process should be in a non-coercive environment, time to reflect, ask Qs, take the form home & bring back later
- In group consent environments be aware of social pressure to consent

"Personally, I wouldn't have signed it."

- Waiver of consent documentation – they are consented but no signature.
- Waiver of consent – only in exceptional circumstances.
- Alteration of consent – don't explain study accurately ahead of time

4 – Consent & Parental Permission

- Use online templates– it has all the components. Put on letterhead.
- Add a cover letter to make it more friendly ☺
- Non-technical language – 8th grade reading level
- Procedures: Be precise: What is being done? How many times? Where is it taking place? Who is doing it to them?
- Duration – how long – differentiate between typical practice & research.



"No, you don't need a permission slip to learn about improper fractions."

- Videotaping – what happens to tapes after? Who sees them. Maybe add a separate permission check box.

5 – Child Assent

- Assent comes AFTER parental permission
- Can be done individually or groups
- Read or written – be aware of reading level not just age
- Let child know parent has signed a form
- Explained in child language
- Use assent template
- In group assent be aware of social pressure or coercion
- I personally assent 4 yr olds using smiley face and straight face

"I didn't feel answers were necessary. All the questions seemed rhetorical."

6 – Engaged or Not?

- What makes a person considered part of the research team or not during the consent process?
- If study team member=CITI + eCOI
- ENGAGED – can recruit, answer Qs in consent process, hand out/collect forms assent people, sign off as study staff
- NOT-ENGAGED – can hand out forms, collect forms & hand to study staff. A conduit between participants & study staff. Cannot answer questions about study or encourage participants to engage in study. Can identify groups of potential participants who are recruited by study staff but not contact them & recruit them into the study.

7 - Videoing

- Things to consider when you video:
- Position of the camera – how do you not include people who have not been consented?
- Where video is kept and viewed – needs to be secure & private environment.
- Video is an "identifier" and is not "de-identified" information
- Needs to be mentioned on all consent forms
- Use of video after the study is terminated. Can use separate check boxes to keep the video after the study for training purposes or presentation at conferences.

"Try not to scream if you don't make it all the way over. You don't want to look like a wimp on the Internet."

8 - Incentives

- Incentives cannot be coercive – this is population specific
- Need to be described in consent documents.
- Need to be pro-rated – how much do you get if you only do a part of the test procedures.
- If you use incentives need to CAREFULLY document who gets them. Gift cards have a very specific process.

9 - Confidentiality

- Ensure confidentiality where possible, pseudonyms, participant #s
- You cannot ensure confidentiality in a group interview. You need wording in your consent form to that point.
- Demographic data may predispose to not assuring confidentiality.
- Qualitative data collection – transcription of field notes by commercialized entity needs to be written into IRB.

10 –Staying Compliant

- Getting IRB is the first step. Staying compliant is equally important.
- Don't change anything unless an amendment is approved.
- Train study staff in procedures and let them know the importance of sticking to protocol. Be detailed oriented in training your staff. Well meaning study staff have got people into hot water.
- Sign consent forms & keep for 3 years post study completion.
- If mistakes happen submit an incident report. The IRB are friendly.
- Reach out to IRB staff for advice. They are fabulous & very focused on supporting faculty.