The IRB is Your Friend

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Chair, Panel Orange

The IRB's Mission

The IRB is charged with the protection of human subjects in research – what does that mean in practice? My definition:

Facilitate human subjects research with appropriate protections – *help* investigators and study teams comply with the relevant regulations and common-sense ethical principles while *meeting their research goals*

A Little History

- I was on the “other side” for many years as an epidemiologist conducting multi-center studies (still wear both IRB and research hats)
- Obtained approval from many IRBs throughout US and other countries
- IRB approval was often the most onerous part of study setup, could take many months
- Individual IRBs could be a real impediment to study feasibility
- Joined BUMC IRB in 2000, hoping to help the process – invited to become Chair of new Panel Orange in 2011

Panel Orange

- 8 members, 3 not BUMC-affiliated
  - 4 non-MD/scientists (1 not affiliated)
  - 2 MD/scientists
  - 2 non-scientists (both not affiliated)
- We usually review
  - Observational protocols
  - Repositories
  - Randomized trials of social interventions
  - Generally minimal or low risk

What I Learned From the Inside

- Our IRB is very much dedicated to being “part of the solution,” with improved organization, better online system, faster response times, etc, *but*
- Investigators too often still see the IRB as an obstacle to be overcome
- There is sometimes a desire to expend as little effort as possible on the IRB process, so as not to “waste time” that could be spent doing actual research

The IRB Can Help With Study Design Issues

Resolution of human subjects concerns that arise during IRB review of applications can lead to improvements in study design

- Especially for local-PI protocols – multi-center trials usually have detailed sponsor protocols
- Recruitment procedures are most amenable to improvement with IRB input
- Sometimes data collection if repeated contact with subjects is involved

Some Recurring Issues With New Protocols

- Poorly completed INSPIR applications
  - Boxes incorrectly checked, leads to missing sections
  - Cutting and pasting from grants (still doing it!)
- Difficult-to-read consent forms
  - Technical language
  - Retention of irrelevant template language
  - Spelling mistakes, poor grammar, etc.
  - Insufficient emphasis on what happens to subject
- More time to correct problematic applications than would take to get it right from the start
- Leads to wasted time and unnecessarily difficult relationships between investigators and the IRB

Recurring Issues With Ongoing Protocols

- Low recruitment frequently raises questions at continuing review
- Deviations
  - Lost consent forms
  - Subjects enrolled who do not meet all criteria
  - Other procedures not followed
  - These result in RENIs and can lead to audits
  - If serious or continuing noncompliance, sponsor must be notified

My Advice

- Embrace the process
  - The IRB is here to help achieve research goals, not stand in the way
  - The process has been greatly improved in recent years
- PIs should read the application and consent forms
  - Remember, it's *your* protocol
  - The consent form is the most important formal communication with study subjects – put yourself in their shoes
- Focus the INSPIR application on procedures that the subjects undergo; summarize lab procedures and data analysis briefly, refer to attached grant or detailed protocol
- Stress attention to detail with staff who are completing the application *and* those conducting the study

Communication is the Key

- If there are questions about the best way to handle some aspect of an application (e.g., appropriate recruitment procedures), ask the IRB staff – they will be glad to help
- Don’t hesitate to pick up the phone and call – often a conversation is much more efficient than multiple emails
- As an investigator, I almost always talk to someone at the IRB before submitting an application
- Remember: *the IRB is your friend!*