



Preparing for an IRB Post-Approval Monitoring Meeting.

During the upcoming Post Approval Monitoring meeting, your research team will be asked the following questions. They may also be asked to show documentation or screenshots to support their answers, for example of current recruiting and consenting materials, current research instruments (surveys etc.), and record-keeping / data-storage arrangements.

1. Who are the various personnel on the study, and what do they do?
2. How is recruiting being done? Who does it, and what flyers/emails etc. are being used?
3. How/where/when are subjects being consented? Who does it, and what scripts/forms are they using?
4. How many participants have been recruited? How many have actually completed the study? If relevant, how many have been screened out, or dropped out before completion?
5. What versions of study “instruments” are being used (i.e. surveys, interview schedules, focus group prompts, experimental stimuli etc.)?
6. How are consent forms and other records being kept?
7. How are data being stored, moved, and processed?
8. How is any compensation being made and tracked? How much compensation has been given out?
9. Have any adverse events occurred, and if so, how were they handled?
10. Have the originally-approved protocol and supporting documents been changed in any way? How were any changes handled, and why were they made?
11. What reports have been made to sponsors and/or other institutions involved in reliance agreements?

If the meeting is on site, your team may be asked to physically demonstrate procedures (including consenting) and data handling arrangements.