

Appendix 3 – IRB STAFF

General

1. Tell us about yourself and elaborate on the training you have received.
2. Does the institution give you opportunity for continuing education?
3. Have you heard about the Belmont report?
4. Do you have adequate resources to perform your duties?
5. Describe what you do when you receive a new proposal.
6. Are you given opportunities for continued education?
7. Do you have regular meetings of the IRB Staff to discuss issues?
8. If you have questions about the IRB policies, how do you find the information you need?
9. What do you think your role is as an IRB Staff?
10. Do you participate in the review process during IRB meetings?
11. Do you feel your opinions are taken into consideration?
12. Do you feel valued for the work that you do in the IRB?
13. What are your feelings about the IRB?

Assigning Submissions

14. How do you assign proposals to reviewers? How do you determine if they have a conflicting interest?
15. How do you assign a request for renewal to a reviewer / meeting?
16. Who decides if a new proposal / continuing review / protocol amendment may be reviewed by expedited review or full board review?

IRB Meetings

17. How do you prepare the meeting agenda?
18. How do you prepare meeting minutes?
19. How do you ensure that there is quorum at the start and during the entire course of the meeting? Have you had a situation when you had last minute cancellations and lost quorum? How did you deal with that?
20. Do members leave during the course of the meeting? If so, how do you determine if the quorum is intact? How is this documented?

Role in Review of Research

21. What is your role in reviewing unanticipated problems including adverse events and protocol deviations?

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22. What do you do when approval for a research study expires before continuing review is conducted?
23. What do you look for when you receive a request for renewal of IRB approval?
24. Have you dealt with emergency use of investigational products? If not, who deals with this?
25. Describe the difference between waiver of consent and waiver of documentation of consent.
26. Do you review the consent documents to ensure that they contain all the elements of disclosure? Do you use a checklist?

Vulnerable Subjects

27. How do you handle research proposals that plan to enroll prisoners?
28. Are there additional protections for proposals that involve vulnerable populations?
29. What do you do when you find out that the researcher plans to recruit prisoners?

Interacting with Researchers

30. Do you receive requests for making determinations whether an activity is human subjects research? How do you make such determinations? What do you ask the researcher to submit to you? Do you document these determinations?
31. Do you help answer questions that researchers may have about human subject protections?
32. How do you deal with researchers who are very demanding?

Other Committees

33. What do you do when you notice that a researcher has disclosed a conflicting interest?
34. Are you aware that there are other institutional committees that look at human subjects research besides the IRB?
35. Have you had a chance to work with the Research Conflict of Interest Committee on a protocol that has been submitted both to the CPHS and the RCOI Committee?

Final Question

36. Is there any message that you would like us to relay to the University officials?