

Appendix 2 – IRB MEMBERS

General

1. How did you become an IRB member? Did you volunteer or were you required to be a member?
2. Do you know whether you are a scientific or non-scientific member?
3. Do you know if you are an affiliated or non-affiliated member?
4. Did you receive any training for being in the IRB?
5. Have you heard about the Belmont report?
6. Do you have adequate resources to perform your duties?
7. What are your feelings about the IRB?
8. Do you feel appreciated for being in the IRB?

Meeting

9. How is the meeting agenda distributed?
10. How much time is spent per protocol during the meeting?
11. Have you been a primary reviewer (Chairperson of Subcommittee) on a research proposal?
12. If you are not on the subcommittee for a research proposal, what are the documents that you review?
13. Do you feel your opinions are taken into consideration?
14. Do you think there is enough time for discussion of each agenda item at IRB meetings?
15. What happens if there is disagreement within the IRB about a particular issue?

Review of Research

16. How do you review a research proposal?
17. How much time do you spend reviewing a research proposal?
18. If you have questions about a research proposal you were assigned, whom do you contact for answers? Do you do literature searches? Internet searches?
19. Who presents the proposal during the meeting?
20. What do you look for when you review a research proposal?
21. Do you use a reviewer worksheet? Are you aware of the regulatory criteria for approval? Where do you find them?
22. How do you determine if the consent document is adequate?
23. How do you determine if the consent process is adequate?
24. What do you look for when you review a change request or protocol amendment?
25. What do you look for when you review a request for renewal?

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26. What do you look for when the investigator has disclosed a conflicting interest?
27. What do you look for when you review a report of unanticipated problems including adverse events, protocol deviations and other problems?
28. How does the IRB decide if a research study needs review more frequently than annually?
29. How often does your IRB seek advice from outside consultants?
30. Do you have statistical support on the IRB? Do you have access to experts outside of the IRB?
31. Have you ever had a conflict of interest with a proposal being reviewed by your IRB? If so, how was it resolved?

Compliance

32. How does the IRB deal with a rogue researcher?
33. Has the IRB requested for monitoring of a research study?
34. Has the IRB ever suspended a research study?
35. If you have questions about the IRB policies, how do you find the information you need?

For non-scientific members

36. Do you think your opinion is valued by the scientific members?
37. What do you think your role is in the IRB?
38. Why do you think having non-scientific members is important?

Final Question

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