

Appendix 1 – Researcher and Research Team

1. What is your research topic?
2. How are prospective subjects identified for the project, i.e. what is your recruitment strategy?
3. Describe what screening method is used to determine the first stage of eligibility and who implements the screening process. How do you document eligibility?
4. Once a prospective subject is identified, describe step-by-step what procedures are implemented to inform the subject prior to obtaining a signature on the informed consent document. Who introduces the research study to the prospective subjects? Who implements the informed consent process in depth? Who addresses/answers questions presented by the subject or subject's family?
5. Is the principal investigator usually/typically present for the informed consent process?
6. What is the time interval between the presentation of the research study information and the actual signing of the consent form?
7. Where do you store study related documents? Do you have a Regulatory Binder?
8. How do you ensure that you protect privacy interests of subjects and the confidentiality of subjects data?
9. How frequently is the study data reviewed, i.e. per subject, per month etc? Does your study have a data safety monitoring plan?
10. How would you handle an unexpected event such as the loss of research records or study data?
11. Who is responsible for preparing and submitting IRB related documents?
12. How are study related responsibilities delegated? Does the research team meet regularly to discuss progress and problems with the study conduct?
13. Do you have any additional mechanisms in place to protect subjects?
14. What do you do when you encounter unanticipated problems involving subjects and others including adverse events?
15. Have you ever been involved in a research in which you had a conflicting interest? How do you handle conflicting interests?
16. Are you aware that there are other institutional committees besides the IRB that look at human subjects research?
17. What do you do if you receive a complaint from a subject? If you are unable to resolve the issue – what do you do?
18. For study staff – if you have a concern about the way the study is being conducted, how do you deal with it?
19. Do you have adequate resources to perform your duties?
20. How do you find out about IRB requirements for review of research?
21. What are your feelings about the IRB?
22. Would you like us to convey any message to the University officials?