

ACCREDITATION OF UTHSC-HSPP

Appendix 4 – INSTITUTIONAL OFFICIAL

1. What is the one thing about the UT human subjects program that keeps you awake at night?
2. What are the challenges faced by the human subjects protection program? By the IRB?
3. Do the IRB's report to you? Do you think there is a conflict of interest that compromises IRB function or credibility?
4. How do you ensure that the IRB has adequate resources?
5. Do you regularly meet with the IRB Chairs / IRB Director?
6. Do you ever review protocols? How do you ensure that your comments are taken into consideration by IRB?
7. Do the IRB members feel appreciated? What does the University do to value the contribution of IRB members?
8. Has there been any feedback on the IRB system?
9. Are researchers supportive of research? Are researchers supportive of the IRB?
10. Do researchers have any reservations and concerns about IRB?
11. Has the institution conducted any satisfaction surveys for researchers?
12. Have any researchers complained to you about the IRB system?
13. How do you handle a dispute between the IRB and the investigator?
14. How do you determine whether your researchers are compliant with protocol and institutional policies and procedures?
15. Is non-compliance a problem at this institution?
16. If there is non-compliance or a trial is suspended, how do you get to know about it?
17. If there is a dominant physician who insists on recruiting a patient who is not appropriate, what would you do?
18. How do you handle whistle blowing?
19. If there is a serious complaint from a research participant, how is this handled?
20. In general, would you say that most researchers have sufficient resources? Would you be informed if researchers do not have sufficient resources? How do you handle this?
21. Does the institution have any training opportunities for study coordinators?
22. Does the institution have any training opportunities for researchers? Junior researchers?
23. Does the institution have a plan for handling institutional conflict of interest?
24. Have you checked or unchecked the box on the institution's FWA? Why?
25. Who provides legal advice to the IRB?