COACH
Helping VA facilities protect veterans in research
Center on Advice & Compliance Help

Sample Interview Questions for Domain III: Investigators and Research Staff

This domain is evaluated during the on-site visit by AAHRPP site survey personnel. The following are suggested questions that your facility may wish to use or modify to assist your human research investigators in AAHRPP preparations. These questions are not official examples from AAHRPP but are presented as samples derived from evaluation of the Elements in Domain III.

Element III.1.A.- Conflict of Interest

1. What are your institution's requirements for financial disclosure before or during the conduct of a human research proposal?

2. What is the importance of disclosing financial conflicts of interest in the conduct of human research?

Element III.1.B.- Study Design

3. Give an example of how you design your research proposal to detect harm promptly.

4. What is a sound study design?

5. What type of research design characterizes the majority of your studies?

6. What is your IRB reporting requirements for reporting deaths that may be related to study participation?

Element III.1.C.- Risk Evaluation

7. Is there anything different about risks that research subjects undertake compared to risks that patients undertake when receiving care?

8. Can you implement a change in your study without having IRB approval?

9. Where would I look in your research protocol if I was looking for how you minimize risk in your studies?

Element III.1.D.- Subject Recruitment

10. How do you determine whether the inclusion and/or exclusion criteria are equitable?

11. What is an example of a recruitment procedure that you employ that maintains equitable selection of subjects in your study(ies)?

12. What do you do if one of your subjects becomes incarcerated after they are enrolled into your study?

13. Can you recruit your own employees into your studies?

14. How do you determine if a subject is decisionally-impaired?

15. What information do you normally put in a recruitment ad for your studies?

16. Explain what type of incentives are allowed to be given to your fellows or staff that assist in recruiting patients into your studies.

Element III.1.E.- Study Resources

17. How do you determine whether you have enough study personnel to assist in your studies?

18. How do you fund your research?

19. Do you have protected time to conduct your research activities?

20. Do you use any special physical (ex. space, hospital services) resources in the conduct of your study, and how do you obtain them?

21. What are your institution's policies on obtained informed consent for human research subjects?

Element III.1.F.- Informed Consent

22. Who administers informed consent to potential subjects in your studies?

23. How do you determine whether an individual that you delegate authority to conduct the informed consent process is qualified?

24. How do you train your study personnel? (Element III.1.E and F)

25. How do you assess decision-making capacity in potential subjects whose decision-making capacity is in question?

26. What do you do when a study coordinator calls you and tells you that a prospective subject does not understand the information he or she is being given?

27. What signatures are required to be documented on your informed consent forms?

28. Who can serve as the legally authorized representative if a potential subject is decisionally-impaired?

Element III.1.G.- Subject Questions and Complaints

29. What is an example of a subject complaint?

30. What do you instruct your study staff to do if they receive a complaint from one of your subjects?

Element III.2.A.- Study Personnel Training

31. What is your training requirements to conduct human research at this institution?

32. How do you consult if you are unsure whether an activity is human research?

Element III.2.B.- Unanticipated Problems

33. What is an example of an unanticipated problem involving risks to subjects that you would have to report to the IRB?

34. What is the reporting requirement at this institution if a non-serious adverse event occurs that is not related to the study?

Element III.2.C.- Investigator Oversight

35. How do you oversee the activities of research staff?

36. What are the qualifications required to be a study coordinator for this study?

37. How does the investigator have oversight of the studies (study coordinator question)?

Element III.2.D.- Data Safety and Monitoring Plans

38. Do all of your studies require a data safety and monitoring plan?

39. Is there a difference between a data safety and monitoring plan and a data safety and monitoring board?

40. Do studies classified as minimal risk require a data safety and monitoring plan?