AAHRPP
Sample Interview Questions by Role

The following questions are not official examples from AAHRPP but are presented as samples derived from feedback from different sources. Some of the questions are not role specific; the same question could be asked to multiple individuals and/or at different times (ex. ACOS/R&D may be asked same questions as Director and Chief of Staff; questions asked during the Program Overview may be asked during individual interviews). Many questions asked during the site visit are specifically based upon the initial accreditation or reaccreditation application materials submitted by the organization and the content in files selected for evaluation during the site visit or responses to the evaluation of the Step 1 application materials reviewed by AAHRPP. This list is not intended to represent an all-inclusive list. It is intended to provide examples of types of questions asked during the site visit.

Director and Chief of Staff/Research and Development

1. What is the Institutional Official's role in the HRPP?
2. What is the role of the Director and/or Chief of Staff in evaluation of the HRPP?
3. What is the strength of the HRPP?
4. What is the deficiency or weakness of the HRPP?
5. When an investigator or IRB member states they have "protected time", how is that operationalized?
6. How are IRB and R&D committee members appointed?
7. How do you communicate with the RCO?
8. How do you communicate with the ACOS/R&D?
9. Is there a collaborative role of the VA facility with another organization (e.g., medical center, other VA facility) in regards to HRPP function, such as education or quality assurance or quality improvement activities?
10. One of the roles of the Director is to establish an educational plan for investigators. How has the plan been developed and implemented at this VA HRPP?

Associate Chief of Staff/Research and Development

1. How do you communicate with the Director to adjust and/or allocate resources to the human research protection program?
2. Are there sufficient resources to carry out the function of the HRPP?
3. How does the HRPP evaluate its performance?
4. Is there a process for monitoring research subjects' satisfaction and/or complaints?
5. If you are a principal investigator (PI), how do you separate your role as a PI from being the ACOS/R&D?
6. What is your process for dealing with institutional conflicts of interest?
7. How do you plan on continuity within the IRB and R&D Committees with you have members that are always going on and off the committees?

Administrative Officer/Research and Development

1. What is the role of the Institutional Biosafety Committee?
2. How do you budget for the HRPP?
3. What is your primary role within the HRPP?
4. How do you communicate issues involving the HRPP to the Director if the Director needs to be made aware?
5. What is your role in making sure all educational training records are current for investigators and research staff conducting human research?
6. What is your role with the execution of clinical trial Cooperative Research and Development Agreements (CRADAs)?
7. What is the role of the AO/R&D for development and dissemination of HRPP policies?
8. What is your role in ensuring that R&D Committees files are maintained as needed by the Research Office?

Research and Development Committee Members

1. How does the Research and Development Committee interact with the IRB?
2. How are the roles of the Research and Development Committee different than the role of the IRB?
3. Does the R&D Committee conduct scientific review? Is so, is this provided to the IRB or does the IRB conduct is own scientific review?
4. How does the R&D Committee verify IRB member qualifications?
5. How does the R&D Committee handle COI: Example: If someone submitting a study was paid $20,000 by Merck, what is the procedure?
6. What is the R&D Committee's role in the participant outreach program?
7. How does the R&D Committee keep people informed about research?
8. What is the R&D Committee's role in establishment of local SOPs for training of research staff and/or R&D Committee members?
9. What is the process for appointing (a) new R&D Committee members and (b) IRB members?
10. How does the R&D Committee monitor the HRPP?
11. How does the R&D Committee review IRB minutes?
12. Does your R&D Committee conduct continuing review of IRB protocols? Is so, what happens if continuing review approval by the R&D Committee does not occur prior to the IRB continuing review approval process?
13. How does the R&D Committee ensure that no research is being done without the appropriate approvals?
14. What is the role of the R&D Committee in approving local SOPs related to research?
15. What if any if the role of the R&D Committee in ensuring that the policies are disseminated?
16. If the R&D Committee is to send a notice of R&D Committee approval to the ACOS/R&D, and the ACOS/R&D is not present (absent, sick), who signs the letter to the investigator stating that the research can be initiated?
17. If an investigator puts in a modification to a previously approved project requiring approval from radiation safety, what is the process for submitting to the radiation safety committee? How does R&D Committee know that it was reviewed by radiation safety?
18. What does the R&D Committee consider to be "proper training" of PIs?
19. How does the R&D Committee interact with "commercial" IRBs or other IRBs, including the VA Central IRB?
20. How is the R&D Chair appointed?

Legal Counsel

1. What is your role in providing assistance to the HRPP in applying laws to research involving human participants?
2. Are there additional requirements or disclosures applicable to informed consent which applies to research conducted within this state?
3. What is the age of a child in your state?
4. If the IRB approves a surrogate consent process, who is allowed to be a legally authorized representative for VA research studies – does it differ from VHA requirements?
5. What is the role of legal counsel in reviewing contracts with sponsors?

IRB Chair and Members

1. Who has the final authority to decide whether a conflict of interest and its management is acceptable and will allow the research to be approved?
2. Who decides with a consultant is needed to participate in the review of a protocol?
3. What does a member do when they declare a conflict of interest during a convened meeting?
4. How do you receive feedback about your performance on the IRB?
5. Who decides whether flagging a medical record is required? How is flagging a record decided?
6. What is the process for designating members who can conduct review using the expedited procedure?
7. How is the IRB notified of approvals using the expedited review procedure?
8. Please give an example of a minor modification and a modification requiring review by the convened IRB because it represented a substantial modification or clarification.
9. Please explain what happens when IRB study approval lapses (expires).
10. Do you use the IRB reviewer tools?
11. What is the difference between privacy and confidentiality?
12. Please give an example in which the IRB might consider observing the consent process as a method to protect participants.
13. Does the IRB conduct its own scientific review?
14. Who are the individuals who can make exempt determinations on your IRB?
15. Is exempt research by definition also ethical research?
16. How are requests for recruiting subjects who have impaired decision-making capacity evaluated?
17. If an investigator submitted a protocol request recruitment of 17 year-old subjects, would your IRB consider the 17 year-old subjects to be children?
18. How does your VA review research involving a request by an investigator to use a surrogate for informed consent?
19. What is the role of the IRB when a physician calls the IRB Chair and states he or she has a patient who may meet the criteria for emergency use of an investigational drug?
20. What regulations do you apply when making a determination that an activity is human subjects research?
21. If the VA did not officially “adopt” Subpart B, what requirements are followed by VA when a study targets pregnant subjects?
22. If your IRB chair or designated IRB reviewer receives a request for a determination of Category 5 exemption, what would you do?
23. Describe your process for reviewing investigator conflicts of interest either before or during a convened IRB meeting.
24. Describe the process if an investigator is pressured an IRB member to approve his/her research.
25. How are serious or continuing non-compliance determinations made by an IRB communicated to the Director?
26. Describe the communication process that occurs after the IRB Chair makes a determination on a protocol.
27. If a VISN Director proposed to have a study conducted at all sites within the VISN, how would the IRB ensure coercion does not interfere with the IRB review process?

28. If an investigator with a dual appointment at the VA and a university contacted you as an IRB member and asked whether his or her activities constituted institutional engagement, how would you respond?
29. What is the IRB's role is reviewing CRADAs?
30. Describe how your IRB evaluates cultural issues that may be applicable to a protocol.

Research Compliance Officer

1. Who is responsible for ensuring that an IND or IDE is valid?
2. What is your role in communicating with the IRB and R&D Committees?
3. Who do you report to in the chain of command?
4. Who receives your audit reports?
5. What is your role in quality assurance and quality improvement activities?
6. If you found an inconsistency between the date on the informed consent form and the date informed consent was obtained according to a progress note, what would you do?
7. If the IRB requires flagging of a subject's medical record, when and how is investigator compliance evaluated?
8. Do any of your investigators hold an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE)? What additional regulations apply? How are these studies overseen?
9. Can an investigator's brochure be used to validate the IND?
10. During convened IRB meetings, what is your role in the IRB review process?
11. What is your role in writing and/or ensuring that suspension or terminations of IRB approval are reported to the appropriate agencies by your Medical Center Director?

IRB Coordinator and/or IRB Administrators

1. How are IRB decisions communicated to investigators and in what time frame does it occur?
2. When a request comes into the IRB office querying whether an activity is human subjects research, how is it processed?
3. When a request comes into the IRB office querying whether another institution in engaged (multi-site research) in the research, who makes the determination?
4. What are the IRB responsibilities when the PI is the main PI of a multi-site study involving other engaged institutions for a non-exempt study?
5. How are requests for exempt and expedited review processed by the IRB administration?
6. Who is responsible for ensuring that you complete your required educational training?
7. Do you have a formal evaluation of your performance as an IRB coordinator?
8. Who is responsible for keeping the IRB rosters and FWAs current and who is responsible for submitting it to the appropriate regulatory agencies?
9. What is the role of the RCO in your duties?

Investigators and Research Staff

1. How you obtain answers to questions or convey suggestions to the human research protection program?
2. What is a conflict of interest and how do you disclose it?
3. How do you decide whether an activity you are designing constitutes human subjects research?
4. What is a "sound" scientific design?
5. What is meant by minimizing risk?
6. How do you approach a subject?
7. How does one promote equitable selection of subjects?
8. How can an investigator oversee research staff effectively?

9. How does an investigator decide that research staff is “qualified” to do what needs to be done in the study?
10. How do you know when to flag a medical record to indicate a subject’s participation in a study?
11. Describe what is meant by informed consent process.
12. Do you ever “reconsent” subjects? If you do, who informs you when it is required?
13. After initially obtaining informed consent, do you reassess whether the subject wants to remain in the study?
14. How do you ensure that you are not using an outdated consent form?
15. What is the process for requesting IRB approval of a surrogate consent process? Who is allowed to be a surrogate for purposes of informed consent?
16. Where are organizational policies and procedures kept?
17. Do you accept recruitment bonuses?
18. What is the difference between a data safety monitoring board (DSMB) and a data safety monitoring plan (DSMP)?
19. Describe the DSMP plan for the selected protocol. What makes it effective?
20. Give an example of an unanticipated problem involving risk to subjects or others.
21. If a problem was not serious and unrelated to the research, is it still an unanticipated problem involving risks to subjects or others?
22. What is the difference between an adverse event and an unanticipated problem involving risks to subjects or others?
23. What is the VA policy for adverse events? How do you determine if an adverse event is related?
24. What is an example of an unfair recruitment strategy?
25. What is your opinion of the effectiveness of the IRB and R&D Committees?
26. If your study had continuing review and approval until June 1, 2009, what is the last date the study could be conducted according to your IRB SOPs and remain in IRB approval?
27. How are continuing review applications submitted (what forms, who completes the documentation)?
28. How do you ensure that there is sufficient documentation to support the interactions or interventions done with the subject in the IRB-approved protocol?
29. What is the difference between privacy and confidentiality?
30. How do you ensure subject privacy in the conduct of studies?
31. How do you ensure that your study files are secure?
32. What is the difference between a minimal risk protocol and a greater than minimal risk protocol?
33. What type of support does the VA facility provide you and/or your research staff for training in how to conduct research at the VA facility?
34. What would you do if a subject called on the weekend and had broken his or her last vial of study medication and needed it replaced?
35. What do you do if a subject makes a complaint to you about the study you are conducting?
36. What do you have to do at this VA Facility in order to be allowed to conduct human research?
37. If a study’s approval expires on 11/1/09, what does that mean? When is the last day that you can conduct research?
38. Have you turned down any studies and why?
39. What incentives are you allowed to receive as an investigator?

Investigational Pharmacist or Pharmacist Responsible for Investigational Drugs

1. How do you ensure that there is sufficient documentation to support the interactions or interventions done with the subject in the IRB-approved protocol?
2. Is there separate dedicated space for investigational drugs that is separate from the non-investigational drugs?
3. If your pharmacy is responsible for security of some of the investigational devices, how is that addressed by your investigational pharmacist?
4. What is the system in place to ensure that the correct person is prescribing the investigational drug and that the patient is actually a subject in the study?

5. Have you ever had an occurrence involving emergency use of an investigational drug? If so, how did the investigational pharmacy ensure that informed consent had been obtained since there is no IRB-approved consent form?
6. What is the investigational pharmacist's role in IND verification/validation/determination whether one should exist?
7. Does your VA facility have any studies in which the investigator holds the IND and serves as the sponsor? If so, what, if any, is the investigational pharmacist's role in education or assisting the sponsor-investigator fulfill their drug accountability requirements?
8. Does the investigational pharmacist or a pharmacist representative sit on the IRB?
9. What type of quality assurance activities is the investigational pharmacist directly involved in, and what other entities within the VA facility receive reports of those activities (both quality assurance and quality improvement)?
10. What is the time lapse of pharmacy notification when the IRB suspends or terminates a study, and how is it communicated?

Affiliate Issues

1. If your IRB of record is an academic affiliate, how does the IRB coordinate conflict of interest management issues with the academic affiliate and the R&D Committee?
2. How are issues between the VA and the affiliate IRB addressed?
3. If you have investigators with dual appointments and there are two IRBs (one at the VA facility and one at the academic affiliate), how is it decided whether the investigator with the dual appointment requires IRB approval at both institutions?
4. If there are studies being conducted at both the VA and the affiliate by the same investigator, how are audits conducted and communicated?
5. Are meetings conducted regularly between the VA and the affiliate?
6. If you could change anything about your relationship with the affiliate, what would it be?
7. What type of support does your VA HRPP provide to the affiliate IRB (affiliate IRB if the IRB of Record for the VA HRPP)?