

AAHRPP

Sample Interview Questions by Topic

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. 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. 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.

Administrative Structure

1. Does your HRPP have sufficient resources (e.g. personnel, physical space, physical resources) to function effectively?
2. What is the Institutional Official's role in the HRPP?
3. How do the different components of the HRPP communicate with each other?
4. What is the strength of the HRPP?
5. What is the weakness of the HRPP?
6. What is the relationship between investigators and the IRB?

Quality Assurance and Quality Improvement

1. What are the most important components of a human research quality assurance and quality improvement program?
2. Who are the individuals and/or groups responsible for quality assurance activities in human research?
3. How do the above individuals and/or groups communicate their findings?
4. Who is responsible for audits of human research studies?
5. How are audit findings communicated to the IRB?
6. What is the Institutional Official's role in reviewing and/or receiving feedback about changes in policies or procedures implemented as a result of quality improvement activities?

7. How does the organization incorporate feedback from participants into quality assurance and quality improvement activities?
8. How does the organization ensure that research is not conducted without IRB approval?
9. What is the IRB's role in quality assurance and quality improvement?
10. Give an example of a quality improvement activity incorporated into the HRPP and how it was evaluated.
11. If you had one policy or procedure that could be implemented to improve the HRPP, what would it be and why?
12. How do you ensure all investigators are sufficiently qualified to conduct human research?

Conflict of Interest

1. What is an example of a financial conflict of interest?
2. Describe how consultants' financial conflicts of interests are evaluated.
3. Who reviews financial conflict of interest disclosure forms and what is your understanding of "review"?
4. Do you believe all financial conflicts of interest can be resolved? Support your rationale.
5. Can an IRB member who is participating in a study as a participant vote on that study when it is evaluated for continuing review and approval? Support your rationale.

Informed Consent

1. Based upon review of the protocol, support the type of informed consent process and/or documentation requested in the investigator's application to the IRB.
2. What type of process does the IRB use to make informed consent documents understandable to participants?
3. Based upon review of protocol "x", the IRB approved a waiver of documentation for informed consent. Support the regulatory basis for approving the waiver.
4. How does the IRB ensure that basic elements of informed consent are present in the IRB-approved consent form (unless the IRB waives a basic element and/or waives documentation of informed consent or the consent process)?

IRB Review of Protocols

1. What is the role of the administrative staff prior to giving the protocol to the IRB reviewers?
2. Describe how consultants are used to review protocols.
3. Give an example of a minimal risk study.
4. What is the most difficult part in reviewing a protocol?

5. Based upon review of protocol “x”, justify the exempt or expedited determination made by the convened IRB or qualified IRB reviewer.
6. Based upon review of protocol “x”, why were “y” actions taken to minimize risk? Justify how the documented actions would minimize risk.
7. Based upon review of protocol ‘x”, go thru each of the approval criteria and describe the mechanism for reviewing each approval criteria.
8. How long does it take to approve a protocol under (a) expedited review or (b) convened IRB review? If the approval time interval could be improved, please describe your opinion of how it could be improved.
9. When does one apply FDA regulations?
10. What does the IRB do when an investigator reports in an application that the study involves an IND or IDE?
11. What is the difference in applying waiver of informed consent and waiver of documentation of informed consent?

Vulnerable Populations

1. What populations other than the vulnerable populations defined in the federal regulations does your IRB consider to require special safeguards when they are targeted as participants in human research studies?
2. What makes a participant population vulnerable?
3. Based upon review of protocol “x”, justify why the IRB required safeguards for the study participant population.
4. How does one determine whether a potential participant is “incompetent”?

Unanticipated Problems Involving Risks to Participants or Others

1. Give an example of an unanticipated problem involving risks to participants or others.
2. What materials are given to the IRB reviewer(s) for review of events or problems that could be unanticipated problems involving risks to participants or others?
3. How does the IRB determine whether a reportable event or problem is an unanticipated problem involving risks to participants or others and an adverse event?

IRB Structure

1. Describe the population of the community served by the organization.
2. Does your IRB have members who are representative of the populations within the community? Support your rationale.
3. If your IRB qualified to review the types of research submitted by investigators?
4. How would you change the IRB?