Tips for AAHRPP interviewees

The following categories were taken from the AAHRPP agenda. Scroll down until you find the title that matches your position/interview category. Under your category are possible questions that reflect our past experience with AAHRPP and are meant to prepare you for your interview. Please refer to the end of this tip sheet for general terms and issues for all to be familiar with.

IRB Member (Non Scientist):
- Are your comments and questions heard at the IRB meetings?
- Are you respected by other IRB members and non members who are scientists?
- What is your role in the review process?
- What is the focus of your review?
- Do you feel noted/appreciated?
- What is your role as a Non Scientist?
- Do the USC HSPP Policies and Procedures have a prescribed role for you?
- Do you know where to seek help/guidance?
- How were you trained initially? Was it adequate? Is it ongoing? If so, how is education provided to you/other members?
- Additional regulations are required for DOD-sponsored studies. USC has provided policies to assure adherence to additional regulations for DOD studies in the form of a DOD Checklist.
- Is member conflict of interest addressed at your meeting? (leaving room, abstaining from vote)
- Do you know about additional requirements for vulnerable subjects? (pregnant women, neonates, prisoners, children). Is there additional discussion allotted for these subjects?
- What is a Certificate of Confidentiality? When is it required?

IRB Member (Scientific):
- How do you review a study? What do you look for?
- You must have general knowledge of approval criteria, consent, safety, risk, benefit, privacy, scientific merit, conflict of interest, etc.
- How do you keep up with training/regulations/rules? (Ed sessions at meetings, attend PRIMR conference, attend meetings, and CITI are some resources)
- Are you cognizant of IRB rules/policies and where they can be found?
- Is level of risk related to sensitivity of information?
- Additional regulations are required for DOD-sponsored studies. USC has provided policies to assure adherence to additional regulations for DOD studies in the form of a DOD Checklist (medical monitor, injury statement and scientific review)
- Is member conflict of interest addressed at your meeting? (leaving room, abstaining from vote)
- If you are a Co-I or Sub-I must you recuse yourself from voting?
- Do you know about additional requirements for vulnerable subjects? (pregnant women, neonates, prisoners, children). Is there additional discussion allotted for these subjects?
What is a Certificate of Confidentiality? When is it required?

**IRB Member Alternate:**
- Is the alternate a true alternate?
- Are you equivalent to the regular member (you should be)?
- You must have general knowledge of approval criteria, consent, safety, risk, benefit, privacy, scientific merit, conflict of interest, etc.
- How do you stay up to date with regulations/ethics/policies?
- Do you attend meetings?
- Are you treated like regular members?
- Alternates should be treated equally and should get equal information. They must have the same expertise as regular member.
- Additional regulations are required for DOD-sponsored studies. USC has provided policies to assure adherence to additional regulations for DOD studies in the form of a DOD Checklist (medical monitor, injury statement and scientific review)
- Is member conflict of interest addressed at your meeting? (leaving room, abstaining from vote)
- If you are a Co-I or Sub-I must you recuse yourself from voting?
- Do you know of the vulnerable subjects subparts? Are additional requirements for these subjects discussed? (pregnant women, neonates, prisoners, children)
- What is a Certificate of Confidentiality? When is it required?

**Investigator / Staff: Drugs, Device, Biologicals**

*Use below per your role*
- AAHRPP team may focus on PI and/or PI and study.
- They will ask about interaction with IRB, about the study listed (e.g. how did you get it through the IRB, how do you protect vulnerable populations, what do you do if subjects complain or get ill, what do you think about the IRB and protecting your subjects, how do you familiarize yourself with issues like intellectual property, how do you communicate with the research staff and the IRB, how and when to report problems, and what do you do if IRB approval lapses?)
- Do you know what/when/how to report SAEs? Have you had reportable events?
- Have you had GCP training?
- How do you and your team stay abreast of and comply with FDA regulations for drugs/devices/biological? Have you had direct interaction with FDA?
- Know your relationship with sponsor, monitor, other sites (if multi-site study), IRB
- Know why your study is full board, expedited or exempt.
- How do you communicate and interact with the investigator?
- Were you trained in human subjects research/ethics/carrying out research duties/etc.?
- Where do you go with problems?
- What do you do day to day?
- How do you stay informed about study changes, issues, regulatory changes?
- What is the funding source for your studies?
- How are subjects recruited for your studies? How is equitable subject selection addressed? Are there extra protections for vulnerable populations?
- How do you handle subject complaints? How do you inform the PI?
How do you report adverse events? Who reports them? Are these discussed amongst the research team?

How do you communicate with other research staff? Are there regular meetings?

Does your study utilize a laboratory? If so, are there laboratory meetings? Is there communication with laboratory management?

How would you describe the general oversight of research? Who trains? Who oversees? How do new research members learn about study procedures?

How do you manage research records? How do you ensure subjects receive proper consent and HIPAA forms?

How are drugs/devices/biological stored? Who has access to these? What happens to these after study completion?

Is your study multi-site? If so, how do sites communicate? Is your site the coordinating center?

Be prepared to describe a study.

If the PI is not available, who runs the study?

Investigator: Social / Behavioral

AAHRPP team may focus on PI and/or PI and study

They will ask about interaction with IRB, about the study listed (e.g. how did you get it through the IRB, how do you protect vulnerable populations, what do you do if subjects complain or get ill, what do you think about the IRB and protecting your subjects, how do you familiarize yourself with issues like intellectual property, how do you communicate with the research staff and the IRB, how and when to report problems, and what do you do if IRB approval lapses?)

Were you trained in human subjects research/ethics/carrying out research duties/etc.?

Do you know what/when/how to report non-compliance? Unanticipated problems?

What kinds of harms may occur in your study? How do you minimize them?

Director Human Subjects Education and Audit:

Do you observe consenting? If so describe what you do and how you do it.

What do you do if the consent form is poor, unsigned, unapproved?

What topics do you cover when you audit?

Consent is a big item. How do you take findings and incorporate them into best practices?

How do you turn findings into educational moments and make them active versus passive?

QA/QC? (Is it person to person interactions like observing consent, or is it all done on a computer at your desk? Or both?)

How do you process improvement?

How do you improve the system with what you’ve learned?

What do you do if you notice systematic problems with a study you audit? How do you address issues that put subjects at risk? Are there audit follow-ups?

AAHRPP will key in on informed consent audits where you physically observe the process.

AAHRPP will ask about internal education/audits as well.

Chair and Members Disclosure Review Committee (CIRC):

How does the process work and who deems a conflict satisfactorily managed?
How does the committee communicate with the IRB?
When appropriate, do disclosures occur in the IRB process? department review process? or is there another process the committee takes?
Managing a conflict – COI makes recommendations to IRB, COI can make an edict, PI may disclose to the IRB in between annual financial disclosures.
How do you educate faculty on policies and changes? How are policies developed? Who is on committee?

IRB Staff:
- Is there a process to complain about the chair, PI, director, staff?
- Are staff members appropriately applying regulations? Are they overdoing it?
- Do you get support from their higher ups?
- What do you do day to day?
- Who oversees your work?
- Do you communicate directly with PI? With Reviewers?
- Are there additional regulations required for DOD-sponsored studies? (USC has provided policies to assure adherence to additional regulations for DOD studies in the form of a DOD FWA Addendum and Checklist). Know medical monitor and injury statement differences.
- How were you trained? Was it adequate? Is it ongoing? If so, how?
- What are the requirements for GCP training?
- How do you manage research records (such as documentation of telephone calls from PI or staff)
- How are meeting minutes generated?

IRB Student Mentor:
- Do you communicate directly with students? Faculty Advisors? Reviewers?
- Did you receive training as student mentor? As an IRB member?
- How were you initially trained? Was it adequate? Is it ongoing? If so, how is education provided to you/other members?
- Is member conflict of interest addressed at IRB meeting? (leaving room, abstaining from vote)
- Do you feel noted/appreciated?
- Are your comments and questions heard at the IRB meetings?
- Additional regulations are required for DOD-sponsored studies. USC has provided policies to assure adherence to additional regulations for DOD studies in the form of a DOD Checklist (medical monitor, injury statement and scientific review)
- Describe your roles
- What is your role in the review process?
- What is the focus of your review?
- What do you do day to day?
- Who oversees your work?
- Where do you go with questions?

IRB Chair/Vice:
Use below per your role
- Both are expected to be conversant with emergency use with an investigational agent (know what FDA expects).
- FDA – emergency use of test article, patient has no alternative

Jan 2010 - 4
FDA – emergency room research - Emergency room research requires community consultation (50 part 42)

- How do you address emergency use?
- You are expected to do expedited reviews correctly (do you use a checklist as a guide), what is the criteria for approval?
- Do you have access to higher ups if PI is giving you trouble?
- Need to know criteria for approval.
- How do you manage meeting?
- Do you support education/training?
- Are you reviewing at an appropriate level?
- How does Chair manage meeting? Interaction w/PIs? Access to big docs? Supportive of training IRB staff and investigators?
- How do members/staff get trained?
- Is the vice chair a chair in training?
- What does your role involve?
- What do you do day to day?
- What is your role in policy making, researcher interactions (own), etc.?

**You may get regulatory questions!**
- What do you do if you suspect noncompliance with an angry PI?
- How do you stay educated and who do you educate?
- Describe your role as vice chair. (AAHRPP will nail you on when do you get consultants, what is VC expected to understand and do (look in P&PS))
- How do you handle investigator conflict of interest?
- How do you communicate with Chair, staff, reviewers, researchers?

**IRB Director:**
- Know the regulations.
- Where do you go with questions?
- Where do you go to complain about chair, staff?
- Describe how you manage staff, your function, how you are managed.
- Do PIs think you are overly bureaucratic? Is there an appropriate level of review?
- What about access to legal counsel?
- Describe interactions with OPRS?

**Office of Compliance / Legal Counsel:**
- How do you interact with the IRB?
- Do you ever review IRB work?
- What are the relationships and communication with the IRB?
- Do you get involved with noncompliance issues with IRB policies?
- How do you help with other legal issues and Contracts and Grants?

**Hospital / Institute / Centers (CEOs or Directors):**
- Know what the IRB is and what they do (protect subjects by reviewing projects)
- If a complaint from PI is received, what do you do? (Investigate it and uphold IRB and regulatory requirements.) CEO’s should discuss matter with IRB.
- Do you support the IRB, ethics/compliance?
- Do you set cultural tone, ethics, compliance, a “go to” person who is fair, balanced, redress, not jump to side of PIs?
- How does your hospital/institute/center oversee compliance?
Do you have an individual dedicated to research administration?
What does your research portfolio consist of?
How does your institute handle cutting edge ethical issues (such as fMRI or stem cell research, incidental findings)?
How does department sign-off on research occur (conflict of interest, budget resources, qualification, study merit)?
Do you conduct your own research?
Are projects in your center/institute funded? If so, are these primarily federal or industry funds?
Who primarily are subjects in studies in your hospital/institute/center and how are they recruited? How is equitable subject selection addressed? Are there extra protections for vulnerable populations?
Do you communicate with HSPP?
How do you identify and manage conflicts of interest within hospitals/institute/centers?

Marshall / Psychology Subject Pool:
How do you make sure students are not forced to participate?
Do they have the option to receive payment for participation instead of course credit?
Mention that minors are excluded, students have an alternative for getting course credit (like a short paper, not 50 pager), etc.
There is no conflict of interest for directing subject pool
Do you have written pool policy? Approved by whom?
What is research portfolio at Marshall? In Psychology department?

Executive Director OPRS:
How do you support HSPP and the various roles in it?
How do problems get handled?
How do you educate employees?
How do you build culture of compliance on campus?
Discuss support and resources.

Department Chairs
What is your role in supporting Human Subjects Protection Program?
What is your criteria for departmental sign off (iStar)?
Do you determine if investigators have adequate resources to conduct studies?
Do you conduct your own research?
When do you get involved with the IRB?
How do you keep informed of IRB policy changes?
How do you handle complaints from PIs? About PIs?
Do you communicate with HSPP?
How do you handle conflicts of interest? Yours? Staff?

Institutional Official (Organizational Official):
What is your role in supporting HSPP? Interactions with compliance office? IRB chairs? Resources?
Are IRB policies and changes approved by you?
How do you know what is going on in the IRB realm?
When do you intervene in the IRB?
How do you know resources are adequate?
How do you support the IRB? Assess situations?
How do you interact with your peers in other institutions on human subjects research issues?

**HRA / Contracts and Grant Officials:**
- Is grant management training required at your institution?
- How are your staff trained? What interactions do they have with HSPP?
- How do you routinely communicate with the IRB? How do you communicate to release money to study? To submit proposals to funding agencies?
- Who do you contact for questions regarding research policies?
- How do you assure consistency between contracts and IRB approved documents?
- How do you ensure funds are properly allocated (research vs. medicare)?
- Are policies the same across all grants? All contracts?

**General Human Subjects Terms and Concepts to be Familiar With:**
- Education (CITI/license/training/newsletters)
- Communication (staff/IRB members/OPRS/USC)
- Ongoing Training (CITI/monthly IRB meeting/newsletter/OPRS educational materials)
- Mentoring (peer/staff/faculty advisor/prior IRB member)
- Handling Complaints (subjects/staff/research assistants/IRB/Compliance Office)
- IRB Policies, Procedures, Regulations (where to find them?/availability)
- What is your role in Human Subjects?
- Vulnerable populations (prisoners/children/pregnant women/neonates/others)
- Risks (how determined/greater than minimal)
- Backgrounds and how did you get involved with HSSP?
- Reportable events (study staff reporting/IRB discussion/Adverse Events/Compliance/Unanticipated Events)
- Problems in study (how handled)
- Orientation (was it provided?)
- Resolving controversial issues/problem protocols (what is your experience?)
- Levels of IRB review
- Informed consent (concepts/importance/practice)
- IRB Approval criteria
- Where do you go for information specific to a project? Regarding general ethics?
- Regarding compliance issues?