

AAHRPP Site Visit Interview Preparation

University of Utah Institutional Review Board

OVERVIEW: ROLES OF IRB ADMINISTRATORS, COORDINATORS AND MANAGERS

Role of IRB Coordinators

1. Receive initial and ongoing education for the regulatory and ethical requirements for the conduct of human subject research.
2. Conduct pre-review of continuing review and amendment applications in a timely manner.
3. Have authority to make the following determinations on behalf of the IRB (this is part of the Coordinator's board member role):
 - a. Approval of expedited amendments
4. Communicate with investigators and study team members for the completion of revisions and other actions required by the IRB
5. Prepare convened IRB agendas and coordinate IRB meetings
6. Assign reviews to board members based upon expertise
7. Record and finalize minutes in a manner compliant with federal and local requirements
8. Promote a collaborative atmosphere with IRB members, IRB staff, as well as researchers and study team members.

Role of IRB Administrators

1. Receive initial and ongoing education for the regulatory and ethical requirements for the conduct of human subject research.
2. Conduct pre-review of new study, amendment, and report form applications in a timely manner.
3. Have authority to make the following determinations on behalf of the IRB (this is part of the Administrator's board member role):
 - a. Non-Human Subject Research
 - b. IRB Exemptions
 - c. Approval of expedited amendments
 - d. Not an Unanticipated Problem
 - e. Not Non-Compliance
 - f. Non-Compliance that is neither serious or continuing
4. Communicate with investigators and study team members for the completion of revisions and other actions required by the IRB.
5. Assign reviews to board members based upon expertise.
6. Record minutes in a manner compliant with federal and local requirements.
7. Conduct routine and for-cause audits for ensuring research compliance with federal and local requirements.
8. Promote a collaborative atmosphere with IRB members, IRB staff, as well as researchers and study team members.
9. Participate as a member of the IRB Executive Committee, which approves new and revised IRB SOPs.

Role of IRB Managers

1. Manage IRB Coordinators and oversee training and quality improvement efforts for these staff.
2. Oversee training of IRB board members.
3. Conduct reliance consultations, work with the lead investigator to officially invite institutions to rely on the UUIRB for SIRB services, and work to ensure appropriate agreements are in place.

The Purpose of Pre-Review

The efficiency and effectiveness of the IRB is supported by administrative procedures that ensure that IRB members not only have adequate time for thorough assessment of each proposed study, but that the

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documentation they receive is complete and clear enough to allow for an adequate assessment of study design, procedures, and conditions. Results of pre-review, such as the IRB Internal Checklist and pre-board revision letters, are available to board members.