AAHRPP Site Visit Interview Preparation

University of Utah Institutional Review Board

OVERVIEW: ROLES OF IRB ADMINISTRATORS

Role of IRB Administrators

Administrators are not responsible for all duties listed and are generally limited to the scope of the team which they are assigned.

- 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, continuing review, 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. Makes determinations for research exempt from IRB review.
- 5. Serves as an IRB member who conducts expedited review.
- 6. Oversees the process for reliance on external IRBs including the execution and implementation of reliance agreements, and provision of local context information to the reviewing IRB.
- 7. Oversees working with external organizations who rely on the University of Utah IRB including the execution and implementation of reliance agreements and the process for collection of information relevant to IRB review from relying institutions.
- Communicate with investigators and study team members for the completion of revisions and other actions required by the IRB.
- 9. For board team administrators, prepare convened IRB agendas and coordinate IRB meetings.
- 10. Assign reviews to board members based upon expertise.
- 11. Oversees or conducts the training of IRB chairs, members, and staff.
- 12. Writes minutes for convened IRB meetings.
- 13. Promote a collaborative atmosphere with IRB members, IRB staff, as well as researchers and study team members.
- 14. Participate as a member of the IRB Executive Committee, which approves new and revised IRB SOPs.
- 15. Conduct routine and for-cause audits for ensuring research compliance with federal and local requirements.
- 16. Facilitate and engage in quality assurance and quality improvement efforts.

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 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.