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What am I agreeing to do when I become a Principal Investigator on a JHSPH IRB protocol?

The Principal Investigator (PI) on a JHSPH IRB protocol is responsible for every aspect of the human subjects research project, from ensuring the quality and appropriateness of the scientific design through overseeing the actual implementation of the study procedures, to ensuring data integrity and the validity of the findings. The PI must have the scientific expertise to oversee the design and execution of a project in the specific research area, and sufficient human subjects research experience to protect participants. Adequate PI oversight includes:

- Assuming full responsibility for the study as its leader, and monitoring day-to-day management of the study to ensure that the study is proceeding according to the IRB-approved protocol;
- Being knowledgeable about the technical aspects of the study topic and methods;
- Developing adequate standard operating procedures for study staff to follow; and
- Establishing good lines of communication among all staff and collaborators to ensure adherence to the protocol and to protect participants.

All JHSPH investigators are expected to protect the rights and welfare of all study participants, follow the IRB-approved research plan without implementing any changes to the protocol without prior IRB approval (except where IRB policies permit), and comply with federal, state, international, or local laws applicable to the site of the research.

The research protocol is detailed in the IRB application. The application includes a management and oversight plan for implementing the study procedures and assuring compliance with the approved plan. The challenges associated with oversight vary depending upon the particular characteristics and procedures of the study, including the nature and magnitude of risk, the study's procedural complexity, and its location.

The adequacy of the oversight plan depends on the various factors which increase or decrease the possibility of noncompliance, harm to participants, and threats to data integrity and security. In general, there is no substitute for physical oversight by the PI to ensure appropriate study implementation and adherence to protocols. However, there are situations when oversight can be adequately provided remotely using well-developed channels of communication, monitoring and evaluation, particularly when there is clear delegation of duties to experienced co-investigators. Monitoring study operation may include the use of periodic audits of executed consent forms and research instruments submitted via email, videotaping of study procedures, and other methods of remote supervision.

Optimizing PI oversight is an often challenging but critical component in supervision of doctoral research, particularly in those situations in which the student's project is not integrated within the PIs own research agenda or existing projects. The design and implementation of an independent research project is a key element of doctoral training and integral to the academic process. However, because students are not agents of the university, the role of PI on IRB protocols is limited to faculty members in part because the liability for any non-compliance falls on JHSPH and its faculty. Thus, the advising faculty member who serves as PI ultimately bears responsibility for the conduct of the study. An appropriate oversight plan should be based on the specific characteristics of the research project and experience and capabilities of the faculty advisor/PI and student.

The IRB may determine, as part of its review and approval process for the application, that a proposed oversight plan which does not include PI visits to the study site is inadequate because the PI's physical absence adversely affects compliance to the study protocol or increases the potential for harm to human subjects. Requirements for a PI's physical presence at the research site will depend upon the nature, character, and magnitude of study-related risks to participants, including physical, psychological, social, legal, and financial risks. Factors that may exacerbate or mitigate such risks include the complexity of the study protocol and the qualifications and experience of the on-site personnel. For IRB applications that do not include PI presence as part of the oversight plan, but for which the IRB determines that PI presence or visitation is warranted, the IRB will explain why such an increased level of oversight is necessary to correct potential areas of threat to research participants or maintain adherence to the approved study protocol.