PROVIDING IT EXPERTISE TO THE IRB

By the Emerging Technologies, Ethics, and Research Data Subcommittee of Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

The use of technologically interconnected products and services continues to revolutionize the design and conduct of research. These technological innovations raise important legal, regulatory, and ethical questions for researchers and institutional review boards (IRB) alike. Among them, do IRBs and researchers understand how information is collected, used, and stored in sufficient detail to protect human research subjects? Can IRBs and researchers assure patients that uses of technology conform to promises or assurances made during the informed consent process? IRBs and researchers need to fully understand how new technologies work to enable reasonable assessments of risks to research data and implementation of data protection safeguards to eliminate, mitigate, or reduce these risks. The incorporation of Information Technology (IT) expertise onto IRBs is one way to help ensure the appropriate evaluation of the safety and potential risks of the technology being utilized to conduct research.

Guide to Onboarding:

1. Initial Conversation: IT member reaches out to IRB with interest, or vice versa. IT member is informed on what it means to be part of an IRB.

2. Expectations
   - How often are meetings?
   - When do they occur?
   - Is my attendance required for all meetings?
   - How far in advance are meeting materials provided for review?
   - How are you expected to prepare for the meeting?
   - What does it mean to be a primary and/or secondary reviewer?
   - What happens during a meeting?
   - Is there a trial attendance?
   - Is there a follow up conversation post attendance? What questions do you have? This should remain an open dialogue, as items will come up over time that the member will want to ask clarification on.
   - What is the decision process to make IT rep an official IRB member?
   - Is there performance evaluation as a member?

3. Organizational/Institutional Training Resources
   - Ethical Principals
     - CITI, NIH, etc.
   - The Belmont Report, Federal Regulations (key terms)
     - Common Rule 45 CFR 46
     - FDA
   - Other federal agencies
   - Electronic platform (or system)
   - In-house training/orientation/mentoring
Case studies
- A Study Involving Multiple Institutions, a Company, and CMS Data
- Managing Data Security with Local and Institutional Partners
- Research Data Loss Incident

Attend an IRB meeting to observe/trial attendance
- Harvard Catalyst IRB Visiting Program

Questions? Email Harvard Catalyst’s Regulatory Foundations, Ethics, and Law Program

4. What makes an IT member perspective “special”
- Researchers increasingly turn to vendor products and technology to enable their work. IT is in a unique position to inform IRBs of the risks introduced by that use.
- Researchers may use social media for recruitment or communication during a study. IT is in a unique position to evaluate privacy and confidentiality issues of social media use.
- IT membership/consultation offers a valuable perspective in the overall review of the project to ensure criteria for IRB approval is met; making adequate provision for monitoring the data collected to ensure the safety of subjects and maintaining the confidentiality of data.

Ancillary Review
- Ancillary review allows individuals, departments, offices, and other additional reviewers to give feedback, approval, and/or provide documentation on the submission in parallel with the IRB review. Ancillary review can also serve to satisfy institutional policies where IT sign off is required. This additional review could be formalized as part of the IRB review process, or the IRB could reach out to IT personnel on a consultant basis when their expertise is needed.
Resources and References

1. Articles:
   - Variety of strategies needed to educate IRB members & chairs:

2. PRIM&R
   - https://www.primr.org

3. Updates to the Common Rule: