

# Multi-Grantee Technical Assistance Meeting— Institutional Review Boards: Challenges and Best Practices

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**HEALTH IT**

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# Chapter 1. Background

A critical milestone in the course of many health information technology (health IT) research projects is approval of the research study by an Institutional Review Board (IRB). With the recent consensus on the role of health IT to facilitate research and improve quality, there are increased requirements that health IT study designs obtain IRB approval.

The multi-grantee open forum addressed several key considerations related to working with IRBs, including: (1) different policies, procedures, infrastructure, and models (e-IRB versus in-person) present within different institutional and community settings, (2) common challenges and issues that may arise during the application and approval process, (3) methods to mitigate challenging issues, and (4) best practices for successful IRB review. The Webinar provided a venue to inform, educate, and support grantees to position them to complete the IRB approval process in a timely manner.

Presenters for the Webinar included the following subject matter experts, both internal and external to AHRQ:

- David Lobach, M.D., Ph.D., M.S.; Duke University Medical Center— *Dealing with the IRB for Health Information Technology Trials: Real World Experience*
- Margaret McDonald, M.S.W.; Center for Home Care Policy and Research, Visiting Nurse Service of NY— *Perspective of a Former IRB Administrator and Current Researcher in a Community Setting*
- Nancy Moody, J.D., M.A.; Human Research Protection Program, Geisinger Health System— *Policies, Procedures, Infrastructure, and IRB models*
- Patrick McNeilly, Ph.D., R.Ph., C.I.P.; AHRQ— *How AHRQ Can Help Support Research Involving Human Subjects*

## Chapter 2. Meeting Summary

This section provides an overview of each presenter’s materials and concludes with a recap of questions asked during the presentations.

### Dealing With the IRB for Health Information Technology Trials: Real World Experience

*David Lobach, M.D., Ph.D., M.S.*

Dr. Lobach presented two case studies highlighting the challenges researchers face in academic and clinical study settings. In the first case study, IRB approval took more than 9 months because of the unfamiliarity of the IRB officials with the nature of health IT study issues. IRB approval in the second case study took only 2 months, in part because the researchers incorporated effective, IRB-approved approaches for gaining participant consent that they found in similar studies in the literature. Citation of these similar studies helped inform and educate the IRB officials, resulting in expedited approval.

Dr. Lobach made several observations and outlined several lessons learned about health IT research:

| Observations  |
|---|
| <ul style="list-style-type: none"><li>• Health IT studies are different from pharmacotherapy trials, which are often more familiar to IRBs; health IT typically provides information as the intervention—nothing more (i.e., does not involve pharmaceuticals/drugs).</li><li>• Providers are often the target of health IT studies, even though the intervention occurs through the patients, which can make communicating the study design to the IRB more complex.</li><li>• The goals of the studies are the same as those of the IRB (e.g., subject safety, security, privacy), and this should be communicated to the IRB.</li><li>• There is a growing understanding among IRBs of the particular needs and issues of health IT research studies.</li><li>• Providers are often the target of health IT studies, even though the intervention occurs through the patients, which can make communicating the study design to the IRB more complex.</li><li>• The goals of the studies are the same as those of the IRB (e.g., subject safety, security, privacy), and this should be communicated to the IRB.</li></ul> |

### Lessons Learned

- Understand the mindset of IRB Chairs to include Identifying which IRB Chairs are more familiar than others with health IT evaluation studies.
- Always ensure that subjects' rights are not violated when developing the study design.
- Discuss issues directly with IRB Chairs rather than simply submitting paperwork.
- Identify those with whom you can work well in your institution's IRB.
- Identify precedents in published studies that can be included; this will make approval much more acceptable to IRB Chair.
- Be persistent and patient—reviewers may not always be familiar with health IT study issues and approaches, which can lengthen the review process
- Become familiar with 45 Code of Federal Rules (CFR) rules regarding consent and the Health Insurance Portability and Accountability Act (HIPAA)
  - 45 CFR 46.116(d)—Waiver or Alteration of Consent: Legitimate ways to not consent subjects
  - 45 CFR 164.512(i)(2)—Waiver or Alteration of HIPAA Authorization

## Perspective of a Former IRB Administrator and Current Researcher in a Community Setting

***Margaret McDonald, M.S.W.***

Challenges encountered by IRBs in community settings include (1) investigators resist following required protocol and submitting other forms as specifically requested by community organizations; (2) researchers do not provide enough detail about how the study will actually be performed; and (3) the proposed research lacks specificity regarding how study subjects will be identified, approached, and recruited (which is the focus of the IRB). In the community setting, researchers must be careful to ensure that consent forms are appropriate for, and tailored to, the target population. Researchers should avoid complicated consent forms.

Ms. McDonald made several suggestions regarding working effectively with IRBs:

- Create study protocols in operating manual format so IRB members can clearly understand what will actually be happening.
- Address the heightened concern regarding confidentiality and use of electronic files.
- Become knowledgeable about different ways your organization can protect data, i.e., encryption, firewalls, and so on; provide a full explanation of these measures in the protocol.
- Remember that many IRB members are non-researchers and may need to be educated on research matters, especially health IT issues.

- Offer to attend IRB meetings to review protocols and provide clarification and answers to questions early in the process.
- Make sure the IRB knows that you have anticipated what might happen in the study; have alternative strategies and solutions in place.

Ms. McDonald suggested that researchers could become IRB members at some point, that they should learn more about the IRB process, and that they should educate IRB members on research matters.

## **Policies, Procedures, Infrastructure, and IRB Models: “Insider Information on the IRB Process”**

***Nancy Moody, J.D., M.A.***

IRBs are very diligent about meeting guidelines for both “waiver of consent” and HIPAA. Researchers should become well versed in the specific policies and procedures of their IRBs.

Ms. Moody outlined several key IRB policies:

- *Exempt research involving human subjects.* Human subject research is broadly defined as research using specimens/data that are individually identifiable and obtained through interaction or intervention with living individuals. Researchers do not have the authority to make independent determinations about whether or not research involving human subjects is exempt. The IRB makes this determination. If research is exempt (i.e., does not meet the definition of human subject research), a full-board IRB review is not required.
- *Honest Broker.* If a study contains protected patient data, the research team may use an “honest broker” to pull the data, strip all patient identifiers, and assign code numbers. A research team never sees patient identifiers; therefore, the researchers can declare that no one on the study team will receive patient-identifying data.
- *Requests for a Waiver.* Waivers may be used when there is minimal risk to subjects and the research could not be practicably carried out without the waiver. To obtain a HIPAA waiver, researchers must address Department of Health and Human Services (HHS) regulations and HIPAA guidelines (see CFR paragraphs cited by Dr. Lobach).
- *Use of de-identified data.* For data to be considered de-identified data, HIPAA requires removal of 19 identifying elements (see below). Researchers should review their institution/organization’s IRB Web site to understand the requirements for specific data elements.

| Nineteen Identifying Data Elements   |  |
|--|--|
| <ul style="list-style-type: none"> <li>• Names</li> <li>• Geographic subdivisions smaller than a state (i.e., no city, no ZIP code), except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census, the geographic unit contains more than 20,000 people</li> <li>• Any date (except year; i.e., no month or day of month)</li> <li>• For subjects older than 89 years of age, specific age may not be mentioned</li> <li>• Telephone number</li> <li>• Fax number</li> </ul> | <ul style="list-style-type: none"> <li>• E-mail address</li> <li>• Social security number</li> <li>• Medical record number</li> <li>• Health plan beneficiary number</li> <li>• Any other account numbers</li> <li>• Certificate or license numbers</li> <li>• Vehicle identification number</li> <li>• Medical device identification or serial number</li> <li>• Personal Web site URL</li> <li>• Internet protocol (IP) address</li> <li>• Fingerprint, voiceprint, or other biometric identifiers</li> <li>• Full-face photographic images</li> <li>• Any other unique identifying number, characteristic, or code</li> </ul> |

Electronic IRB submission (e-IRB) is becoming more common, especially in academic settings. This approach streamlines the entire application and review process through standardization of the IRB processes. Researchers can usually check the status of their e-IRB application at any point, and the time for IRB approval is often shortened.

## How AHRQ Can Help Support Research Involving Human Subjects: “HIT and IRBs: Some AHRQ Perspectives”

*Patrick McNeilly, Ph.D., R.Ph., C.I.P.*

AHRQ provides excellent support for researchers involved in the IRB approval process. Dr. McNeilly noted that not all research requires IRB review. The Federal Office for Human Research Protections (OHRP) requires that researchers conduct federally funded human subject’s research only at facilities covered by a Federal Wide Assurance (FWA). The FWA document designates the IRB that will review and oversee the research, specifies the ethical principles under which the research will be conducted, and names the individuals who will be responsible for the proper conduct of the research. An FWA is required whenever one of the following conditions is met:

- The research is funded by a grant from the Federal Government.
- The federally supported research is not exempt from IRB oversight.
- Employees or agents of the site are engaged in the federally supported research.

Because of the complex nature of research studies, researchers should contact their IRBs to determine whether their activities make them “engaged” in research and whether IRB approval is needed for their study. Dr. McNeilly noted that secondary data analysis is often exempt.

Dr. McNeilly identified three areas of research that present *new* challenges to IRBs: personalized health care, genetic information, and personal electronic health records (EHR). Each of these areas has unique ethical issues; researchers who are involved in studies dealing with these areas should expect many questions from their IRBs.

The following resources can assist grantees with IRB issues:

- Available at: U.S. Department of Health and Human Services. Office for Human Research Protections. <http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>. Accessed September 15, 2010.
- Available at: U.S. Department of Health and Human Services. HHS/Office for Civil Rights. <http://www.hhs.gov/ocr/office/index.html>. Accessed September 15, 2010.
- Bankert EA, Amdur RJ. Institutional review board: management and function. 2nd edition. Sudbury: Jones and Bartlett Publishers; 2006.
- Available at: Agency for Healthcare Research and Quality. Protection of Human Subjects in Research. <http://www.ahrq.gov/fund/hsubjects.htm>. Accessed September 15, 2010.  
Available at: Agency for Healthcare Research and Quality. The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research. <http://www.ahrq.gov/fund/informedconsent/ictoolkit1.htm>. Accessed September 15, 2010.

## Chapter 3. Questions and Answers

An attendee raised a question about the way patient consent issues are addressed in the AHRQ application and review process. AHRQ responded by noting that the grant applications are reviewed by peers conducting similar studies. When peer reviewers raise concerns, applicants often receive follow-up questions for response and clarification.

Another attendee asked about the use of “commercial IRBs.” In response to the question, AHRQ noted that commercial IRBs are acceptable alternatives to academic IRBs, although they tend to be more expensive and often focus on pharmaceutical studies. Researchers should expect similar questions from all IRBs.

A researcher asked about how to deal with multiple IRBs when research is conducted at multiple academic institutions. Suggestions from panelists included developing an informational packet for the other organizations’ IRBs and ceding authority to another IRB if the principal investigator is located at another organization. Panelists noted that other organizations may not be willing to take on the responsibility for the IRB approval process because of concerns about institutional liability.