



# AHRQ NRC Technical Assistance Topic Summary

## Institutional Review Boards (IRBs) and Health IT Research

### **Background**

A critical milestone in the course of many health services research projects is approval of the study protocols by an Institutional Review Board (IRB). This summary provides an overview of challenges and best practices for obtaining IRB approval specifically for health IT-based study designs.

### **What Is an Institutional Review Board (IRB)?**

An IRB is a board that reviews research involving humans as subjects. IRBs can approve, require modification to, or disapprove research activities covered by the HHS and FDA Protection of Human Subjects Regulations. In addition, IRBs must periodically review these research studies and protocols.

### **Key Definitions**

- ▶ **“Code of Federal Regulations (CFR) Title 45 Part 46 (45 CFR 46)”**
  - Defines “research” and “human subjects” and describes special procedures for “vulnerable populations”
  - Describes what needs to be reviewed and approved; what can be exempted from review, OR reviewed and exempted from further review; and what does NOT need review
  - Describes requirements for obtaining informed consent and requirements for waiving consent or its documentation
  - Mandates the existence of an IRB and specifies its composition and structure
- ▶ **“De-identified data”** requires the removal of 19 identifying elements by HIPAA (e.g., names, telephone numbers, social security numbers, fingerprints, and so on). Researchers should review their organization’s IRB Web site to understand the requirements for specific data elements.
- ▶ **“Human Subject”** is a “living individual about whom an investigator conducting research obtains
  - (1) data through intervention or interaction with the individual, or

- (2) identifiable private information” [45 CFR 46.102(f)]

- ▶ **“Research”** is “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” [45 CFR 46.102(d)]
- ▶ **“Waiver or Alteration of Consent or HIPAA authorization”** requires that the research study poses no greater than minimal risk to subjects and the privacy of subjects, will not adversely affect the rights and welfare of subjects, could not practicably be carried out without waiver or alteration. [45CFR46.116(d)] and [45CFR164.512(i)(2)]

### **Key Observations on Conducting Health IT Research**

The unfamiliarity of IRB officials with the nature of health IT study issues can lead to extended IRB review times. However, there is a growing understanding of the particular needs and issues of health IT research studies. In addition, electronic IRB submissions (e-IRB) are becoming more common. This approach streamlines the application and review process and the time for IRB approval is often shortened.

Below are some key observations from AHRQ staff and Health IT Grantees on the IRB process:

- ▶ Remember that health IT studies are different from pharmacotherapy trials, which are often more familiar to IRBs
- ▶ Understand the mindset of IRB chairs and those that are more familiar with health IT evaluation studies
- ▶ Discuss issues directly with IRB chairs rather than simply submitting paperwork
- ▶ Be persistent and patient—reviewers may not always be familiar with health IT study issues and approaches, which can lengthen the review process
- ▶ Understand that 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

- ▶ Communicate to the IRB that the goals of the studies are the same as those of the IRB (e.g., subject safety, security, privacy)

### **Best Practices**

- ▶ Become familiar with 45 Code of Federal Rules (CFR) rules regarding consent and the Health Insurance Portability and Accountability Act (HIPAA)
- ▶ Ensure that subjects' rights are not violated when developing the study design
- ▶ Identify those with whom you can work well in your institution's IRB
- ▶ Work with Agency staff on methodology prior to IRB submission
- ▶ Identify precedents in published studies that can be included; this will make approval much more acceptable to IRB chair
- ▶ Modify protocol and prepare forms as requested by the community agency or work with IRB coordinator on alternative approaches

### **Key Challenges and Possible Solutions**

- ▶ *Interacting with IRB members, many of whom are nonresearchers*
  - Create protocol with primary focus on the involvement of study subjects instead of submitting grant proposal
  - Become an IRB member
  - Offer to attend IRB meeting to review protocol
- ▶ *Providing a good explanation of the clinician-vs. patient-level intervention*
  - Review the issue with the IRB chair and administrator
  - Repeat study subject of interest throughout the protocol
  - Clarify patient involvement as separate to a clinician intervention
- ▶ *Being clear about data being requested for approval under a Waiver of Authorization and data a consent form may cover*
  - Determine what is allowed under your organization's patient notice of privacy practices
  - Do not reinvent –if others received a Waiver approval look at request and wording and see if it can apply to your study protocol
- ▶ *Addressing heightened concern over confidentiality and use of electronic files*
  - Become knowledgeable about the different ways data can be protected within your organization and apply to study procedures as appropriate (e.g.,

encryption, firewalls, limited access or password protections, and time de-identification occurs)

- Provide a clear and complete explanation in the IRB protocol

- ▶ *Three areas of research present new challenges to IRBs because of their unique ethical issues: Personalized health care, genetic information, and personal electronic health records (EHRs).*

### **Questions**

- ▶ *How are patient consent issues addressed in the AHRQ application and review process?*
  - Peers conducting similar studies review grant applications. When peer reviewers raise concerns, applicants often receive followup questions for response and clarification.
- ▶ *Are there special considerations when using 'commercial IRBs'?*
  - 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
- ▶ *Is there a best practice for dealing with multiple IRBs when research is conducted at multiple academic institutions?*
  - Suggestions 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. In addition, organizations may not be willing to take on the responsibility for the IRB approval process because of concerns about institutional liability.

### **Resources**

- ▶ [HHS Office for Human Research Protections](#)
- ▶ [OHRP IRB Guidebook by Topic](#)
- ▶ [Protection of Human Subjects in Research](#)
- ▶ [The AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research](#)
- ▶ [Office for Civil Rights \(OCR\)](#)
- ▶ [HIPAA Privacy Rule](#)
- ▶ [HHS Guidance](#)
- ▶ [The Belmont Report](#)
- ▶ [World Medical Association Declaration of Helsinki](#)
- ▶ Bankert EA, Amdur RJ. Institutional review board: management and function. 2nd edition. Sudbury: Jones and Bartlett Publishers; 2006.

### **About the Multi-Grantee Technical Assistance Webinar**

The information included in this summary was generated from a TA Webinar, held on January 27, 2010, which addressed several key considerations related to working with IRBs, including:

- ▶ Different policies, procedures, infrastructure, and models (e-IRB versus in-person) present within different institutional and community settings
- ▶ Common challenges and issues that may arise during the application and approval process
- ▶ Methods to mitigate challenging issues
- ▶ 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:
  - David Lobach, M.D., Ph.D., M.S.
  - Margaret McDonald, M.S.W.
  - Nancy Moody, J.D., M.A.
  - Patrick McNeilly, Ph.D., R.Ph., C.I.P.

#### **Sources**

- ▶ Multi-Grantee Technical Assistance Webinar: Institutional Review Boards: Challenges and Best Practices. January 27, 2010.
  - Presentation Slides ([PDF](#), 4.43 MB)
  - Discussion Summary ([PDF](#), 190 KB)
- ▶ [Department of Health and Human Services Office for Human Research Protections \(OHRP\) Regulations](#)
- ▶ [Code of Federal Regulations \(CFR\) Title 45 Part 46 \(45 CFR 46\)](#)

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#### **About the National Resource Center for Health IT (NRC)**

AHRQ's health information technology (health IT) initiative is part of the Nation's strategy to put information technology to work in health care. By developing secure and private electronic health records for most Americans and making health information available electronically when and where it is needed, health IT can improve the quality of care, even as it makes health care more cost-effective.

The broad mission of AHRQ's health IT initiative is to improve the quality of health care for all Americans. The Agency has focused its health IT activities on the following three goals:

- ▶ Improve health care decisionmaking.
- ▶ Support patient-centered care.
- ▶ Improve the quality and safety of medication management.

**For additional information on AHRQ's health IT initiative, [sign up for e-mail updates or subscribe](#) to AHRQ's free monthly Patient Safety and Health Information Technology E-newsletter.**

#### **About the AHRQ Technical Assistance (TA) to Health IT Grantees Program**

The Agency for Healthcare Research and Quality (AHRQ) provides technical assistance (TA) to health IT grantees to help them achieve their research and grant objectives and disseminate their findings to advance the field. AHRQ's TA program develops and provides a wide range of resources and tools to assist grantees in completing their projects on-time to ensure the timely sharing of new findings that can transform clinical practice.

AHRQ's TA Program provides a range of resources, including:

- ▶ General TA provided through a series of Webinars and workshops
- ▶ Communication between grantees through the Listserv
- ▶ Pairing individual grantees with subject matter experts
- ▶ Dissemination of materials based on the Webinars

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#### **Contact Information:**

More information about the NRC is available at [healthit.ahrq.gov](http://healthit.ahrq.gov). Please contact the AHRQ NRC at [NRC-HealthIT@ahrq.hhs.gov](mailto:NRC-HealthIT@ahrq.hhs.gov)

#### **For Technical Assistance, please contact:**

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