



# Institutional Review Boards: Challenges and Best Practices

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January 27, 2010  
Multi-Grantee Open Forum #2

*AHRQ National Resource Center for Health IT*



# Agenda

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- Welcome and overview of AHRQ Technical Assistance
  - Barbara Lund, AHRQ NRC TA Lead, Massachusetts eHealth Collaborative
  - Vera Rosenthal, AHRQ NRC, Junior Service Fellow
- Format for today's session
- Presentations
  - Margo Edmunds, Facilitator
- Discussion



# Overview of AHRQ Technical Assistance

- Goal: To support grantees in the meaningful progress and on-time completion of Health IT-funded grant projects
- Technical Assistance (TA) services include
  - One-on-one grantee technical assistance
  - Multi-grantee open forum technical assistance
  - Frequently Asked Questions posted on the AHRQ Health IT site
- Multi-grantee open forums
  - Webinars focused on topics of interest for groups of grantees
  - Format includes presentations by subject matter experts, peers and peer-to-peer discussion
  - We welcome your ideas for future webinars



# Key Resources

- AHRQ National Resource Center for Health IT
  - [www.healthit.ahrq.gov](http://www.healthit.ahrq.gov)
- AHRQ Points of Contact
  - Vera Rosenthal, [vera.rosenthal@ahrq.hhs.gov](mailto:vera.rosenthal@ahrq.hhs.gov)
  - Rebecca Roper, [rebecca.roper@ahrq.hhs.gov](mailto:rebecca.roper@ahrq.hhs.gov)
- AHRQ NRC TA Team
  - Erin Grant, Booz Allen Hamilton, [grant\\_erin@bah.com](mailto:grant_erin@bah.com)
  - Margo Edmunds, Booz Allen Hamilton, [edmunds\\_margo@bah.com](mailto:edmunds_margo@bah.com)
  - Barbara Lund, Massachusetts eHealth Collaborative, [NRC-TechAssist@AHRQ.hhs.gov](mailto:NRC-TechAssist@AHRQ.hhs.gov)
  - Jessica Kriss, Booz Allen Hamilton, [kriss\\_jessica@bah.com](mailto:kriss_jessica@bah.com)
- AHRQ NRC Monitoring and Reporting Team: John Snow Inc.



# Format for Today's Session

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- Please mute your phone line during the presentation
  - Press \*6 to mute; \* 7 to un-mute
- Questions and discussion
  - Clarifying questions are welcome after each presentation – remember to un-mute your line
  - Discussion among attendees and presenters following completion of all presentations
  - Questions may also be submitted to the Chairperson at any time via 'Chat' feature on webinar console
- Discussion summary will be developed and distributed to attendees
- Formal, brief evaluation requested from each attendee
  - sent directly from ReadyTalk at conclusion of webinar



# Today's Presentation

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## Institutional Review Boards: Challenges and Best Practices

Margo Edmunds, PhD  
Booz Allen Hamilton



# Meet Today's Panelists

- **David Lobach, MD, PhD, MS**, Duke University Medical Center
  - *The IRB Approval Process: a View from the Trenches (Academic Settings)*
- **Margaret McDonald, MSW**, Center for Home Care Policy and Research, Visiting Nurse Service of NY
  - *The IRB Approval Process: a View from the Trenches (Community Settings)*
- **Nancy Moody, JD, MA**, Human Research Protection Program, Geisinger Health System
  - *Policies, procedures, infrastructure, and IRB models*
- **Patrick McNeilly, PhD, RPh, CIP, AHRQ**
  - *How AHRQ can help support research involving human subjects*



# Today's Objectives

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- How to effectively navigate the IRB approval process
- “Views from the trenches”: differences between academic, clinical and community research settings
- Unique IRB challenges for Health IT researchers
- Understanding IRB exemptions



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

David F. Lobach, MD, PhD, MS  
Duke University School of Medicine



Duke University

# Overview

- Case Histories
  - HIT Value
  - HIT Medication Management
- Rule Awareness
  - 45CFR46.116(d) – Consent Alteration/Waiver
  - 45CFR164.512(i)(2) – HIPAA
- Observations about HIT Evaluation Studies
- Lessons Learned & Words of Advice

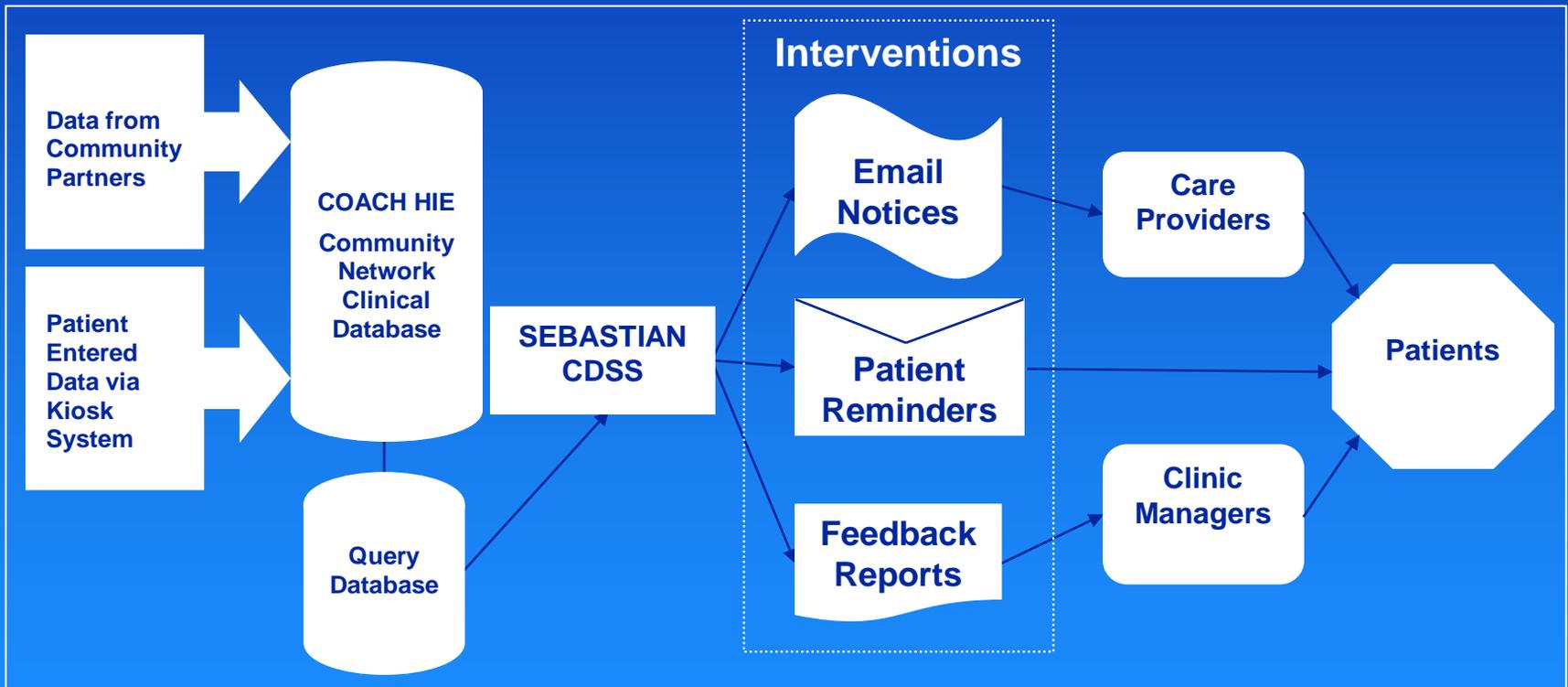
# Case History #1

- AHRQ-funded project on HIT Value
- Send notices to care managers via email, clinic administrators via printed reports, and patients via letters about sentinel care issues related to care coordination or quality
- Provide information about hospitalizations, ED utilization, missed appointments, or HEDIS metrics
- Report delivery began August 2006

# Case History #1 (cont)

- 12-month randomized controlled trial
- 4-arm study involving 22,180 subjects
  - Usual care
  - Email notices to care managers
  - Feedback reports to clinic administrators
  - Letters to patients
- Primary outcome measure: ED utilization

# Population Health Management



# Case History #1 IRB

- Department reviewer
  - Insisted on signed informed consent
  - Refused to sign off on protocol
- Appeal to IRB Chair
  - Several phone calls
  - Numerous emails and written explanations
  - Involved Department Chair
  - 9 months to get IRB approval

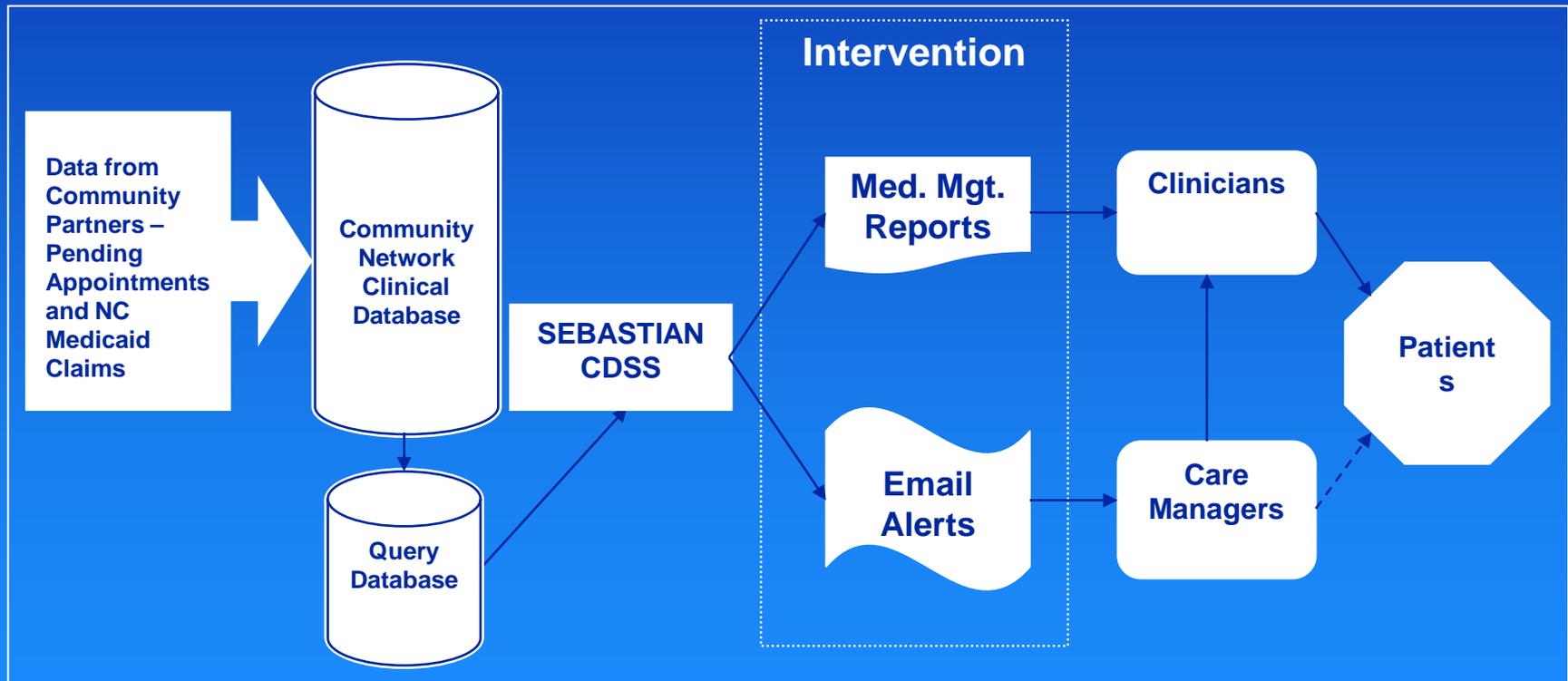
# Case History #2

- Send point-of-care reports about filled prescriptions to 14 clinic sites
- Provide evidence-based pharmacotherapy recommendations about 6 priority conditions (IHD, CHF, Htn, Stroke, Persistent Asthma, Diabetes)
- Email notifications to care managers
- Report delivery began August 2009

# Case History #2 (cont)

- 12-month randomized controlled trial
- 3-arm study on 4,600 subjects
  - Usual care
  - Med. mgt. reports
  - Med. mgt. report + notices to care managers
- Primary outcome measure: adherence to EB pharmacotherapy guidelines

# Intervention Overview



# Case History #2 IRB

- Found similar studies in the literature
- Contacted IRB while writing application
  - Agreed on patient opt out letters
  - Agreed to consent providers
- Submitted IRB protocol
  - Requested waiver of consent
  - Requested waiver of HIPAA authorization
  - Expedited review
  - Approval in 2 months

# 45CFR46.116(d)

- Waiver or alteration of consent
- Requires:
  - No greater than minimal risk to subjects
  - Will not adversely affect rights and welfare of subjects
  - Minimal risk to privacy of subjects
  - Could not practicably be carried out without waiver or alteration

# 45CFR164.512(i)(2)

- Waiver or alteration of HIPAA authorization
- Requires
  - No greater than minimal risk to subjects
  - Will not adversely affect rights and welfare of subjects
  - Minimal risk to privacy of subjects
  - Could not practicably be carried out without waiver or alteration

# Observations

- HIT is not a drug
- HIT evaluation projects break the norms of pharmacotherapeutic trials
- HIT evaluations can easily involve thousands of subjects
- Target of interventions is often providers even though the outcomes may be measured at the level of the patient
- Our goals are the same as those of the IRB – subject safety, security and privacy
- Understanding of needs for HIT evaluations is growing

# Lessons Learned

- Understand the mindset of IRB chairs
- Discuss projects and issues with IRB chairs
- Identify whom you can work well with in the IRB at your institution
- Identify precedent setting studies from the literature
- Become familiar with 45CFR rules on consent and HIPAA
- Be persistent, be patient



# Questions?

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# **Institutional Review Boards: Perspective of a former IRB administrator and current researcher in a community setting**

Margaret McDonald, MSW  
Visiting Nurse Service of New York



# Challenges Encountered as an IRB Administrator in the Community Setting

- Resistance of investigators to submitting protocol and other forms as requested by the community organization
- Receiving protocols prematurely; investigators not understanding community setting
- Lack of specification on how study subjects (staff/patients) will be identified, approached and recruited
- Consent forms that are inappropriate to the targeted patient population



# Lessons to be learned

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- Modify protocol and prepare forms as requested by the community agency or work with IRB coordinator on alternative approaches
- Work with agency staff on methodology prior to IRB submission
- Be specific about the involvement of the study subjects at the community agency
- Complicated consent forms – describe the consenting process



# Researcher Perspective: IRB challenges and how they were addressed

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- Interacting with IRB members many of whom are non-researchers
- 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



# Researcher Perspective: IRB challenges and how they were addressed

- Providing a good explanation of the clinician- vs. patient- level intervention
  - Initially reviewing the issue with the IRB Chair and Administrator
  - Repeating study subject of interest throughout the protocol
  - Clarifying patient involvement as separate to a clinician intervention



# Researcher Perspective: IRB challenges and how they were addressed

- 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



# Researcher Perspective: IRB challenges and how they were addressed

- 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
    - Time de-identification occurs
  - Provide a clear and complete explanation in the IRB protocol



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Don't just try to get through  
the IRB process but try to  
improve it along the way



# Questions?

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# Insider Information on the IRB Process

Nancy Moody, JD, MA  
Geisinger Health System



# What is Human Subject Research: Can I Be Exempt?

- In order for research with human specimens or data to involve **human subjects**, The investigator EITHER is obtaining or obtained-

specimens or data through interaction or intervention with living individuals;

OR

individually identifiable health information.



## What are examples of research involving human specimens or data that would not be considered human subjects research? EXEMPT RESEARCH

“Research involving the collection or study of **existing data**, documents, records, pathological specimens, or diagnostic specimens, if these sources are **publicly available** or if the information is recorded by the investigator in such a manner that **subjects cannot be identified, directly or through identifiers linked to the subjects.**” CFR [46.101\(b\)\(4\)](#)

if:

the specimens or data were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals;

**and**

the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the data or specimens pertain

# Honest Broker

- In the world of politics, an **honest broker** is a 'neutral mediator.' In the human research setting, the **honest broker** plays a similar role, serving as a disinterested intermediary between the researcher and the individual whose data are being studied.
- Identifiable information about the subject (data, specimens, etc.) may be gathered from several sources (if necessary) and collated by the **honest broker**, who then replaces identifiers with a code.
- The de-identified data, is then forwarded to the investigator.
- Only the **honest broker** can have access to the list that links the code number to the subject's identity.



# Requesting A Waiver

## Requests for waiver or alteration of the informed consent document.

- The research involves no more than **minimal risk** to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not **practicably** be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Caveat: Can not be FDA study – FDA does not have a waiver provision for informed consent process



# Obtaining HIPAA Authorization Waiver or Alterations

To approve a request for a waiver of HIPAA's authorization requirements, an IRB must determine that:

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
  - An adequate plan to protect the identifiers from improper use and disclosure;
  - Adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by the Privacy Rule.
  - The research could not practicably be conducted without the waiver or alteration.
  - The research could not practicably be conducted without access to and use of the PHI.



# Using Data that is De-Identified

- Researchers may use or disclose health information that is **de-identified without restriction** under the HIPAA Privacy Rule.
- Data is considered de-identified under HIPAA when none of the 19 elements are present.



# Anonymous

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- **Anonymous** - where a person's name and other personally identifying information is not known.
- **Note:** The data itself might seem anonymous, but when paired with other existing data, reidentification becomes possible.



# Limited Data Sets with a Data Use Agreement

A data use agreement entered into by both the covered entity and the researcher. A limited data set excludes specified direct identifiers of the individual.

The data use agreement must:

- Establish the uses and disclosures of the data by the recipient consistent with the purposes of the research;
- Limit who can use or receive the data; and
- Require the recipient to agree to the following:
  - Not to use or disclose the information other than as permitted by the agreement or as otherwise required by law;
  - Use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in the agreement;
  - Report to the researcher/institution any use or disclosure of the information not provided for by the data use agreement of which the recipient becomes aware;
  - Ensure that any agents, including a subcontractor, to whom the recipient provides the limited data set agrees to the same restrictions and conditions that apply to the recipient; and
  - Not to identify the information or contact the individual.



# e-IRB Submission

- *Seamless* - streamlines the entire application preparation and review process by enabling secure electronic collaboration among all key stakeholders; Routing time is instantaneous, and IRB members can view application status at any time regardless of their location
- *Communication* - automatic e-mail notifications; Check status at any point in time
- *Reliable Archive* - audit trails for all activities
- *Optimal Submission* - sends users to the right forms, prompts for missing information, provides help text and web links to answer reviewers' questions, and ensures completeness; system-generated completeness checks and error checking



# Questions?

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# HIT and IRBs: Some AHRQ Perspectives

Patrick McNeilly, PhD, CIP  
AHRQ



# Engagement in Research

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- Non-exempt human subjects research
- FWA required
- IRB review required??
- OHRP guidance

<http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html>



# Secondary Data Analysis

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- Doesn't mean the same to everyone
- Usually exempt but ...
- Coded  $\neq$  de-identified



# Issues for the future

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- Personalized healthcare
- Genetic information
- Personal electronic health records



# Personalized Healthcare

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- Genetic markers
- Direct-to-consumer marketing
- Risk analysis



# Genetic Information

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- Ultimate identifier
- Withdrawal from research
- Return of research results
- Validity of tests



# Personal EHR

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- Consent for research activities
- “Ownership” of data
- Representative sample?



# Questions?

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# Resources

- Office for Human Research Protections
  - Excellent site which provides guidance to individuals and institutions conducting HHS-supported human subject research
  - <http://www.hhs.gov/ohrp>
  
- HHS/Office for Civil Rights
  - Federal civil rights laws and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, together protect fundamental rights of nondiscrimination and privacy
  - <http://www.hhs.gov/ocr/office/index.html>
  
- “Institutional Review Board: Management and Function”, Elizabeth A. Bankert and Robert J. Amdur – 2nd edition © 2006 Jones and Bartlett Publishers, Sudbury MA



# Group Discussion

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- We welcome your questions and comments
- Be sure to un-mute your line before you speak (press \*7)



# Final Comments

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- Discussion Summary
  - Will be distributed to all webinar participants
- Evaluation Form
  - Will be sent to each participant directly from ReadyTalk at conclusion of webinar
  - We value your input
  - Thank you for joining us today!



# Panelist Bios (I)

## Margo Edmunds, PhD

Margo Edmunds, PhD, is a health policy researcher, strategy consultant, educator, and writer who began her clinical career in disease management at Johns Hopkins Hospital. Prior to joining Booz Allen Hamilton, Dr. Edmunds taught health policy and health communications at Johns Hopkins Bloomberg School of Public Health, where she introduced strategic communications approaches to policy research and analysis methods training and worked with researchers to disseminate policy-relevant research and clinical findings to policy makers, consumers, and the media. Dr. Edmunds' current work at Booz Allen Hamilton focuses on the use of health information and communications technology in healthcare and public health.

[edmunds\\_margo@bah.com](mailto:edmunds_margo@bah.com)

## David F. Lobach, MD, PhD, MS

David F. Lobach is an endocrinologist and internist in the Department of Community and Family Medicine at Duke University Medical Center. He is an associate professor and chief, Division of Clinical Informatics at Duke Medical School. Dr. Lobach has many published articles in the field of health IT. Dr. Lobach is an active AHRQ Health IT grantee. His current project is titled: Improving Care Transitions for Complex Patients through Decision Support.

[David.lobach@duke.edu](mailto:David.lobach@duke.edu)



# Panelist Bios (II)

## Margaret McDonald, MSW

Margaret McDonald is a Senior Research Manager at the Center for Home Care Policy and Research at the Visiting Nurse Service of NY. She joined the Center in 1998 and is involved in conducting research on the quality and outcomes of home health care. Ms. McDonald has worked with the Penny Feldman, the Principal Investigator of one of AHRQ Health IT grants, on several intervention projects. Their work has largely focused on developing and testing strategies that promote the use of evidence-based practices in the home health environment. Ms. McDonald was formerly an IRB Administrator and currently has primary responsibility of developing IRB protocols for the intervention projects that she manages.

[MMcDonal@VNSNY.org](mailto:MMcDonal@VNSNY.org)

## Nancy Moody, JD, MA

Nancy Moody is the Director of the Human Research Protection Program at Geisinger Health System. Ms. Moody manages the day-to-day operations of the Geisinger IRBs and contracted IRB services. Responsible for establishing, maintaining, and continually improving the policies, systems, and procedures for review, approval, and continuing oversight of the use of human subjects or their PHI by researchers affiliated with Geisinger. Responsible for ensuring Geisinger Health System's compliance with international, federal, state, and local rules and regulations and ethical principles regarding the use of human subjects in research, the use of PHI in research activities (HIPAA), and ensuring that research involving human is conducted in a manner which protects their safety, rights, and welfare. Ms. Moody also has extensive experience in other settings including universities and other healthcare systems.

[njmoody@geisinger.edu](mailto:njmoody@geisinger.edu)



# Panelist Bios (III)

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

Dr. McNeilly currently serves as the Human Protections Administrator for the Agency for Healthcare Research and Quality (AHRQ). He joined AHRQ in September 2007 and is responsible for ensuring compliance with regulations for protecting human subjects in AHRQ intramural and extramural activities. He is a registered pharmacist and was originally trained at the Rutgers University, College of Pharmacy and received his doctoral degree in medicinal chemistry from the University of Maryland, School of Pharmacy. Dr. McNeilly is a commissioned officer of the U.S. Public Health Service and has nearly 20 years Government experience. His assignments have included positions with the Office for Human Research Protections, the Food and Drug Administration, and the Office of the Assistant Secretary for Health within the U.S. Department of Health and Human Services.

[Patrick.McNeilly@AHRQ.hhs.gov](mailto:Patrick.McNeilly@AHRQ.hhs.gov)