

University of Utah

AAHRPP Site Visit Interview Preparation

What is AAHRPP?

- Association for Accreditation of Human Research Protection Programs
- The University of Utah has been accredited since June 2007. We reaccredited in 2010, 2015, and 2020.
- We must maintain accreditation in order to serve as the IRB for the VA.

Accreditation Domains

1. The organization
 - VP, OSP, COI, REd, investigational pharmacies, OQC, RPA, ancillary reviews, legal counsel
2. The IRB
 - Reviews, documentation, applying the regulations
3. The researchers and research staff
 - Compliance, knowledge

Site Visit

- Site visitors review our policies, forms, applications, minutes, etc.
- Site visitors conduct interviews with
 - Organization representatives
 - IRB staff
 - IRB members
 - Investigators and study teams
- They will not observe a board meeting

Site Visitors

- **John Baumann, PhD – Team Leader**
Former Associate Vice President for Research Compliance
Indiana University
- **Matthew Hodgson, MA, MS, MJ, CHRC, CCRP**
Vice President, Research Compliance & Regulatory Affairs
The Children's Hospital of Philadelphia
- **Hiromi Martorano, PhD, CIP, CCRP**
Assistant Director of Expedited Review
Mass General Brigham Incorporated
- **Rebecca Dahl, PhD**
Assistant Vice President for Research Compliance
State University of New York at Stony Brook

Interview Focus

- What are your roles and responsibilities in the Human Research Protection Program? Focus on philosophical aspects (ethical reasoning) of your role first, then know the regulatory details.
- What is your general understanding of the full process for the review and conduct of research? What are the specific details for your part in that process?

UUtah Human Research Protection Program

Vice President
for Research

IRB

IBC

COI

TLO

OSP

RDRC-HUS

Research
Education

Research
Misconduct

Supporting
Components

CCTS

PRMC

IDS

RGE

CRCE

Privacy
Office

General
Counsel

Researchers &
Research Staff

CTOs

University
of Utah

Shriners
Hospital,
Intermountain

Affiliated
HRPPs

Veterans
Affairs

Intermountain
Healthcare

Interview Focus

- Where do you obtain answers for ethical/regulatory behaviors expected of you in conducting research duties?
- How do you access institutional policies and procedures relevant to your role?
- What human subjects research training or education have you received and how it is utilized in your role?

Resources

- CITI training
- REd trainings
- Institutional websites
 - IRB, COI, OSP, etc.
- Federal guidance and regulations
- In person meetings and discussions
- Collaborations across departments

Interview Focus

- How do you handle problems that are discovered with the research review process or the conduct of specific research protocols?
- How do you ensure compliance with your part of the research process, including quality improvement and assurance activities that you conduct?

Quality Assurance and Compliance

- Consult with relevant officials regarding non-compliance and complaints
 - IRB, OSP, COI, VP, Privacy Office, General Counsel, etc.
- Determine need for reporting (internally and externally)
- Corrective and preventive action plans
- Updating policies and procedures
- Documentation

Questions/Comments?
