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

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

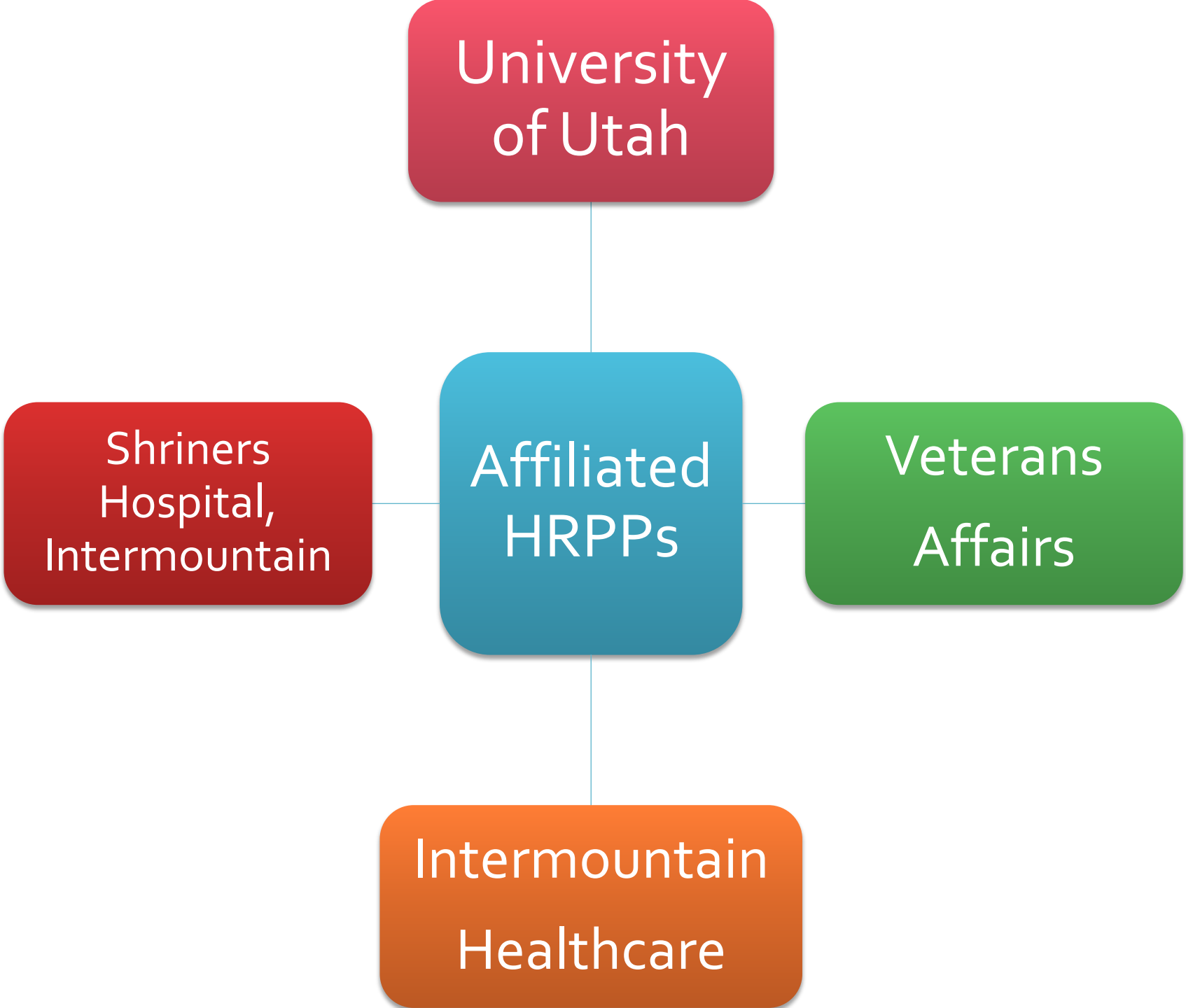
- IRB
- IBC
- COI
- TLO
- OSP
- RDRC-HUS
- Research Education
- Research Misconduct

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?