

# Office of Research Integrity and Compliance

Erin Rothwell, PhD

Associate Vice President for Research

Research Integrity Officer

Institutional Conflict of Interest Officer

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- Mission Statement

- To advance research integrity and compliance through developing, demonstrating, and disseminating innovative processes, tools and outreach that improve scientific outcomes, transparency and accountability throughout the translational research continuum

- 2002 NIH Audit of Research leads to creation of the AVP for Research Integrity Office.
  - Jeffrey Botkin named AVP for Research Integrity
  - 13 employees: Bob Larsen, Heather Sudbury, one COI/RGE staff/ten IRB staff members.
  - Housed in SOM and MREB.



- 2003 Revised Conflict of Interest Policy implemented



- 2004 Research Education Office developed



- 2005 Research Administration moves to the RAB under AVPRI guidance

- ERICA electronic system adopted University wide.



- 2007 AAHRPP Accreditation achieved



- 2008 Research Participant Advocacy Office developed

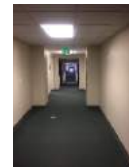


- 2012 Institutional Conflict of Interest Policy implemented

- AVPRI named as ICOI Officer



- 2016 RAB Basement remodel

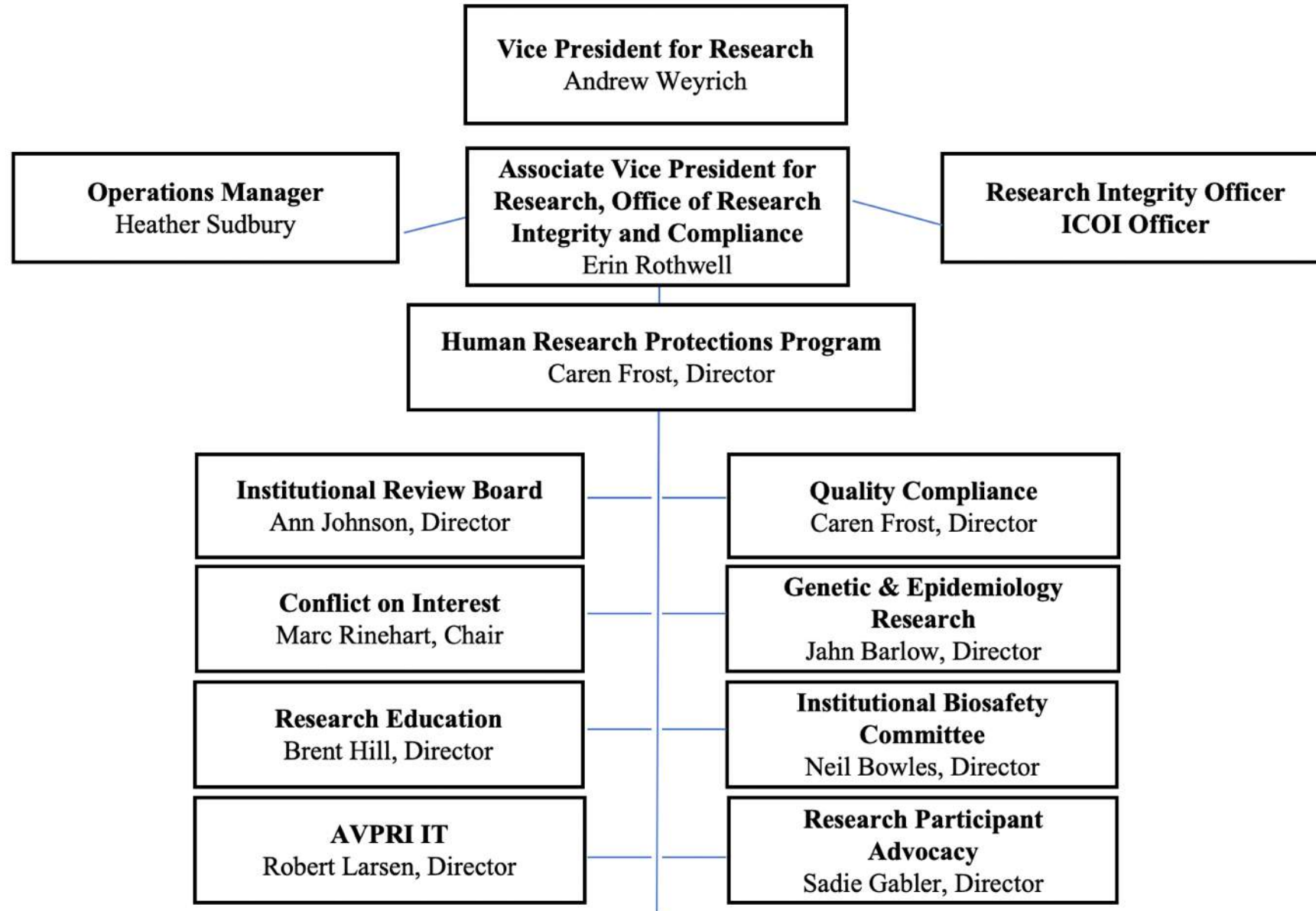


- 2018 Erin Rothwell named AVP for Research, Office of Research Integrity

- Compliance and HRPP emphasized.
- 48 total employees



- 2002-2019 Forty misconduct cases reviewed.



## **Mission Statement**

To support the University community by helping to ensure scientific integrity and ethical practices. Through its mission the COI Office works to protect the University, its employees, and human research participants from the risks created by financial conflicts of interest.

- **New Initiatives**

- Increasing reporting of disclosures on Main Campus
- Ensuring that COI Management Plans are shared with direct supervisors
- Improving purchasing oversight

# Institutional Biosafety Committee (IBC)

([ibc.research.utah.edu](http://ibc.research.utah.edu))



## Mission Statement

To support safe, secure and responsible research by assuring the safety of researchers, research materials, the environment and the public.

Register with IBC if labs work with

- Recombinant or synthetic nucleic acid molecules or infectious agents
- Large scale cultures (>10 liters)
- Human or animals pathogens, including materials known to harbor pathogens (i.e., blood from HBV-positive patients)
- Acute Biological Toxins
- Materials potentially containing human pathogens (i.e., unfixed human specimens, human blood and cell and organ cultures, including established cell lines)
- Administration of human or non-human primate cells (i.e., primary cultures and established cell lines) or tumors into whole animals

## **Mission Statement**

To protect the rights and welfare of human research participants by ensuring compliance with state and federal laws, as well as the high ethical standards set forth in University policy.

## **Common Rule Updates**

[https://irb.utah.edu/\\_pdf/IGS%20-%20Transitioning%20to%20the%20Final%20Rule%20011519.pdf](https://irb.utah.edu/_pdf/IGS%20-%20Transitioning%20to%20the%20Final%20Rule%20011519.pdf)

## **New Initiative**

myIRB

## What is myIRB?

A participant and community focused outreach campaign.

**The Goal:** Create awareness of human subject research in the community at large.

The IRB's mission is to **focus on human participants**; and yet, we spend most of our time consumed with regulations and research teams. A concerted effort will be undertaken in the next 5 years to **establish a connection** with the state, national, and international communities we serve.

A public awareness campaign on campus and in Salt Lake Valley.



A website just for participants and the community.

Videos and social media to connect with normal people.



Education events in schools and community organizations.



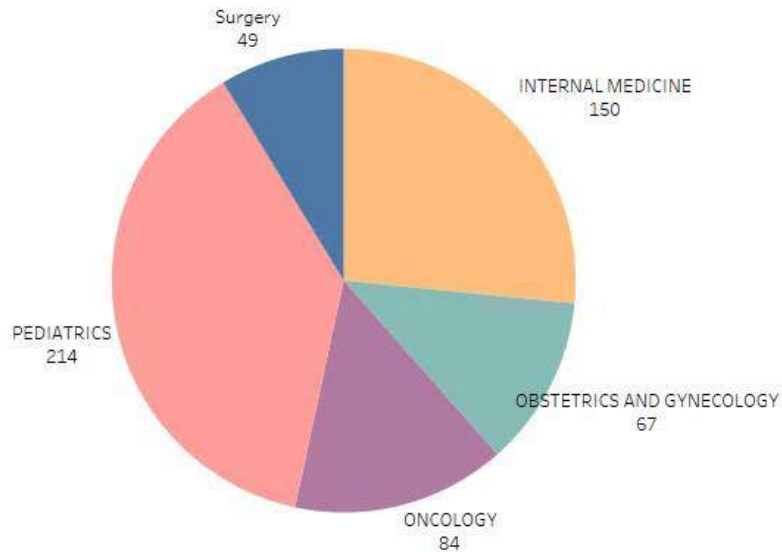
# Office of Research Information Systems (IT)



Department  
 (Multiple values) ▼

ProjectStatus  
 Approved ▼

IRB Studies



Studies by Risk Level & Department



IRB #	PI First	PI Last	Title of Study	Department	Project Status	Risk Level	Review Process
IRB_00004389	Lisa	Gren	Prostate, Lung, Colorectal, & Ovarian Cancer Screening Trial - Screening Centers	ONCOLOGY	Approved	Greater Than Minimal	Convened Board Review
IRB_00004965	Saundra	Buys	High Risk Breast Cancer Clinic & Breast Cancer Family Registry	ONCOLOGY	Approved	Minimal	Convened Board Review
IRB_00006824	Steven	Hunt	Morbidity And Mortality Related To Gastric Bypass Surgery	INTERNAL MEDICINE	Approved	Greater Than Minimal	Convened Board Review
IRB_00007324	David	Viskochil	Natural History Of Plexiform Neurofibromas In Neurofibromatosis Type 1	PEDIATRICS	Approved	Greater Than Minimal	Convened Board Review
IRB_00007604	James	Scott	Long-term Follow Up of Daughters of Transplant Patients	OBSTETRICS AND GYNECOLOGY	Approved	Minimal	Expedited Review
IRB_00007971	David	Viskochil	University Of Utah Neurofibromatosis Type I Patient Registry	PEDIATRICS	Approved	Minimal	Expedited Review
IRB_00008643	Phillip	Barnette	ANBL00B1: Neuroblastoma Biology Studies	ONCOLOGY	Approved	Minimal	Convened Board Review
IRB_00008700	Phillip	Barnette	COG-D9902: A COG Soft Tissue Sarcoma Biology And Banking Protocol	ONCOLOGY	Approved	Greater Than Minimal	Convened Board Review

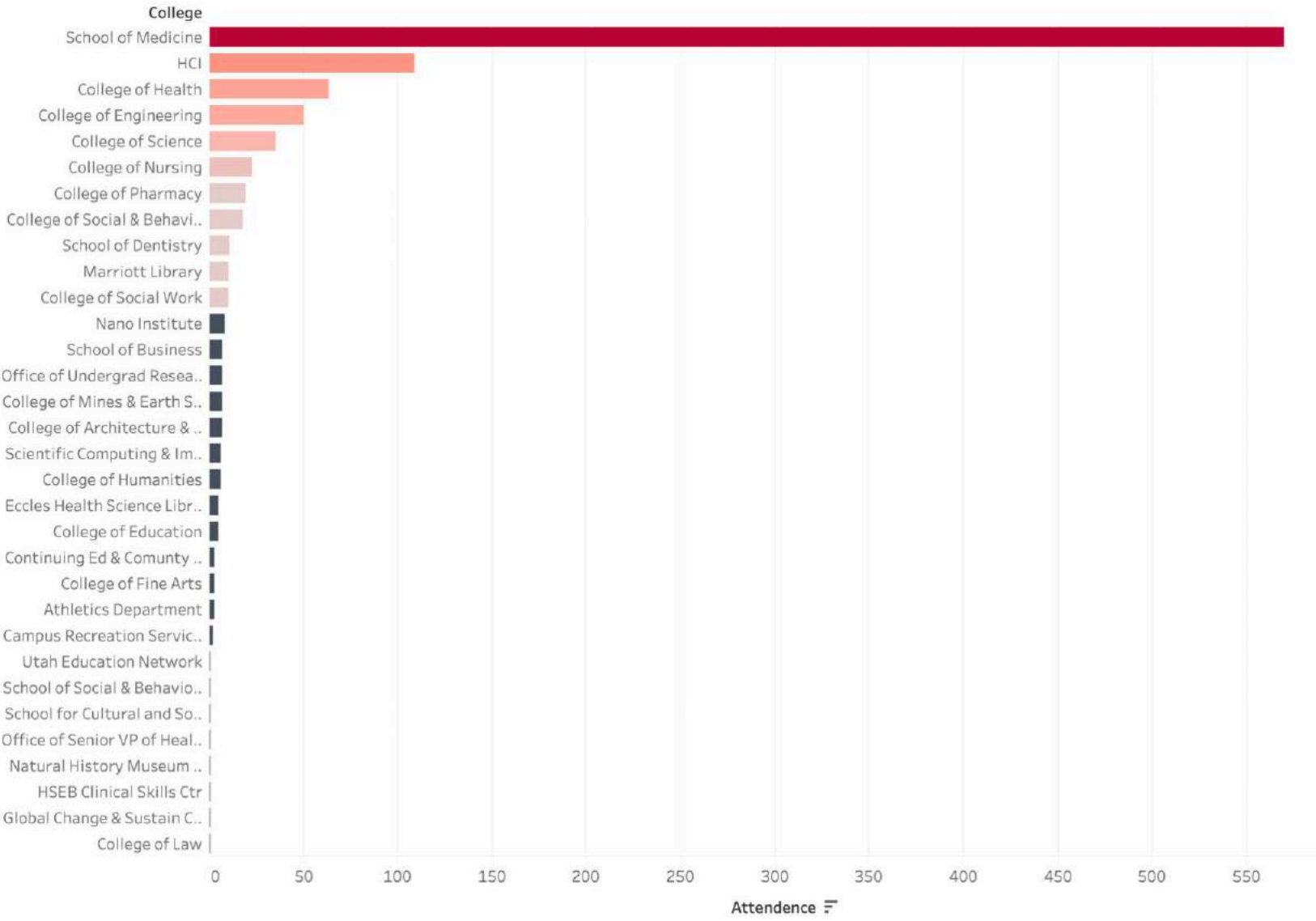
## Mission Statement

To improve research support at the University of Utah by providing accessible and relevant education and training to the research community.

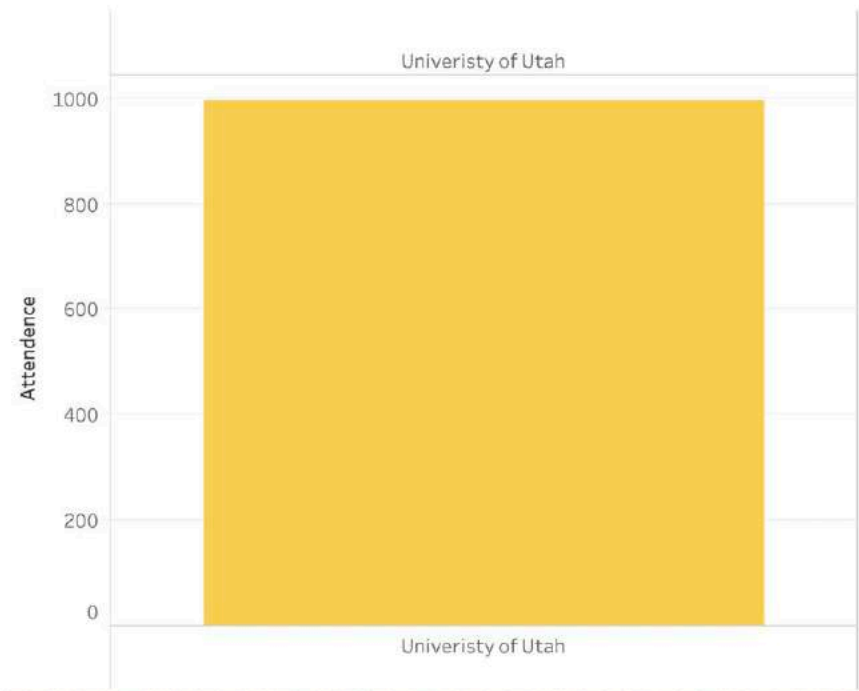
## New Initiatives

- Re-vamping! Research Administration Training Series (RATS)
- New! Principal Investigator Knowledge Assessment (PIKA)
- Lab Safety
- Deer Valley Grant Writing Workshop
  - Return on Investment

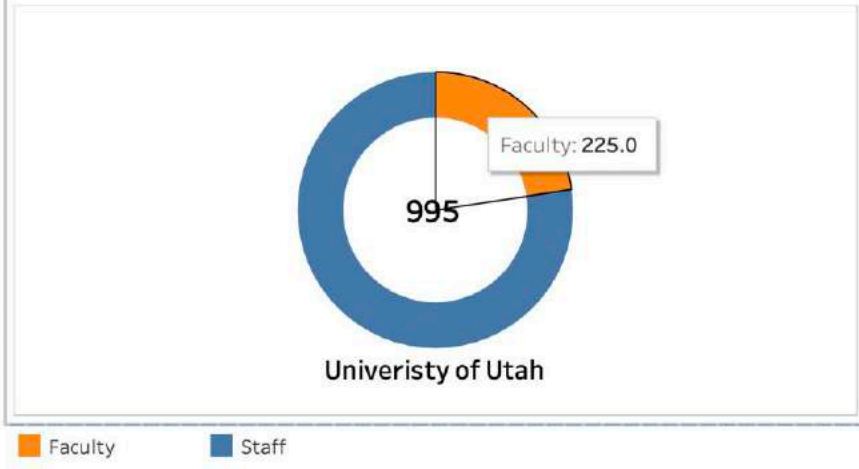
Research Education Responsible Conduct of Research Training Attendance  
2014 - 2019



Research Ed RCR Training Attendance (by Department)  
2014 - 2019



Research Ed RCR Training (Faculty/Staff)  
2014 - 2019



A unique and trusted resource of data for research and statistical purposes to reduce morbidity or mortality or to improve the quality of hospital and medical care

## FY19 Metrics

Type	n	RGE days	Revisio n days	Total days
New Study	42	39	48	87
New Study (on Amendment)	5	21	13	34
Continuing Reviews	155	17	8	25
Amendments	164	18	9	27

## Data accessible through approval

Utah Population Database (UPDB)  
Family History  
Vital Records  
Driver License  
Voter Registration

Utah Cancer Registry (UCR)  
Utah Registry of Autism & Dev Disabilities

Utah Birth Defects Network (UBDN)

All Payer Claims Data (APCD)  
Healthcare Facility Data (HFD)

Links to

UHealth EDW

Intermountain Healthcare EDW

## SERVICES

### Researcher Resources

- Research Participant Advocate
- Language services for inclusion on non-English speaking participants.
  - Interpretation
  - Translation

### Community Resource

- Voice for research participants
- Community Outreach
- Work closely with the CCTS

## **Mission Statement**

To facilitate safe, ethical, efficient, and high quality research, as well as to provide research resources to ensure protecting the welfare of human subjects and overall data integrity

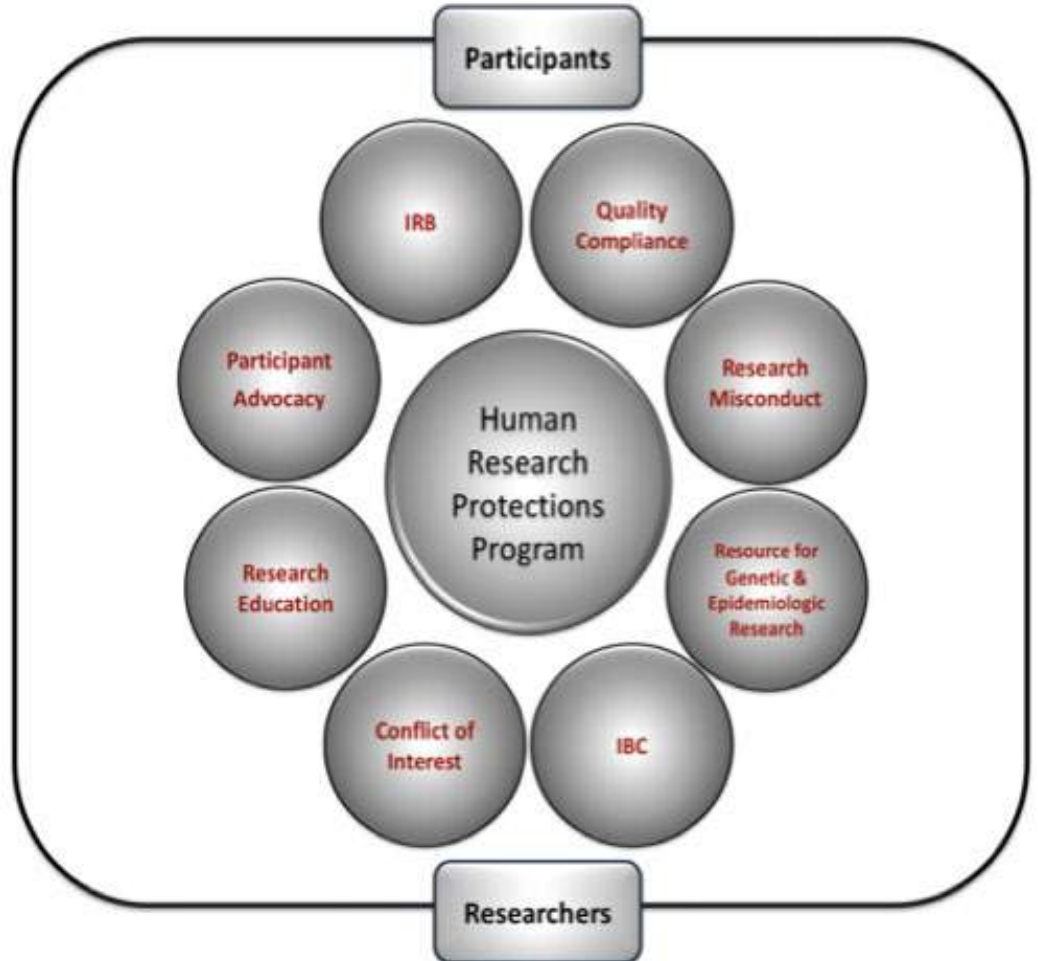
## **New Initiatives**

- Best Practice Reviews, For-Cause Audits, Routine Audits
- Self Assessment Tools
- Unit evaluations of each HRPP department



## Structural Updates

**Human Research  
Protections Program  
(HRPP)**



## Research Ethics Consultations (Dept of Philosophy and CCTS)

- Need advice on a research project?
  - Informed consent, research relationships, benefit/risk assessment, subject selection/recruitment, disclosure of incidental findings/research results, privacy/confidentiality or study design.
- Need to discuss authorship expectations?
- Have questions about COI relationships?
- Confidential, informal
- 1 hour research consults or 10-15 minute Curbside Consults ([researchintegrity@utah.edu](mailto:researchintegrity@utah.edu))





## E3: Ethics, Education, and Engagement Discussion Series 2019-2020

- *Authorship in the Era of Interdisciplinary Collaboration: Should the UU have an Authorship Policy?*  
September 10 @ HSEB 1730  
September 17 @ GWHB 155
- Sexual Harassment, Discrimination and Bullying (February 2020)
- Data Management and Rigor (April 2020)

## Research Misconduct and Conflict of Interest

- Fabrication, Falsification and Plagiarism
- Ethics Hotline (Anonymous)
  - [www.ethicspoint.com](http://www.ethicspoint.com)
    - Enter Organization Name: University of Utah
    - Click University of Utah
- Research Misbehaviors
- Conflict of Interest
- **What would U do?** See something, say something

## Research Culture Survey

- Faculty, Staff and Graduate Students
- Results returned on a department level
- Baseline for office effectiveness and awareness
- Launched August 28<sup>th</sup>
- <https://redcap01.brisc.utah.edu/ccts/redcap/surveys/?s=FC77WD8HAK>

NIH Discussion from Last Week

- <https://nexus.od.nih.gov/all/2019/08/15/thoughts-on-how-institutions-can-promote-a-culture-of-research-integrity/>

# Other Initiatives



- MTA
- E-consent for UU investigators
- Study Finder
  - Results Finder
- Working with Graduate School
  - All graduate students to have 8 hours RCR
  - Onboarding new faculty/staff
- OEO/HR/Ombudsman/OSP
- 6 minute Podcasts for RCR Faculty

# Office of Research Integrity and Compliance



Email us:

[researchintegrity@utah.edu](mailto:researchintegrity@utah.edu)

**New Website Launches Soon! (September 2019)**

[www.integrity.research.utah.edu](http://www.integrity.research.utah.edu)

**Oct 16<sup>th</sup> CRAM 12 pm HSEB**

**Return of Research Culture Results**