



THE
UNIVERSITY
OF UTAH

OFFICE OF RESEARCH
INTEGRITY AND COMPLIANCE

ANNUAL
REPORT

2019
2020

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Letter from the Associate Vice President

For the past two years, the team at the Office of Research Integrity and Compliance (ORIC) has worked tirelessly to build on the solid foundation set by my predecessor, Dr. Jeffrey Botkin. We've been busy making substantial and innovative additions to ensure sustainable growth and future success. I am excited to share the results of our hard work with you.

I want to express great thanks to the research community for their support and patience during the COVID-19 pandemic. I am amazed by the increase in research studies submitted to the Institutional Review Board (IRB) and encouraged by the creation of innovative approaches that seek to address societal changes related to COVID-19. A special thanks goes out to our regulatory committee members—the IRB as well as Conflict of Interest and Resource for Genetic and Epidemiologic Research (RGE)—who navigated difficult conditions to provide peer review of human subjects protections to meet rapid turnaround needs.

This past year, we again received Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation for our Human Research Protections Program. I am pleased to announce that during this review, the Research Participant Advocacy Office was awarded Area of Distinction status. This coveted award is reserved for institutions that stand out as exceptional compared to their peers. We also received significant praise for both our single IRB and Research Education programs. None of this could have been accomplished without the help of our research community, so again, many thanks.

Finally, we would like to thank YOU for your support and involvement with the ORIC. We are only as good as each and every member of our team, and ours is remarkable. It brings me great pleasure to take a moment to recognize my team and share some of our accomplishments with you. Read on to learn more about who we are, find out what we've been up to, and get updated highlights on some of our services provided to the U of U research community.

With gratitude,



Erin Rothwell, PhD
Associate Vice President for Research
Research Integrity Officer
Office of Research Integrity and Compliance
Dept of Ob/Gyn, School of Medicine
Professor, University of Utah

Meet the ORIC

Mission Statement

The mission of the Office of Research Integrity and Compliance is to advance research integrity and compliance through developing, demonstrating, and disseminating innovative processes, tools, and outreach that improve scientific outcomes, transparency, and accountability through the translational research continuum.

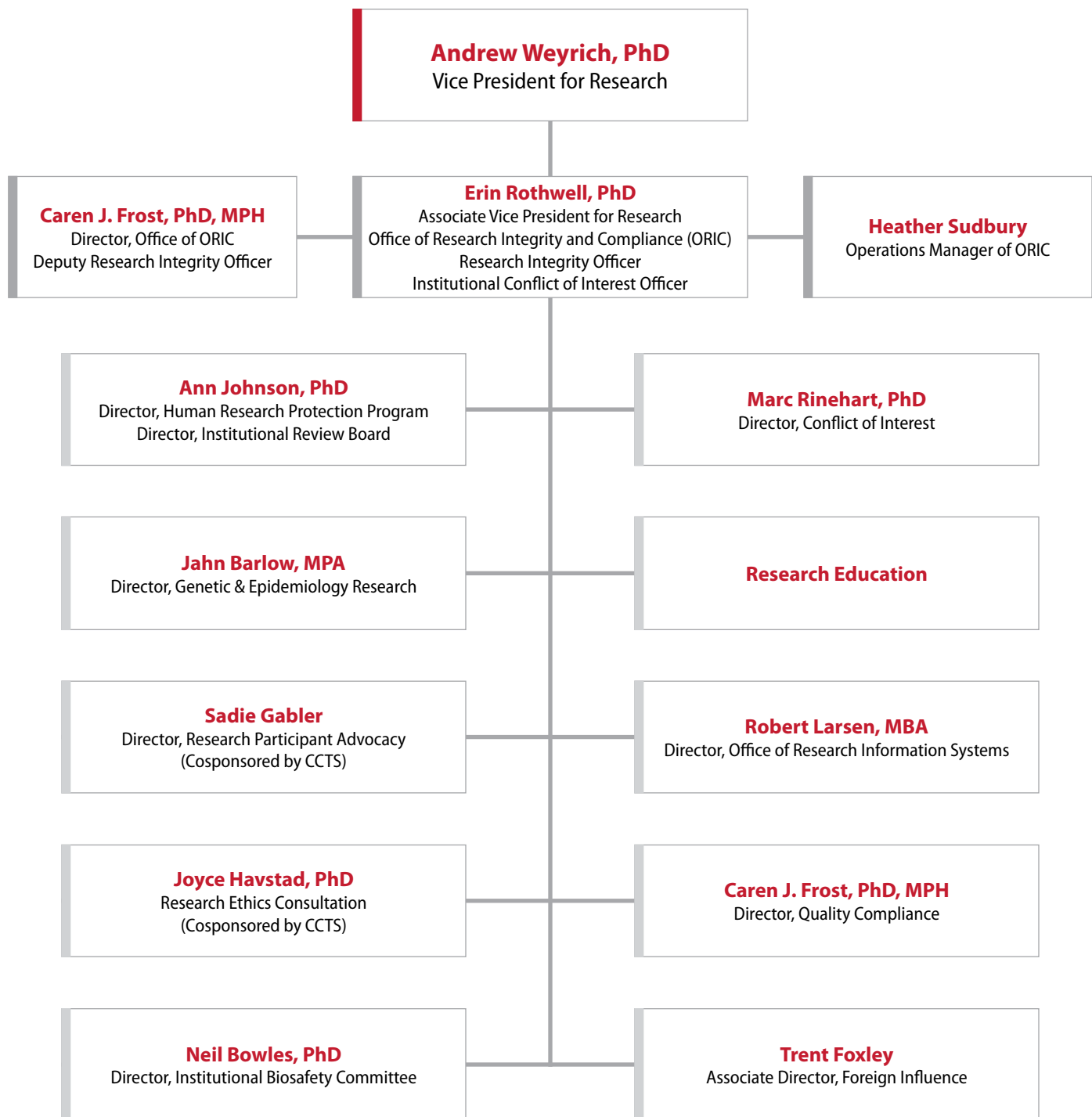
Our Values

- Transparency
- Accountability
- Integrity
- Advocacy
- Diversity

Recently, the Vice President for Research (VPR) made a statement against racism, and we would like to repeat that racism and discrimination of any kind will NOT be tolerated by the U of U research community. As an Office, we will continue to stand behind this statement and have already made changes to our processes to ensure we improve. Read the VPR's statement at <https://attheu.utah.edu/facultystaff/vpr-on-fighting-systemic-racism-in-research/> or scan this QR code →



Organizational Structure



Leadership Team



Associate VP, Office of Research Integrity & Compliance

Erin Rothwell, PhD, is the Associate Vice President of Research in the Office of Research Integrity and Compliance. She is also a professor in the Department of Ob/Gyn in the School of Medicine. Dr. Rothwell has extensive experience in bioethics and human subjects protections having served on the IRB and hospital ethics committees, as well as completing a competitive bioethics fellowship from the Medical College of Wisconsin. She also brings a wealth of experience from her successful program of research on informed patient decision-making and the ethical implications of emerging technologies within the context of genomics, population screening, and public health across the reproductive continuum of care.



Director, Office of Research Integrity & Compliance

Caren J. Frost, PhD, MPH, is the Director of the Office of Research Integrity and Compliance and Deputy Research Integrity Officer. Dr. Frost has been a research professor in the College of Social Work since 2001 and currently serves as the Interim Associate Director of the Master of Social Work program. She was the cochair and a panel member for the Institutional Review Board (IRB) for over 16 years and continues to consult with faculty and students about research studies and IRB applications and processes. Currently, Dr. Frost is working with the Office of Research Education (REd), other HRPP units, and entities across campus to revamp REd offerings and update class information for the U of U. In addition, she is the Director of the Office of Quality Compliance. This new office at the U of U is developing mechanisms for a variety of study review opportunities that will assist research investigators and study teams in ensuring that (a) studies meet federal and local regulations, and (b) grant fidelity is maintained. Dr. Frost works with the Clinical Trials Office in Pediatrics to house the new clinical trials standard operating procedures (SOPs) through the Office of Quality Compliance.



Director, Human Research Protections Program (HRPP)

Ann Johnson, PhD, is the Director of the Human Research Protections Program (HRPP) and the IRB. As the HRPP Director, she is responsible for the accreditation process, improving synergy and communication across the HRPP units, improving the material/data transfer agreement (MTA/DTA) process, and the single IRB. Dr. Johnson has conducted these activities in the past, but this official designation as the HRPP Director recognizes her extraordinary achievements and commitment.



Operations Manager, Office of Research Integrity & Compliance

Heather Sudbury is the Operations Manager for the Office of Research Integrity and Compliance. She has worked with this office for over 16 years and is a recipient of the University Staff Excellence Award. Heather provides infrastructure and management for the organization as a whole. She is responsible for the day-to-day office business, oversees budget operations, provides support to the directors, and assists with the regulatory and advisory committees.

Contact Us

Synergy and collaboration are essential for a healthy and thriving research and campus community. Your thoughts matter to us.

We look forward to hearing from you!

🌐 Visit our updated website at integrity.research.utah.edu

@ You can also send us a message at researchintegrity@utah.edu

Highlights for 2019–2020



4-Hour RCR Graduate Requirement

REd introduces a unique collaboration with the Graduate School to ensure training of the next generation of workforce.

Page 14



Main Campus COI Policy

Led by Dr. Rinehart, the new COI Policy establishes consistent disclosure requirements across our campuses.

Page 9



Anonymous Reporting

Anonymous reporting is available for those who do not feel comfortable reporting directly.

Page 26



Study Locator

COVID has increased awareness of inequalities, and we are increasing efforts to improve outreach about research studies for our community.

Page 21



Authorship Policy Developments

Based on institutional feedback, we are closer to getting an authorship policy at the U of U.

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Revamping Research Education

The REd team conducted a university-wide needs assessment to determine current training needs for faculty, staff, and students involved in research and/or scholarly activities. We are pleased to announce substantial changes that improve our research education offerings.

Page 15



Foreign Influence

After a taskforce led by Andy Weyrich and Julie McAdams, we now have a new department to address foreign influence.

Page 10



Research Ethics Consultations

We collaborated with the Department of Philosophy and the Center for Clinical and Translational Science (CCTS) to create a tenure line to support President Watkin's One U initiative.

Page 17



E3 Series

This discussion series focused on ethics, education, and engagement and encourages in-depth dialogues about how these issues are affecting our U of U research community. It aims to address emerging national research integrity and ethical issues.

Page 18



MTA Revisions

Dr. Johnson, the HRPP Director, has led an interdisciplinary team to improve efficiency and tracking of data and material transfer agreements.

Page 12



Dashboards

We have data, and we want to ensure you have access for increased transparency and support of your research. Bob Larsen is working with his team to improve transparency with human subjects data.

Page 19



National Initiatives

We will host the Association of Research Integrity Officers annual conference in September 2021. In fall 2022, we will host a research forum with the Office of Human Research Protections.



Research Climate Survey

Every institution should empirically assess their research climate according to federal regulations. We did in 2019, and these data are available to support grant proposals and research education.

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Pilot Study with Development Office

Working with Chris Ostrander, Dr. Rinehart is piloting COI reviews and implications on research with the Development Office to improve transparency and public trust.



AAHRPP Accreditation

Led by Dr. Johnson, the U of U was accredited again and awarded Area of Distinction for our Human Research Protections Program (HRPP).

Page 13 and Page 20



Professional Misconduct

We are working to explore if professional misconduct such as sexual harassment, discrimination, and bullying in the research context should have similar consequences as research misconduct.

Departments

The Office of Research Integrity and Compliance is composed of nine independent but collaborative departments. We also have committees and other services to meet the needs of the research community.

Visit our website to learn more: <https://integrity.research.utah.edu/>



Conflict of Interest



Foreign Influence



Institutional Biosafety Committee



Institutional Review Board – Human Research Protections Program



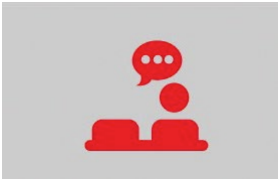
Quality Compliance



Research Education



Research Ethics Consultations



Research Participant Advocacy



Resource for Genetic & Epidemiologic Research

Conflict of **Interest** (COI)

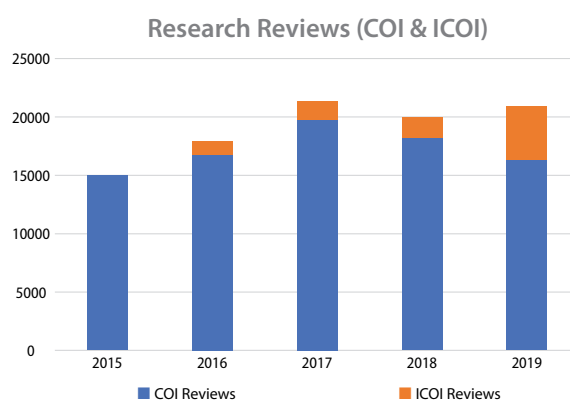
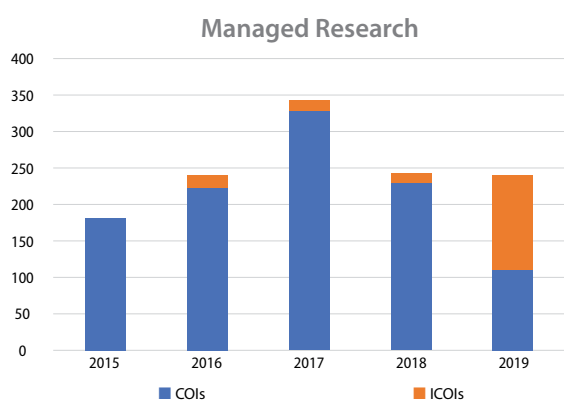
Mission: The mission of the COI department is to support research and innovation at the University of Utah by protecting the integrity and scientific merit of our research community through effective management of financial conflicts of interest.

Services: Individual and institutional reviews for COI, reporting, compliance, research, education, and training



Mark Rinehart, Director

Statistics



Main Changes to the COI Policy

The following changes were made to the COI policy to ensure better compliance, consistency with other University regulations, state law, and federal requirements, and clarity of existing requirements:

- I. A required annual disclosure through the **University's Business Relationship** Reporting for the following groups
 - Faculty members (excluding emeritus, visiting, and adjunct faculty)
 - Staff employed at the manager level or above
 - Staff with purchasing authority or delegated purchasing authority, including account executives and their delegates, staff authorized to use a PCard, and staff authorized to make purchases through UShop
- II. Zero-dollar threshold for disclosing financial relationships that are reasonably related to an employee's job responsibilities
- III. Three new rules to provide guidance in each of the domains covered by the policy
 - **Research**
 - **Scholarly or Educational Activity**
 - **Transactions**
- IV. Updated definitions

Visit us:



Foreign Influence



Mission: The mission of the Office of Research Integrity and Compliance's Foreign Influence department is to educate, identify, and implement best practices and reporting requirements to mitigate the risk of undue foreign influence.

Services: Foreign influence education, outreach, and compliance.

Trent Foxley, Associate Director

Foreign Influence Task Force

According to our Foreign Influence Task Force's February 2020 report, "undue foreign influence is defined as an influence by non-U.S. persons or entities, including foreign governments, that seek to compromise U.S. national security and economic security or which results in loss, including by theft, of United States' intellectual property or academic opportunities. [...] Advancing research and discovery involves robust exchange of intellectual ideas and collaboration. These efforts must, simultaneously, uphold U.S. standards for research integrity and give due consideration to legitimate threats to national and economic security."

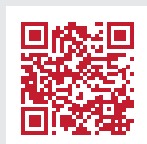
Compliance with Regulatory Requirements

- U.S. Export Control laws and regulations establish a set of requirements for the transfer of technology and data to foreign countries and/or foreign nationals in the U.S.
- The Office of Foreign Assets Control (OFAC) restricts interactions with individuals or entities on the sanctions list.
- The Centers for Disease Control and Prevention (CDC) and the Department of Agriculture (USDA) require permits for the importation of many biological materials.

To learn more, visit the Disclosure of Foreign Affiliations page on our website:

<https://integrity.research.utah.edu/disclosure->

Visit us:



Institutional Biosafety Committee (IBC)

Mission: The mission of the IBC is to support safe, secure, and responsible research with biological materials by providing technical assistance and oversight to assure the safety of researchers, research materials, the environment, and the public.

Services: Oversight of work involving hazardous materials by reviewing:

- Nonexempt recombinant or synthetic nucleic acid molecules research
- Studies using human or animal pathogens
- Work with acute biological toxins
- Human subjects research involving the introduction of recombinant molecules or biohazards into human subjects:
 - Biosafety training
 - Inspections of laboratories
 - Assistance with risk assessments



Neil Bowles, Director

What Is an Institutional Biosafety Committee?

An institutional biosafety committee (IBC) is required at institutions that receive funding from the National Institutes of Health (NIH) to review research involving recombinant or synthetic nucleic acid molecules, in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. (Learn more at https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm)

At the University of Utah, the IBC also has the responsibility of reviewing a variety of experimentation

that involves biological materials, such as risk group 2 or higher pathogens, and other potentially hazardous agents, including acute biological toxins, human blood, tissues, and cell lines. The IBC works in conjunction with the Biosafety Office in the Office of Environmental Health and Safety to develop procedures to facilitate the safe conduct of biological research at the University of Utah.

Register your lab with Bioraft:

https://utah.bioraft.com/frontpage_panel

Committee Accomplishments

249 New or renewal protocols reviewed by the convened IBC

192 Lab inspections

85 Training classes

1,611 Trainees

Find guidelines, fact sheets, SOPs, and manuals at <https://ibc.utah.edu/library.php>

Visit us:



Institutional **Review Board** (IRB)/HRPP



Ann Johnson, Director

Mission: The mission of the IRB/Human Research Protections Program (HRPP) department is 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.

Services: We are a fully functioning single IRB and provide IRB review services for multicenter research across the United States.

We have the review expertise for:

- Common Rule
- FDA
- HIPAA
- Veterans Affairs
- Department of Defense
- Fetuses
- Neonates
- Children
- Prisoners
- Cognitively impaired adults

ERICA

We use the ERICA online system for high-quality, efficient IRB and HRPP reviews. This includes access for external users using our single IRB. Log on to ERICA at <https://erica.research.utah.edu/>

Material and Data Transfer Agreements (MTAs/DTAs)

Led by HRPP Director, Ann Johnson, PhD, a number of U of U offices are collaborating to improve the efficiency of the MTA/DTA process as well as compliance to protect the institution and our investigators. Offices involved include Partners for Innovation, Ventures, Outreach and Technology (PIVOT), Utah Resource for Genetic and Epidemiologic Research (RGE), Office of Sponsored Projects (OSP), and Office of Research Integrity and Compliance (ORIC).

In the future, when a faculty member, researcher, or staff member seeks to send or receive material or other information to another institution/company, PIVOT will begin the process to put the appropriate agreements in place. The Office of Sponsored Projects may need to review the form after PIVOT. Finally, the ORIC reviews the form to ensure compliance with the IRB and that it does not overutilize an institutional resource for our own investigators.

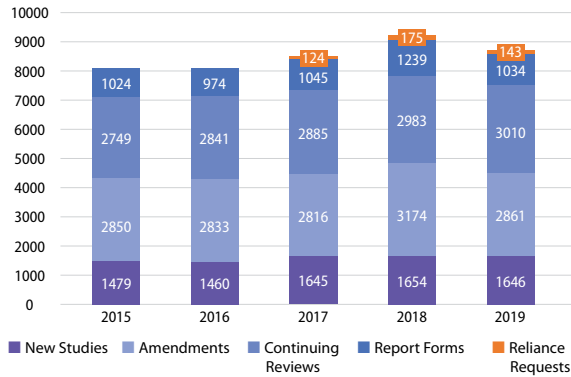
To request a new MTA, DTA, CDA, NDA, or an amendment to an existing agreement, please complete the form at the PIVOT website at <https://pivotcenter.utah.edu/tvc-agreement-request/>

Visit us:

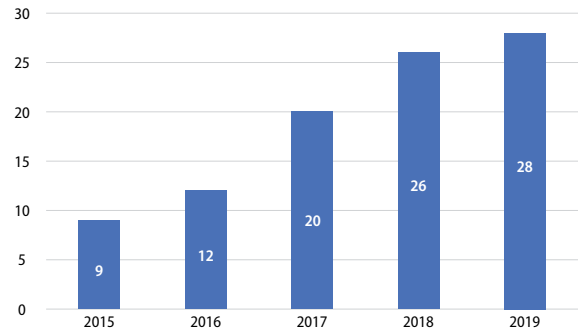


Statistics

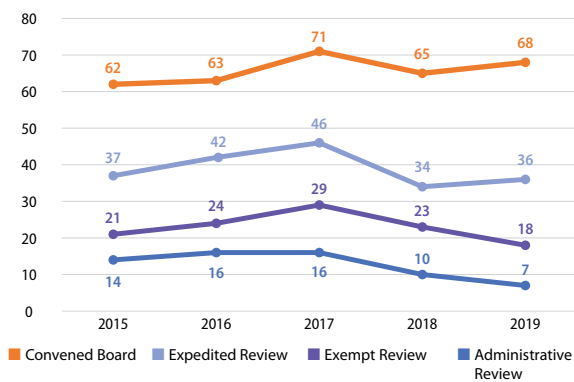
IRB Submission Totals



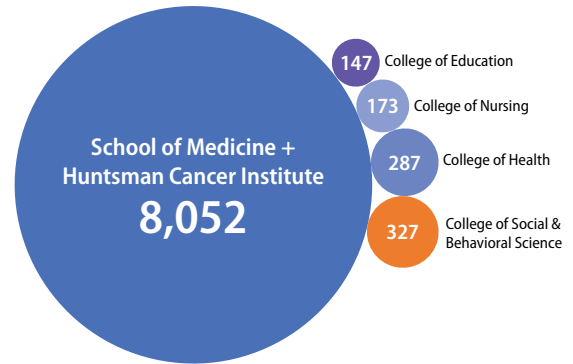
Number of New UU Single IRB Submissions



Median New Study IRB Review Times | Median Number of Days



Top 5 Colleges: Total Submissions



AAHRPP Accreditation

We again were awarded Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation for our Human Research Protections Program.



Research Education (REd)



REd Objectives:

- Offer up-to-date courses and seminars linked to the research enterprise
- Ensure that faculty, students, and staff develop the necessary skills to implement best practices for research
- Provide faculty, students, and staff with access to appropriate resources and tools

Since 2004, Research Education (REd) has been the central hub for the campus distribution of information from the Office of the Vice President for Research (VPR). REd develops and launches classes and workshops to accomplish its mission of “providing comprehensive training and learning opportunities and resources for faculty, students, and staff engaged in responsible conduct of research at the University of Utah.”



Dr. David Kieda

A huge thanks goes out to Dr. David Kieda, Dean of the Graduate School, and the Graduate Council for helping us achieve this important milestone and ensuring we keep our students relevant and ready for future research roles!

Responsible Conduct of Research Training

Responsible research training is a key need for students in the twenty-first century. U.S. institutions of higher education have found that offering this training increases the likelihood of integrity throughout the research process and improves compliance with federal requirements.

Moving forward, we are excited to offer the Responsible Conduct of Research (RCR) training to all graduate programs on campus. This four-course graduation requirement will be offered for free through Research Education (REd). Successful completion results in recognition via certification and documentation on graduate transcripts.

RCR Areas of Focus

- The mission of the Office of Research Mentoring
- Authorship
- Conflict of interest
- Research standards/ethics
- Research misconduct
- Compliance with federal and state requirements

Features of RCR

- Asynchronous online course offerings
- Flexible sequencing
- Choice of two separate tracks, Bioscience or Non-Bioscience

Research Education

Academic Courses

Required Classes *(select 2)*

- Introduction to Responsible Conduct of Research (RCR)
- Advanced Consideration of the Criteria for IRB Approval of Research
- Managing and Maintaining Your Scholarly Profile
- Getting Published: Responsible Authorship and Peer Review



Bioscience Students

(select 2)

- Research Participants and the Informed Consent Process
- Data and Safety Monitoring: Plans, Boards, & Committees
- Rigor, Transparency, and Reproducibility in Research
- Source Documentation in Clinical Research

Non-Bioscience Students

(select 2)

- Informed Consent: Models and Requirements
- Research Participants and the Informed Consent Process
- Rigor, Transparency, and Reproducibility in Research
- Mentoring Roles and Responsibilities

ECE 6900 (1 Credit)

Graduate Seminar

NURS 7101 (2 Credits)

Research Ethics & Protection of Human Subjects

PHIL 3570 (3 Credits)

Research Ethics

MBIOL / PHIL 7570 (1 Credit)

Case Studies and Research Ethics

Revamping Research Education

In 2019, REd conducted a needs assessment to determine current training needs and interests for faculty, staff, and students involved in the research enterprise. Between December 2019 and January 2020, we met with 92 town hall participants and received 326 survey responses.

The results of the surveys and town hall discussions were used to identify class topics and logistics needed to move REd into the future. Through the concerted work of the REd team, we identified the top 25 classes that would be useful for promoting a climate of research integrity at the U of U.

Need:	Revise certificates of achievement		
Solution:	<p>Create six different certificates: five for faculty and staff and one for graduate students.</p> <p>These certificates will build on the synchronous and asynchronous class context and will be good for three years once completed. To earn a certificate, participants will need to complete 16 hours of classes with eight hours in foundational classes and eight hours in electives. Two more certificates (pre-award and post-award) will begin in 2021, developed with Dr. Diane Pataki, Associate Vice President for Research and the pre-award unit.</p>		
Need:	Explain class units and types of classes through REd		
Solution:	<p>Record explanations of course units and how to find online resources for these units, and enable ease of content change when new information becomes available.</p> <p>All VPR leaders will prepare and record a 10-minute explainer video to add to their courses.</p>		
Need:	Shorten class times to two hours or less		
Solution:	<p>Offer synchronous (in-person) and asynchronous (online) courses using a “flipped classroom” approach.</p> <p>To help us build our online and in-person classes, we called on the pedagogical Dr. Donna Ziegenfuss of the Marriott Library. We are proud to be able to offer this additional professional development to our hardworking and dedicated REd instructors.</p> <table border="0" data-bbox="378 1186 1382 1430"> <tr> <td data-bbox="378 1186 885 1430"> <p>Flipped Classroom Model</p> <ul style="list-style-type: none"> • 30 minutes of prep work before coming to class • 45–60 minutes of face-to-face instructor interaction • 30 minutes of post-class content application </td> <td data-bbox="901 1186 1382 1430"> <p>Online, Self-Paced Model</p> <ul style="list-style-type: none"> • 30 minutes of individual classwork activities • Instructor-led videos to teach and supplement activities </td> </tr> </table>	<p>Flipped Classroom Model</p> <ul style="list-style-type: none"> • 30 minutes of prep work before coming to class • 45–60 minutes of face-to-face instructor interaction • 30 minutes of post-class content application 	<p>Online, Self-Paced Model</p> <ul style="list-style-type: none"> • 30 minutes of individual classwork activities • Instructor-led videos to teach and supplement activities
<p>Flipped Classroom Model</p> <ul style="list-style-type: none"> • 30 minutes of prep work before coming to class • 45–60 minutes of face-to-face instructor interaction • 30 minutes of post-class content application 	<p>Online, Self-Paced Model</p> <ul style="list-style-type: none"> • 30 minutes of individual classwork activities • Instructor-led videos to teach and supplement activities 		
Need:	Update Best Practices Networks & Grant Writing Academy		
Solution:	<p>Realign Best Practices Roundtables (BPRs) to better satisfy participant requests and campus unit needs. Develop new grant writing workshops.</p> <p>Rename BPRs to Best Practices Networks (BPNs). The BPNs will consist of a short presentation followed by a long period for discussion. Collaboration with Dr. Diane Pataki, Associate Vice President of Research, will bring our grant writing workshops up to speed with highlights such as how to apply for funding from a variety of entities.</p>		

Research Ethics Consultation Service

Do you or your students have questions about any of the following?

- What are research ethics consultations?
- Informed consent?
- Research relationships?
- Benefit/risk assessment for study design?
- Subject selection/recruitment?
- Disclosure of incidental findings/research results?
- Privacy/confidentiality or study design?



Joyce Havstad, Director

Earlier this year, we collaborated with individuals within the College of Humanities, the Department of Philosophy, and the Center for Clinical and Translational Science (CCTS) to create a tenure line to support President Watkin’s One U initiative. We are thrilled to introduce Dr. Joyce Havstad as the right fit for this position.

In addition to standard expectations of an associate professor at the U of U, Dr. Havstad will further develop and lead research ethics consultation (REC) services on campus. Her responsibilities include teaching the RCR training for graduate students, conducting guest lectures through REd, and collaborating on research initiatives. Dr. Havstad will also play a role as key member of the Utah CCTS and contribute to ongoing research on how to best integrate ethics into our translational research framework.

Need to schedule a research consult with Dr. Havstad?

All consultations are informational and confidential.

Office Phone: 801-581-7170

Email: researchintegrity@utah.edu

Four Contexts Where Clinical Research Ethics Consultation Can Be Valuable

For investigators seeking advice **before regulatory review begins and after it ends**

For investigators, staff, and IRBs facing **challenging and novel ethical issues**

For IRBs and investigators facing **increasing challenges of informed consent and risk/benefit analysis**

Collaborative assistance to overcome study hurdles, mediate conflicts within a team, or directly engage with research participants

E3 Series: Ethics, Education, and Engagement

E³ Ethics Education & Engagement

During the 2019–2020 academic year, Research Education (REd) and the Research Ethics Consultation department developed the E3 Series to address emerging national research integrity and ethical issues. This discussion series focused on ethics, education, and engagement and encourages in-depth dialogues about how these issues are affecting our U of U research community.

The current E3 topics address concerns such as authorship, bullying, and professional misconduct in the research settings. Discussions will be led by panelists from the health and social/behavioral sciences who have expertise in the areas of preventing misconduct activities and developing effective solutions for managing these events.

2019–2020 Series

Discussion Topic	Description
Authorship in the Era of Interdisciplinary Collaboration: Does the U Need an Authorship Policy?	Determining manuscript authorship for publications can be a daunting task whether you are working with a new research team or if you are working with a well-established team. This kick-off E3 discussion, led by a panel of experts from the University of Utah, will highlight the appropriate steps and conversations researchers should consider when establishing authorship parameters for their work with other researchers. A draft authorship guideline will be shared for discussion. The audience is junior and senior faculty (tenure and career line), study coordinators, and graduate students.
Should I Publish There? Identifying and Avoiding Predatory Journals	Have you received emails encouraging you to submit your valued research findings to a new journal? How do you know if the journal is legit? This panel discussion will highlight how to use the Beall's List of Predatory Journals and to determine which journals to avoid. Part of the discussion will include how to identify an appropriate journal for your work.
Reproducibility and Data Management	The concept of reproducibility of results became part of the research lexicon in 1989. In 2014, the NIH developed key goals and guidelines that highlight processes to ensure that data are collected rigorously and research steps can be reproduced. This discussion will explore (1) why rigor in research studies is crucial to the scientific endeavor and (2) how to ensure research activities can be reproduced using the eight transparency standards developed by the NIH. What types of guidelines are needed at the U of U to ensure data rigor and reproducibility?
Bullying & Unprofessional Behavior in the Research Setting (Rescheduled to 2020–2021 academic year due to COVID-19)	According to recent scholarly work, bullying is defined as physical, social, and/or verbal actions that cause harm to a person or a group. These repeated actions present negative consequence for the victim(s) as well as the bully. Bullying, one form of unprofessional behavior, “always involves aggressive behavior” and a differential in power dynamics. A recent case in Australia highlights the mechanisms through which this type of behavior occurs. This panel dialogue will address what the U of U is doing to reduce bullying and address professional misconduct in the research setting. Resources on campus will be identified.

Research Information Systems (ORIS)

Mission: To be a leader in providing effective and sustainable technology and quality services that enhance productivity and research that supports the mission of the University.

Services: ERICA is the primary system managed by ORIS. The Electronic Research Integrity and Compliance Administration (ERICA) system allows HRPP members, including study teams, 24-hour access from any location with an internet connection to manage existing projects, submit new projects, and complete a wide variety of other tasks.

Additional services include:

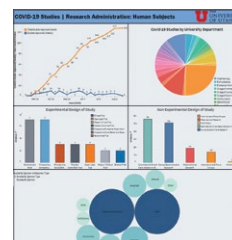
- Agreement management
- Help desk & desktop support
- Tableau visualizations and other reports
- Database and server administration



Robert Larsen, Director

Dashboards

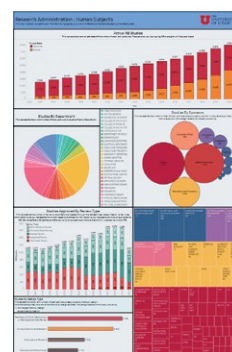
The COVID-19 Studies Dashboard displays a snapshot of information for all COVID-19 related, IRB approved studies. This dashboard contains multiple graphs that provide views by week approved, department, design of study, and sponsor type. Additional details for each study contained in the filter criteria are displayed in a table at the bottom.



The ORIS Awards (by Sponsor) Dashboard displays a snapshot of information for all awards that have been issued since 2005. This dashboard contains multiple graphs that provide views by sponsor, sponsored vs. non-sponsored, and active awards by sponsor.



The Research Administration: Human Subjects Dashboard displays a snapshot of information for all active human subjects studies approved since 2006. This dashboard contains multiple graphs that provide views by approved or exempt, department, sponsor type, sponsor, and review type. Additional details for each study contained in the filter criteria are displayed in a table at the bottom.



To obtain access to these dashboards, please email oris@utah.edu.

Visit us:



Research Participant Advocacy (RPA)



Sadie Gabler, Director

Mission: Empower our research enterprise to provide equal access, opportunity, and inclusion of ALL members of our community into our research efforts to increase diversity, generalizability, and reproducibility of research results to eliminate health care disparities by eliminating barriers to research.

Services: Provide translation and interpretation service for all non-English speaking participants—providing participants a voice before, during, and after participation by serving as a liaison between study teams and participants—community outreach/engagement, and recruitment support.

The Research Participant Advocacy department is cofunded by the ORIC and the CCTS.

Area of Distinction Status

The Research Participant Advocacy Office was awarded Area of Distinction status. This coveted award is reserved for institutions that stand out as exceptional compared to their peers. We also received significant praise for both our single IRB and Research Education programs.



RPA-Specific Projects

Training

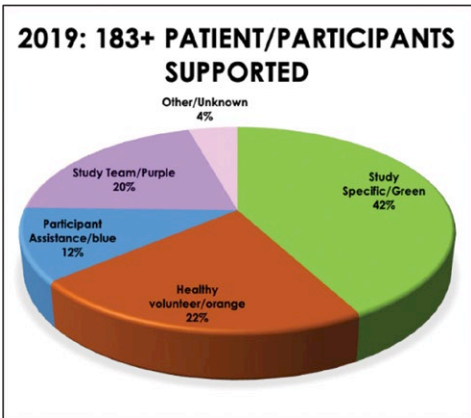
HCI community health workers were trained on the importance of research and how to discuss it with the community members they serve and how to request our services when interacting with patients to increase diversity into research.

Visit us:



Research Brochure

We completed a generic lay-friendly NICU research brochure for NICU researchers.



Health Fairs

We attended 11 health fairs with over 9,500 attendees in total. Three were large and family focused, including the Telemundo Hispanic Health and Dental Fair and multiple smaller senior fairs across the valley.

Translations

We audio-recorded Short Form and Bill of Rights into nine languages as well as a version for the visually impaired or nonliterate.

We had 79 new studies requesting full ICF translations (up from 62 studies the previous year), and 53 studies required amendments to previously translated documents.

We had 147 interpreter-facilitated research study visits in 2018 and 49 in the first two months of 2019.

Because of increased opportunities and awareness, we now have 29 Short Forms available in other languages and American Sign Language. A few years ago, we only had 11.

We added four new languages to our Audio Translation Language Library with two currently in progress: Czech and Albanian.

Study Locator

To say that COVID-19 has raised some unique challenges to conducting research is an understatement. The silver lining, however, is that it has also highlighted disparities in research and the need to improve recruitment approaches to reach underrepresented persons.

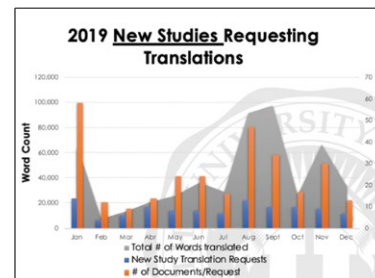
In combination with the Institutional Review Board (IRB) and the Office of Research Information Systems and the Research Participant Advocacy department led by Sadie Gabler, we have crafted a community outreach web page (<https://rpa.utah.edu/covid-19.php>) to disseminate research studies. This website will provide another avenue to give opportunities to everyone in our community to identify potential studies for participation.

To make sure your study is included in the search results, you must provide general language about your study for the IRB. You can also do this when you renew your study application in ERICA.

Through the creation of a community facing website, listserv and COVID specific registry we will continue to actively connect individuals in the community with research opportunities by removing potential barriers to research.

Outreach

We reached more than 110 individuals with research opportunities via email alone and held six community outreach events with a total of more than 3,400 attendees.



FIND A RESEARCH STUDY BELOW TO TAKE PART IN:

Social Behavior Clinical Trial

Available for participation to **almost** everyone:

1. Lifestyle changes during COVID-19. A study to look at stress, sleep, diet, and physical activity during the COVID-19 pandemic
2. Study to look at people's views of Covid-19 and the advice on how to stay safe
3. COVID-19 and the Effect of Social Isolation on Health

Only available for participation to limited individuals (Please see study descriptions):

1. Tracking COVID-19 and cancer symptoms from home on the Symptom Care at Home (SCH) telehealth system
2. Impact of COVID-19 pandemic on University of Utah Students leisure behavior and health
3. Impact of COVID-19 stay-at-home orders and domestic violence
4. Impact of being a frontline worker during the COVID-19 pandemic
5. Access to family planning services during COVID-19 pandemic
6. Understanding the impact of COVID-19 on Work and Work Culture

Lifestyle changes during COVID 19. A study to look at stress, sleep, diet, and physical activity during the COVID-19 pandemic

Study Summary: The purpose of this study is to better understand how COVID-19 affects stress, sleep, diet, and exercise.

If you qualify you will complete:

- 1 - 15-minute survey, and
- 3 - 7-day surveys, 3 times over a period of 3 months.
- This study will be done from your home.

You may qualify if you:

- Are 18 or older.
- Live in Utah.
- Own a smartphone.

Will I be paid for my time? Yes.

For more information contact: 801-585-1123 or sleeplab@utah.edu

Resource for Genetic & Epidemiologic Research



Jahn Barlow, Director

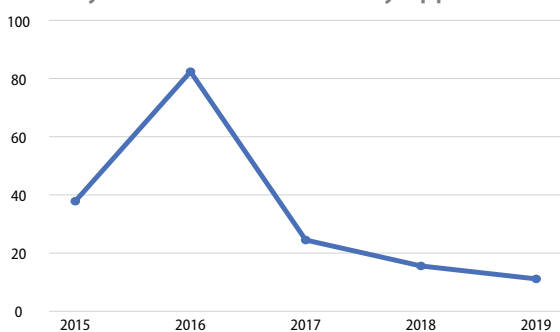
Mission: The mission of the Resource for Genetic and Epidemiologic Research (RGE) department is to administer a trusted resource for genetic and epidemiologic data to cultivate unparalleled research opportunities that will reduce morbidity and mortality or improve the quality of health care.

Services: RGE is a data resource for the collection, storage, study, and dissemination of medical and related information for research and public health projects.

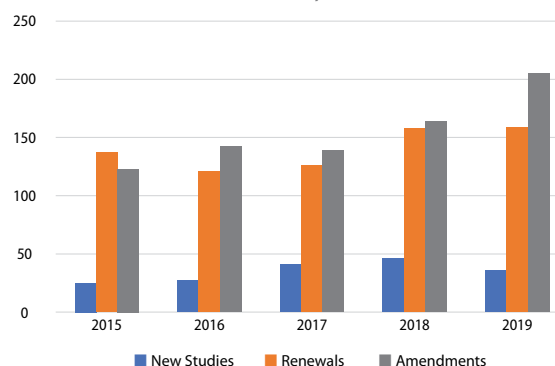
RGE approves access to data from the Utah Population Database, Utah Cancer Registry, Utah All Payer Claims Database, the University of Utah Enterprise Data Warehouse, the Intermountain Healthcare Enterprise Data Warehouse, and other sources of contemporary and historical data about Utah residents.

Statistics

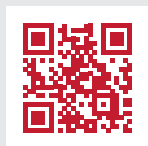
RGE Office/Committee Average Number of Days for Review of New Study Applications



RGE Reviews, 2015–2019



Visit us:



Quality Compliance

Mission: To facilitate safe, ethical, efficient, and high-quality research. The OQC provides research resources to ensure the protection of the welfare of human subjects and overall data integrity.

Services:

- Offer reviews for research teams across campus to use
- Provide standard operating procedures (SOPs) and guidance for clinical research teams across campus
- Furnish premade templates for use with monitoring and tracking study activities



Caren J. Frost, Director

The Office of Quality Compliance (OQC) is our newest department, created in January 2019. We are quickly getting up to speed and working hard to determine how best to serve constituents at the U of U. The team has been busy creating methods of data capture for reviews as well as a survey for satisfaction with reviews completed.

Recent Contributions

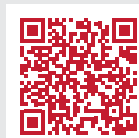
Standard Operating Procedures (SOPs)

SOPs are being finalized and will be available on the OQC website. In addition, the OQC has been working with the Clinical Trials Office in Pediatrics on SOPs for clinical trials. These SOPs provide guidance for clinical research and are available for any study team conducting clinical trial research activities across campus.

Research Quality Compliance Network (RQCN)

The first RQCN meeting was held in July 2020. The purpose of this network is to bring personnel and study teams working on compliance activities together to increase research connections and create a working group that will share information about compliance successes at the U of U.

Visit us:



Quality Control Reviews

The OQC has developed three types of reviews for research teams across campus to use. Beginning in the 2020–2021 academic year, the OQC will assist with three to five best practice reviews per month and conduct three to five routine reviews per month. For-cause reviews will be handled on an as-needed basis.

Best Practice Reviews

Reviews that can be completed by study teams wherein the study team answers questions about a specific study and the OQC team can review findings with the study teams


Routine Reviews

Reviews conducted by the OQC team wherein they will identify studies at random and conduct a compliance review of the selected studies

For-Cause Reviews

Reviews that the Associate Vice President for Research Integrity and Compliance requests the OQC complete due to a triggered event

Stay
Tuned →



Beginning in July 2021, we will be reaching out to research teams on the Health Sciences and Main campuses to ensure they are aware of the resources we offer!

Institution-Wide Initiatives

Research Climate Survey

Across the board, research has shown that an institution's "research climate" can contribute to how research is taught and practiced by professionals and students alike. In fall 2019, the University of Utah conducted an institution-wide survey to collect reliable data on the research and scholarship climate on campus.

We employed the Survey of Organizational Research Climate (SOURCE) to measure seven areas related to research/scholarship climates. The SOURCE is the most widely used validated instrument for assessing integrity climate for research and allows for comparisons to other institutions nationally.

Our goal was to identify areas where we excel as well as places where we can improve. We plan to repeat the survey in 3–4 years so we can assess our progress and continue to stimulate positive change.

The Associate Deans of Research have access to the survey data for all departments in their College, and Department Chairs have access to the survey data for their department. To access the full results of the survey, please visit the SOURCE website:

<https://source.nationalethicscenter.org/>

On the home page, please click Reset Password to receive an email with login information, and an email will be sent with a temporary password. When you are in the system, click Results to begin the review process.

Seven Areas of Focus

- Responsible Conduct of Research Resources (RCR)
- Regulatory Quality (RQ)
- Integrity Socialization (IS)
- Integrity Norms (IN)
- Adviser-Advisee Relations (AAR)
- (Lack of) Integrity Inhibitors (II)
- Departmental Expectations (DE)

How to Use the SOURCE Results

- Start or continue the discussion on the research climate within your department
- Identify areas of need for policies, resources, and practices for research activities across the University
- Assess the perceived efficacy of educational and mentoring activities
- Document trends over time with future administrations of the survey
- Strengthen grant applications by using the results to demonstrate an institutional commitment to improve the research climate

Institution-Wide Initiatives

Anonymous Reporting at the U of U

Reporting research misconduct or undisclosed conflicts of interest can be uncomfortable, but knowingly disregarding research misconduct or undisclosed conflicts of interest may entangle you with an allegation or investigation.

Research misconduct does not just happen. It stems from a slippery slope of bad behaviors. Although misbehaviors may not result in severe consequences, they can contribute to a lack of research integrity.

Examples of Research Misconduct	Examples of Research Misbehavior
<ul style="list-style-type: none"> • Fabrication of information • Falsification of information • Plagiarism of information • Other serious deviation from commonly accepted practices in the relevant scientific community for proposing, performing, or reviewing research or for reporting research results 	<ul style="list-style-type: none"> • Bullying, discrimination, and harassment in the research context • Failing to get informed consent • Not admitting missing data • Not attributing other authors • Not disclosing conflicts of interest • Failing to conduct an adequate literature review • Not including data on side effects in clinical trials

Recently we collaborated with Randy Van Dyke and the Internal Audit department to expand their ethics and compliance hotline to include research misconduct, conflicts of interest, and other research misbehaviors. Now, anonymous reporting is available for those who do not feel comfortable reporting directly.

To report anonymously, visit the website at EthicsPoint and complete the following tasks:

1. Enter University of Utah under Organization Name
2. Review the categories for reporting
3. To make a report, click your chosen category or call 888-206-6025

EthicsPoint



To report directly, communicate via one of the channels below:

- To request an ethics consult, email researchintegrity@utah.edu
- To report misconduct directly, email erin.rothwell@hsc.utah.edu or researchintegrity@utah.edu
- To report a financial conflict of interest, visit <https://coi.utah.edu/forms/activity-report.php>

New Institutional Policies for 2020

Authorship Policy

Based on attendee feedback at our recent E3 discussion on authorship, we recognized the need for an institution-wide authorship policy and are currently working on developing one. Michele Ballantyne, Caren J. Frost, and Allyson Mower are working with key stakeholders such as the Institutional Policy Committee and Academic Senate and Past Senate President Julio Facelli to create this policy. We thank everyone for their feedback and hope you will continue to join our dialogue to create a policy that will provide more guidance and prevent potential disputes.

Changes and additional resources were made to the Researcher's Handbook. A bit of sample text is included below.

Approximately 200 faculty, staff, and students attended our E3 authorship discussion, *Authorship in the Era of Interdisciplinary Collaboration: Does the U Need an Authorship Policy?*

Countless voices expressed "Yes."

We Heard U!

Sample Text: Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work. The University of Utah recognizes that authorship is important for faculty academic careers and that the lack of clear authorship policies may lead to unnecessary conflicts. The University also recognizes that authorship practices are very different for different disciplines and that general authorship policies and guidelines may not be the appropriate approach. Therefore, the University establishes the following as authorship policy: Each academic unit should explicitly adopt authorship policies consistent to the established practices of its discipline, these policies should be approved by the unit faculty, and the unit administrators should make every effort to make faculty, trainees, and research staff aware of the policies. It is recommended that each unit's policies follow those from the leading academic societies and journals relevant to the unit.

Biospecimen Policy (7-002A)

With help from Brian Watts, JD, a new policy was created to improve investigator responsibility and expectations for the ownership, access, and use of biospecimens and associated data.

This rule provides a framework to prevent and resolve disputes involving access to and use of biospecimens. Such disputes are routinely managed and resolved at the local level by University researchers and the applicable academic and administrative units. This rule is not intended to replace such management and resolution practices. Rather, it specifies general expectations associated with biospecimens and outlines a process that will be utilized by the VPR to address biospecimen access and use issues that cannot be adequately resolved by the applicable University researchers and academic and administrative units.