Human Research Protection Program Overview

Introduction

This document provides an overview and summary of the University of Utah Human Research Protection Program (University HRPP). This document is not a full representation of University policies and procedures governing the conduct of human subject research.

For more information about the mission and management of the University HRPP, review the University of Utah Research Handbook available online at http://osp.utah.edu/policies/handbook/. Additional information about the components of the University HRPP is available on the websites for each component.

Mission Statement

Protect the rights and welfare of human participants in research at the University of Utah and its research affiliates.

Management of the Human Research Protection Program

As per the Research Handbook[1], the Office of the Vice President for Research administers support for research and scholarly/creative work within the University community. This support includes responsibilities for:

- Extramural and intramural funding of scholarship. Externally supported research and sponsored programs from a significant part of the academic enterprise at the University of Utah. The Vice-President for Research administers all intramural funding programs as well.
- All pertinent federal mandates and guidelines related to support of research programs.
- Necessary infrastructure relevant to the administration of research and scholarly activities. Organizations reporting to the Vice-President for Research are responsible for:
    - Assisting faculty in identifying and obtaining funding for research, training and scholarly activities;
    - Assisting faculty in proposal and pre-award processing;
    - Assuring that all research applications, awards and activities comply with University policy;
    - Managing approved cost-sharing arrangements on grants and contracts; and
    - Assuring University compliance with state and federal research regulations.

The Vice President for Research has been designated by the Board of Trustees and the University President to serve as the Institutional Official on the University's Federal-wide Assurance and is ultimately responsible for the oversight and conduct of the HRPP. The Vice President is the signatory authority for all assurances.

Ethical Principals and Regulatory Adherence

The University HRPP subscribes to ethical principles set forth in The Belmont Report, which include respect for persons, beneficence, and justice.

The University of Utah has an active Federal-wide Assurance (FWA) with the Office for Human Research Protections (FWA00003745) and agrees to apply 45 CFR Part 46 whenever the University "becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance."

[1] University of Utah Research Handbook, Section 1.1

The University HRPP adheres to 21 CFR Parts 50 and 56 as well as other parts of 21 CFR as appropriate for clinical investigations regulated by the Food and Drug Administration (FDA). The University HRPP applies the principles of the International Conference on Harmonization's Good Clinical Practices (ICH-GCP) to clinical investigations, as adopted by the FDA and insofar as the standards and requirements are consistent with 21 CFR.

The University HRPP applies the standards of the HIPAA Privacy Rule (45 CFR Part 160 and Subparts A and E of Part 164) to research that involves the use of protected health information (PHI).

Additionally, the University HRPP adheres to the following regulations as applicable to specific research projects:

- Under a Memorandum of Understanding, the University of Utah IRB adheres to the IRB responsibilities and requirements outlined in 38 CFR Part 16 and the VHA Handbooks when reviewing and making determinations for research conducted at the Veterans Affairs Salt Lake City Health Care System (VASLCHCS).
- Under a Federal-wide Assurance Addendum with the Department of Defense (DoD), the University HRPP adheres to the requirements outlined in 32 CFR Part 219, 10 USC Section 980, and other applicable DoD instructions and research policies when conducting or collaborating in DoD supported human subject research.

The University HRPP applies different but comparable protections for research activities that are not subject to the FWA and other federal regulation in the following situations:

- For studies with no federal oversight or federal funding, the University of Utah IRB permitted continuing review to occur within two (2) years of approval. Granting two-year approval for new studies was discontinued in 2023 but the ongoing use of the two-year approval for studies undergoing continuing review is still allowed. Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review, including studies with no federal oversight or federal funding. See IRB SOP 404: Continuing Review.
- For studies with no federal oversight or federal funding, the University of Utah IRB designated additional exemption categories (A-E) allowing minimal risk research that fits into one or more of the additional exemption categories to be exempt from IRB review. See IRB SOP 401b: Research Activities Exempt from IRB Review.
- For studies with no federal oversight or federal funding, the pre-2018 Common Rule requirements for informed consent are required. The informed consent requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent in the Final Common Rule are not required but may be included. See IRB SOP 701: General Requirements of Informed Consent.
- For studies with no federal oversight or federal funding, the IRB will not reporting to OHRP if the IRB
- takes any of the following actions(see IRB SOP 905: Institutional Reporting Procedures):
    - Determines that an event represents an unanticipated problem involving risks to participants or others
    - Determines that non-compliance was serious or continuing
    - Suspends or terminates approval of research
- For studies with no federal oversight or federal funding, the IRB will apply the criteria and additional duties outlined in Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, with the exception that the IRB will not provide written certification to the Secretary that the duties of the Board have been fulfilled (outlined in §305(7)(c)). See Investigator Guidance Series: Research Involving Prisoners.

University Research Portfolio

As of June 2024, the University HRPP oversees more than 7,000 active human research projects, including studies of the types listed in Table 1.

Table 1: Types of Studies Overseen by the University HRPP

Biomedical Science Research	Social & Behavioral Science Research	Categories of Participants Included in Research
• Clinical Trials (Phase I, II, III and IV) • Placebo controlled studies • Retrospective chart reviews • Registries and databases • Tissue banks • Psychiatric research • Genetic research • Epidemiologic studies • Pharmacokinetic studies	• Qualitative research • Surveys/questionnaires • Interviews • Exercise and sports science research • Experiments involving deception	• Children • Adults • Pregnant women, fetuses, and neonates • Prisoners • Cognitively impaired individuals • Economically or Educationally Disadvantaged

Components of the Human Research Protection Program

The following components report through the Office of the Associate Vice President for Research Integrity and Compliance and formally constitute the HRPP.

Conflict of Interest (COI)

The Conflict of Interest Office supports the University community in identifying and managing financial conflicts of interest. The Office works with faculty, staff, postdoctoral fellows, students, and others who are required to disclose external financial interests to the University for evaluation. The Individual Conflict of Interest Committee and the Institutional Conflict of Interest Officer provide review and management of all potential conflicts by applying University policy.
https://coi.utah.edu/

Institutional Biosafety Committee (IBC)

The Institutional Biosafety Committee is part of the Office of Environmental Health and Safety for the University of Utah. The committee reviews and approves research involving the use of recombinant DNA and other biological toxins, rules on the appropriateness of proposed containment procedures, and sets suitable biosafety levels.
https://oehs.utah.edu/topics/biosafety

Institutional Review Board (IRB)

The IRB is charged with the review of all research projects that involve humans to ensure they comply with local, state, and federal laws, as well as the high ethical standards set forth in University policy. The IRB also acts as the HIPAA Privacy Board for research submissions. The IRB has seven panels and over 100 members who contribute to the review of these projects. The IRB continually strives to provide investigators and study teams the support and resources they need to conduct high quality research and foster excellent research practices that protect participants.
http://irb.utah.edu/

Office of Quality Compliance (OQC)

The mission of the Office of Quality Compliance is to facilitate safe, ethical, efficient, and high-quality research. The Office provides research resources to ensure the protection of human subjects and overall data integrity. The Office provides best practice reviews, self-assessment guidance, and audits for study teams to improve the quality of research activities. OQC also facilitates the Research Quality Compliance Network (RQCN). RQCN provides a forum for those involved in research to share and seek guidance on compliance-related topics from peers within the research community. The RQCN holds quarterly virtual network events and Compliance Cafés, a networking and informative session
https://qualitycompliance.research.utah.edu/

Research Education

Several continuing education and training opportunities are offered to the University community, which are

provided to support, develop and maintain a standardized body of knowledge and best practice methodology for all research personnel. Research Education (REd) provides a comprehensive curriculum for overall research administration and includes traditional classes and lectures, interactive workshops and educational resources designed to ensure compliance with governing regulations and to enhance the overall productivity of researchers. A Certificate of Achievement program is available in specialized Pre-Award, Post-Award and Clinical Research tracks of study.
https://education.research.utah.edu/

Research Misconduct
The Research Integrity Officer (RIO) is responsible for the evaluations of allegations of research misconduct. University policy regarding research misconduct is consistent with federal policy. "Misconduct" or "Misconduct in Research" is defined as fabrication, falsification, or plagiarism in proposing, conducting, or reporting research. Allegations of research misconduct undergo inquiry, investigation and hearing phases as appropriate.
https://integrity.research.utah.edu/research-integrity-officer/index.php

Research Participant Advocacy
The Office of Research Participant Advocacy engages with research participants during recruitment, participation, and post-participation to facilitate effective participant interactions and enhance participant safety. In addition to direct advocacy interactions, the Office provides language translation and interpretation services for clinical research, as well as community education and outreach.
https://rpa.utah.edu/

The Resource for Genetic and Epidemiologic Research (RGE)
The RGE governs access to certain data and research resources provided to the University of Utah for use in biomedical research. Datasets include the Utah Population Database (UPDB), health department records, and family and medical data from individuals enrolled in the High Risk Cancer Clinics (HRCC) at the Huntsman Cancer Institute. Access to these research resources requires review and approval by the RGE in addition to the standard research review process.
https://rge.utah.edu/

Additional Components Supporting Human Research Protection

The following components of the University report through the Office of the Vice President for Research and the Senior Vice President for Health Sciences Research. They provide support the HRPP to assess and implement human research protections.

Clinical and Translational Science Institute (CTSI)
The CTSI builds on the University's strengths in genetics and bioinformatics to translate promising bench science into practices that improve human health. The CTSI provides an optimal setting for medical investigators to conduct safe, controlled, state-of-the-art, in-patient and outpatient studies of both children and adults. Investigators who have research project funding from NIH and other peer-reviewed sources may use the CTSI. CTSI also supports the Clinical Research Support Office (CRSO) serves a central resource to support investigators and research teams that conduct clinical research across campus. Services and support are made available to all investigators and coordinators to promote smooth, efficient conduct of their research at the University of Utah.
https://ctsi.utah.edu/

Office of Sponsored Projects (OSP)
OSP is responsible for the effective and timely handling of research proposals. This includes preparing, interpreting, negotiating, and executing agreements on behalf of the University of Utah for projects funded by federal and state agencies, foundations, and other public and private sources. OSP also drafts, negotiates, and executes awards and sub-awards for collaborative research.
http://osp.utah.edu/

Protocol Review and Monitoring Committee (PRMC)
The PRMC has responsibility for reviewing cancer-related protocols for scientific merit (before a protocol is activated), scientific progress (after the protocol has been initiated) and participant accrual. It also prioritizes cancer protocols that may compete for the same patient population. If the study involves cancer patients, it must receive PRMC review and approval in addition to the standard research review process. Its function is complementary to that of the Institutional Review Board, which focuses on the protection of human subjects in research.

Radioactive Drug Research Committee & Human Use Subcommittee (RDRC-HUS)
The RDRC-HUS is required to evaluate and to approve or disapprove all research and developmental uses of radioisotopes on or in humans. As required by Utah Division of Radiation Control, the HUS evaluates and approves or disproves all proposed uses of ionizing radiation sources on or in humans for investigational or non-routine clinical procedures.
https://rso.utah.edu/committees/rdrc.php

Technology Licensing Office (TLO)
Technology Licensing Office (TLO) is a recognized leader in transforming new ideas into practical, commercially viable products and services. Technology Licensing Office provides process support services to companies and universities to help them successfully commercialize their intellectual property. TLO also facilitates the execution of Material Transfer Agreements for human subject research.
https://technologylicensing.utah.edu/

University of Utah Healthcare Investigational Drug Studies Program (IDS)
The IDS program provides investigational pharmacy services to University of Utah investigators. Services include the coordination of drug inventory and drug control procedures. The IDS pharmacists are responsible for ensuring that investigational drugs are handled according to state and federal laws and regulations, hospital policy, IRB policy, and sponsor protocol.
https://pharmacyservices.utah.edu/investigational-drug-service/index.php

Clinical Research Compliance and Education (CRCE) Office
The primary purpose of the CRCE Office is to ensure clinical research billing compliance through regulatory adherence; policy development; training and education; and auditing and enforcement.
https://uofuhealth.utah.edu/crce/

Information Privacy Office
The Information Privacy Office has responsibility for building and maintaining the necessary infrastructure to support the security of protected health information (PHI) for University patients and research participants. In addition, this office oversees the University's compliance with the HIPAA Privacy Rule.
https://uofuhealth.utah.edu/privacy-office/

Affiliated Human Research Protection Programs

Primary Children's Hospital (PCH)
PCH is physically located within the University of Utah Health Sciences Campus, but is owned and operated by Intermountain Healthcare and is affiliated with the University HRPP as well as the Intermountain Healthcare HRPP. The HRPPs work together to oversee collaborative research. The University of Utah serves as the primary IRB of record for studies conducted at PCH, as the majority of the physicians who practice at PCH are also University faculty. The University of Utah and Intermountain Healthcare have an active Memorandum of Understanding that addresses the responsibilities of each institution in this partnership. The Intermountain Privacy Board works closely with the University of Utah IRB for the review of waivers of authorization according to HIPAA.

Veterans Affairs Salt Lake City Health Care System (VASLCHCS)
VASLCHCS is physically located adjacent to the University of Utah campus. The University of Utah IRB serves as the primary IRB of record for VASLCHCS, as many of the physicians who practice at the VA are also University faculty. The IRB works closely with the VASLCHCS HRPP to ensure that research conducted at the VA is according to federal regulation and VA policies. The University of Utah and VASLCHCS have an active Memorandum of Understanding that addresses the responsibilities of each institution in this partnership.

Shriners Children's Hospital (SCH)
A number of physicians who practice at SCH are University faculty, and all human research conducted at this facility must be reviewed and approved by the University of Utah IRB. The University of Utah and SCH have an active Memorandum of Understanding that addresses the responsibilities of each institution in this partnership.

HRPP Communication Methods

The University HRPP communicates between its components, with investigators, and with affiliated HRPPs. Below is an overview of the communication methods that are utilized.

- The University HRPP utilizes the internet for the presentation of information, including policies and procedures, guidance, news and announcements, and so on. Many of the HRPP components have their own websites for which information specific to the component is posted and viewable by the research community, as well as the public.
- The University HRPP uses email listserv messages to communicate new information to the research community, including new and revised policies and procedures, news and announcements. Members of the research community can register for listserv messages that are relevant to their research responsibilities.
- The ERICA system is used to communicate with research teams and between HRPP components regarding study-related concerns, research review determinations, procedural reminders, etc. The ERICA system includes a substantial body of help text that reflects the policies and procedures of the University HRPP. The ERICA system is also used during research review to communicate requisite changes to study materials due to new or revised policies and procedure.
- The University HRPP communicates information about various policies and procedures via several education venues, primarily Research Education (REd). Additionally, components of the HRPP may choose to target educational outreach to defined research groups that may be most interested in new or modified policies and procedures.
- Leaders of the University HRPP regularly meet together and with officials from affiliated HRPPs to discuss ongoing concerns and changes to policies and procedures.

HRPP Quality Improvement and Compliance Plan

Quality improvement and compliance initiatives within the HRPP are coordinated by the University's Office of the Associate Vice President for Research Integrity & Compliance (AVPRIC). Within the HRPP are eight units that each have a vision statement, a five-year strategic plan, goals, and metrics from which to evaluate the work completed by the unit. Each unit has developed standard operating procedures (SOPs) as well as University-approved policies for its work. For four of the units, these SOPs and policies stem from federal regulations, which are reviewed in the context of the unit evaluations to determine how current and compliant units are with these defined operating procedures.

The following evaluation activities are conducted annually with each Unit Director.

At the beginning of the year, the Unit Director completes a self-assessment to describe how well the unit is currently achieving its mission and goals. The completed self-assessment documents are provided to the HRPP Director for review prior to an evaluation planning meeting. Using the unit's self-assessment, vision statement, five-year strategic plan, goals, and metrics, the HRPP Director and Unit Director meet to create an annual evaluation plan for the unit. Unit staff may be invited to be interviewed as well during this phase, specifically on questions about resources and environment. The unit uses the annual evaluation plan to perform at least one quality improvement and compliance project during the year. A copy of the evaluation plan is also provided to the AVPRIC.

At the end of the year, once the unit has had the opportunity to complete its quality improvement and compliance project(s), the HRPP Director evaluates the unit based on documentation provided by the Unit Director showing execution of the plan and achievement of strategic goals. The HRPP Director provides a written response to the Unit Director to acknowledge whether the evaluation has resulted in successful outcomes and if additional corrective/preventive actions are needed to improve quality and compliance within the unit. A copy of the response is also provided to the AVPRIC. Once the response is provided, the Unit Director and HRPP Director meet to review the report and create a plan of action to address any necessary issues or deficiencies. The Unit Director reports to the HRPP Director and AVPRIC within 30 days on steps taken to correct deficiencies. The results of this evaluation, in turn, may be used to modify the unit's goals and draft the next year's evaluation plan.

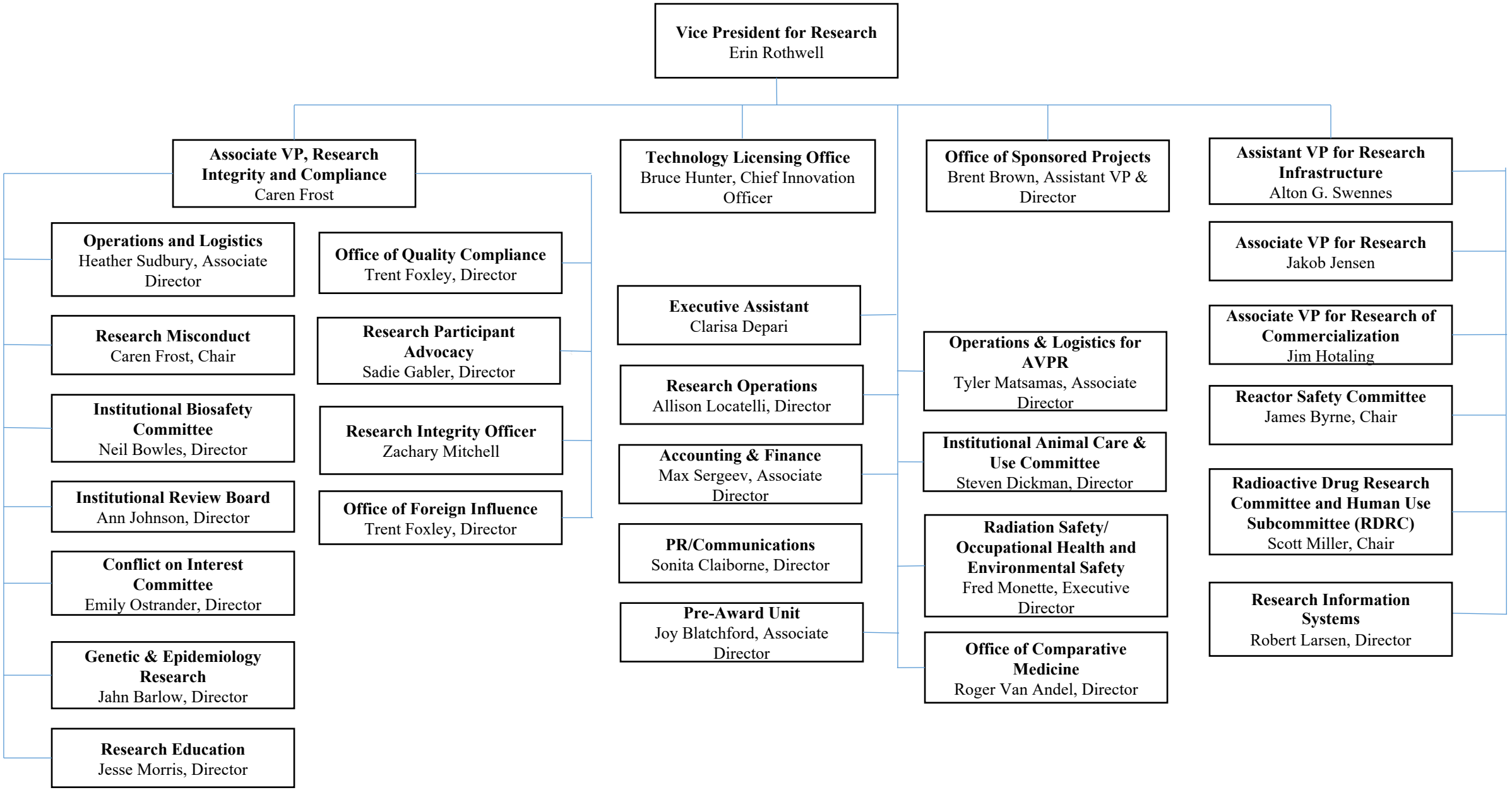
A summary of the evaluation outcomes for all eight units is provided to the Vice President for Research in the annual evaluation of resources needed for the units of the HRPP.

The following evaluation activities are conducted every three years.

- A strengths, weaknesses, opportunities, and threats (SWOT) analysis is conducted with the Unit Directors during a two-hour retreat with all Unit Directors in attendance.
- The HRPP Director initiates an audit of each unit to ensure that high quality, ethical, and compliant operations are being maintained.

The HRPP also participates in external monitoring events and utilizes these outcomes toward improving the compliance of the HRRP components. External monitoring may be conducted by, but is not limited to, the following agencies/groups:

- Office of Human Research Protections (U.S. Department of Health and Human Services)
- U.S. Food and Drug Administration
- Veterans Affairs Office of Research Oversight
- University of Utah Office of Internal Audit (external to the Office of the Vice President for Research)
- National Institutes of Health
- Centers for Disease Control and Prevention
- Utah Division of Radiation Control



HRPP Organizational Chart