

Institutional Review Board (IRB)

The IRB reviews proposed research protocols to protect human subjects involved in research within the Intermountain Healthcare system. We also review protocols that involve human biological material and protected health information.

IRB is responsible for the following:

- Reviewing and approving applications to conduct research that involves human subjects.
- Continuing review of approved protocols.
- Monitoring reported adverse events that involve subjects in approved protocols.
- Assuring and facilitating the ethical conduct of biomedical research that involves human subjects.

The IRB of record for Primary Children's Medical Center is the University of Utah.

Faculty from the Department of Pediatrics at the University of Utah apply through the ERICA system – <http://www.ERICA.research.utah.edu>

Studies lead by investigators outside the Department of Pediatrics that utilize Intermountain resources and data must submit an IRB application through the Intermountain Office of Research.

Intermountain employees leading research projects within Intermountain Healthcare apply for IRB approval through the Intermountain Office of Research and the Research Management System – <http://intermountainhealthcare.org/qualityandresearch/researchmanagement>.

Intermountain Privacy Board

In order to facilitate pediatric research at Primary Children's Medical Center, we will accept approvals from the University of Utah Institutional Review Board for data research using Intermountain pediatric patients. The approval will apply to principal investigators who are pediatricians and pediatric subspecialists at the University of Utah within the Department of Pediatrics as well as university staff who specialize in pediatric ophthalmology, pediatric dermatology, pediatric orthopedics, and pediatric surgery. The applications entered into ERICA for Primary Children's data research will be reviewed by the Intermountain Privacy Board. Then the decision of this Board will be submitted to the University of Utah's IRB for final approval.

Primary Children's Medical Center

Medical research complements the mission of Primary Children's Medical Center and the Department of Pediatrics at the University of Utah by providing and improving excellent patient care in the following ways:

BETTER MEDICAL OUTCOMES —

Primary Children's focuses on translational research studies and clinical trials that directly improve quality of care. These outcomes are shared broadly through presentations and publications.

TREATMENT INNOVATIONS —

Research offers patients opportunities to receive treatment innovations and bring funding into the facility.

ATTRACTING MEDICAL EXPERTS —

Primary Children's research support helps attract leading physicians, nurses, and caregivers. This contributes to better patient care.

GETTING STARTED

1. Research projects must identify how the research may improve patient care or enhance clinical outcomes.
2. Projects require prior departmental approval and, in some cases, approval of departments and service lines that will be impacted. Please communicate with affected areas before submitting the proposal to the Institutional Review Board (IRB).
3. Plan ahead. Consider consulting the IRB and Intermountain Privacy Board when preparing the project. The IRB of record for Primary Children's Medical Center is the University of Utah. Primary Children's does not delegate oversight of records to the University of Utah. IRB and privacy review and approval takes time.

We are a learning organization and know that supporting research improves outcomes, furthers knowledge, and advances medical innovation.

OFFICE OF RESEARCH/PEDIATRIC EDUCATION SERVICES
LOCATED AT PRIMARY CHILDREN'S MEDICAL CENTER

E-MAIL: JONELL.MURRAY@IMAIL.ORG
PHONE: 801.662.3511
FAX: 801.662.3522

PEDIATRIC CLINICAL TRIALS OFFICE
LOCATED AT THE WILLIAMS BUILDING

E-MAIL: STEFANIE.BJERREGAARD@HSC.UTAH.EDU
PHONE: 801.587.7484
FAX: 801.585.9410



Research at Primary Children's Medical Center

Primary Children's and the Department of Pediatrics at the University of Utah are committed to support and assist clinicians and patients with medical research.

Data and Statistical Resources for Investigators:

UNIVERSITY OF UTAH PEDIATRIC RESEARCH EXCELLENCE PARTNERSHIP (PREP)

The PREP office in the Department of Pediatrics and under the guidance of Dr. Carrie Byington, provides data extraction, analysis and statistical support for pediatric clinical research. Assisting Pediatric Clinical Translational (PCAT) scholars in IRB preparation, study design, and data support is our top priority. However, we will assist any pediatrician with clinical research, if our workload allows, or we can direct investigators to resources available to them. The PREP data support team has access to data in the Intermountain Healthcare enterprise data warehouse (EDW), pediatric hospital information system (PHIS), and Healthcare Cost and Utilization Project Kid's Inpatient database (HCUP-KID). They can partner with other data sources such as the Utah Population Database (UPDB) or Select Health to extract appropriate data required to answer your research questions.

Contact: Kent Korgenski at kent.korgenski@imail.org or 801.213.3293.

INTERMOUNTAIN STATISTICAL DATA CENTER

The Statistical Data Center is a team of statisticians available to help with design, analysis, and interpretation of research within Intermountain Healthcare.

Statisticians can help with research study design and results analysis. Although help is available at any stage, most researchers benefit from talking with a statistician earlier in the process rather than later.

The Statistical Data Center does not collect data or write proposals or articles, but helps with data entry and statistics.

Initial consultations are free. If a grant is involved, then the Statistical Data Center should be included on the grant. Short-term projects, less than 20 hours, and certain other projects are accomplished without charge to the investigator. Ask about rates for other projects.

Contact: Greg Snow, PhD at greg.snow@imail.org or 801.408.8111.

SYSTEM IMPROVEMENT AT PRIMARY CHILDREN'S MEDICAL CENTER

The Primary Children's Department of System Improvement includes a team of data analysts with the ability to extract data from the various clinical information systems used at the hospital. This group can create research data sets, prepare charts and graphs, and provide basic statistical support to researchers.

Contact Tanya Stout at tanya.stout@imail.org or 801.662.6508.

STUDY DESIGN AND BIostatISTICS CENTER (SDBC)

The SDBC, in collaboration with the University of Utah Pediatric Research Excellence Partnership (PREP) office, provides biostatistical collaborations for grant applications, study design, measurement, and data analysis for research performed by Primary Children's investigators. The SDBC is the statistics core of the University of Utah Center for Clinical and Translational Science, and includes 34 members with a wide array of statistical and epidemiologic expertise. Meetings with a biostatistician, epidemiologist, or survey design expert can be requested using the Research for Collaboration form on their website.

<http://www.ccts.utah.edu/biostats/>

Other Resources:

PEDIATRIC CLINICAL TRIALS OFFICE (PCTO) – UNIVERSITY OF UTAH

The Pediatric Clinical Trials Office (CTO), developed under the Women and Child Institute, is a collaboration between the Department of Pediatrics and the Department of Obstetrics/Gynecology at the University of Utah School of Medicine. The CTO's mission is to provide clinical investigators and sponsors with comprehensive support services, research tools, and support staff to conduct research studies.

The CTO employs a pool of research coordinators and research assistants who coordinate start-up implementation, quality control, and completion of clinical research studies while helping principle investigators determine and accomplish study objectives.

Contact: Stefanie Bjerregaard at stefanie.bjerregaard@hsc.utah.edu or 801.587.7484.



GRANT PROPOSALS AND PUBLICATIONS

The Intermountain Office of Research helps its investigators locate funding opportunities and maintain relationships with many agencies that support health research. Proposal and manuscript preparation assistance is also available. Specifically we offer: budget preparation (including pricing patient costs), coaching, editing scientific scope, and aligning applications to the sponsor's specifications.

Contact: Shauna Bruun at shauna.bruun@imail.org or 801.408.2137

PRIMARY CHILDREN'S FOUNDATION

Primary Children's Foundation supports several small grant programs that provide funding for innovative research (clinical and basic science) in pediatric medicine and surgery. Grants range between \$5,000 and \$25,000 annually for a maximum of two years. Information is available on the University of Utah Department of Pediatrics website or through the Primary Children's Foundation office.

Contact: 801.662.5959.

CONTRACTS

The Intermountain Office of Research reviews, negotiates, and accepts grant terms and conditions, contracts, and subcontracts related to research at Primary Children's Medical Center. The Intermountain Office of Research also coordinates contract review with Intermountain's legal department and prepares grants and contracts for Intermountain's Chief Medical Officer's signature.

Contact: Jesse Whitfield at jesse.whitfield@imail.org or 801.408.1729.

INSTITUTIONAL ACCOUNTS AND PATIENT BILLING

The Clinical Research Financial Analyst and the PAS Team maintain all institutional accounts related to clinical studies at Primary Children's Medical Center. To ensure appropriate patient billing, all applicable accounts are maintained in the STAGES system.

Contact: Donnette Hill at donnette.hill@imail.org or 801.442.8426
Ricardo Curletto at ricardo.curletto@imail.org or 801.662.6285.