Welcome, Research Colleagues!

The Intermountain Healthcare Research 2016 Guidebook represents just one of many ways that Research is working to keep you informed and provide you with the tools you need for conducting groundbreaking clinical research. As our vision grows and transforms the way we do research at Intermountain, we will continue to build our comprehensive support structure for researchers.

The Guidebook includes an abbreviated Annual Report, containing relevant data points regarding our research activities over the past 12 months, followed by content specific to the processes and resources available to you as you conduct research.

We are working to keep you *informed* and provide you with the tools you need for conducting *groundbreaking research*.

Within the pages of this publication you will find research roles clarified, assistance in understanding current research processes, available research education classes and other resources.

If, after studying this material, you have any questions, feel free to contact me or another appropriate Office of Research colleague for more help.

*Raj Srivastava*

Raj Srivastava, MD, MPH
Assistant Vice President of Research
Intermountain Healthcare
“Wherever the art of medicine is loved, there is also a love of humanity.”
— Hippocrates

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## Research Resources

<table>
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<td>Medical Librarians</td>
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<td>Data and Analytics</td>
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<td>Enterprise Data Warehouse (EDW)</td>
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<td>EDW Data and Support Staff</td>
<td>20</td>
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<td>Process for Requesting Data from the EDW</td>
<td>20</td>
</tr>
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<td>20-21</td>
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<td>Intermountain Leadership Institute</td>
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<td>Statistical Data Center (SDC)</td>
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<td>Biospecimens</td>
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<td>Intermountain BioRepository</td>
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</tr>
</tbody>
</table>

Medical research complements Intermountain’s core mission to help people live the healthiest lives possible.
Back in the 1950s, long before Intermountain came into being in 1975, investigators at our original flagship LDS Hospital were conducting formal, structured biomedical research studies. Since then, Intermountain’s research activities have expanded dramatically. Our current flagship quaternary adult facility, Intermountain Medical Center, joins the region’s leading academic children’s institution, Primary Children’s Hospital, three other major tertiary teaching hospitals, 17 community hospitals, and almost 200 community-based outpatient clinics in advancing the healing professions’ shared biomedical knowledge. Over the years, Intermountain has been involved in many thousands of studies across dozens of clinical specialties. Currently, over 1,500 studies are open and actively underway within the Intermountain system.

Medical research complements Intermountain’s core mission of providing and improving excellent patient care. We have invested very heavily in clinical data systems and management structure to assure world-leading clinical performance. Our aim is to consistently provide our patients “the best medical result at the lowest necessary cost.” The resulting data infrastructure means that every patient treated at any Intermountain inpatient or outpatient facility contributes structured data for formal learning. Intermountain thus stands as an example of a “Learning Healthcare System,” where routine state-of-the-art patient care also produces rapid advances in formal medical knowledge.

**OUR RESEARCH PRIORITIES ARE:**

- **First**, Type I studies, research that will have a rapid impact on care delivery performance, focused on achieving the best medical result at a lowest necessary cost. Very often, these studies arise from Intermountain’s Clinical Programs, which oversee care delivery performance within the Intermountain system.

- **Second**, studies initiated by Intermountain-affiliated clinician-researchers, usually with sponsored external funding and often with academic collaborations.

- **Finally**, Intermountain participates in multi-center trials sponsored by industry-based national groups.

Intermountain-based research expands our patients’ access to a wide variety of treatment options. It also helps attract leading physicians, nurses and other caregivers who are interested in world-class clinical investigation that leads to demonstrably better patient care.
Research improves patient care and wellbeing for many. We conduct high quality research focusing on areas of high impact; partner with Intermountain’s Clinical Programs; convert concepts into state-of-the-art clinical care; distribute results across the Intermountain system for integration into clinical practice; and communicate results externally for extramural benefit.

Research encourages expertise. We work to attract and retain clinicians with the interest, knowledge, and focus to advance clinical care.

We effectively communicate accomplishments. We have purposes and benefits that are well-communicated and well-understood both internally and externally, and that help distinguish Intermountain as a model system where new techniques are both explored and implemented.

Research is financially responsible. We establish partnerships and manage project selection to minimize system subsidy, bringing about tangible care improvements as efficiently as possible.

We are effectively resourced and optimally efficient. We provide the clinical investigator with efficient access to research support services and to funding mechanisms; establish standardized process flows where appropriate and integrate line management into the process for successful implementation.

The Office of Research stays abreast of all rules and regulations to ensure internal compliance.

Research improves patient care and wellbeing for many. We conduct high quality research focusing on areas of high impact and partner with Intermountain’s Clinical Programs.
### JANUARY – DECEMBER 2015

#### Open Studies

<table>
<thead>
<tr>
<th>Year</th>
<th>2015</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1583</td>
<td>1471</td>
<td>1515</td>
</tr>
</tbody>
</table>

#### Sponsored Funding

<table>
<thead>
<tr>
<th>Year</th>
<th>2015</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>External Funding</td>
<td>$13,571,642</td>
<td>$18,604,636</td>
<td>$21,132,522</td>
</tr>
<tr>
<td>Expenses</td>
<td>19,916,368</td>
<td>19,259,160</td>
<td>26,067,281</td>
</tr>
<tr>
<td>Excess Expense Over Revenue</td>
<td>6,343,710</td>
<td>654,524</td>
<td>4,934,759</td>
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</table>

#### Grants Submitted

<table>
<thead>
<tr>
<th>Year</th>
<th>2015</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>55</td>
<td>65</td>
<td>78</td>
</tr>
</tbody>
</table>

#### Intermountain Research and Medical Foundation

<table>
<thead>
<tr>
<th>Year</th>
<th>2015</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>29 projects submitted; 12 funded</td>
<td>43 projects submitted; 16 funded</td>
<td>37 projects submitted; 17 funded</td>
</tr>
</tbody>
</table>

#### Contract Activity

<table>
<thead>
<tr>
<th>Year</th>
<th>2015</th>
<th>2014</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>293</td>
<td>256</td>
<td>184</td>
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</table>
LEADERSHIP TEAMS

RESEARCH GUIDANCE COUNCIL (RGC)
Chaired by Raj Srivastava, MD, MPH, Assistant Vice President of Research
The Council guides strategy and provides oversight to encourage research excellence within the Intermountain system. Its principle focus is the funding and support of research that will improve health and reduce unnecessary healthcare expense. It serves as an oversight body for the Intermountain system, ensuring a consistent research cycle that ranges from prioritization and resourcing of initial ideas to identification of best practices to system-wide implementation of those best practices to measurement of results to publications and presentations.

EFFECTIVE RESEARCH RESOURCES (ERR)
Led by Raj Srivastava, MD, MPH, Assistant Vice President of Research
The focus of ERR is to support researchers by improving how Intermountain conducts research and communicates the results. The team places emphasis on developing processes and building an organizational structure that leads to efficiency and higher quality within the research study process.

RESEARCH AREAS AND LEADS
- Behavioral Health
  - Brenda Reiss-Brennan
- BioRepository
  - Patti Spencer
- Blood/Marrow Transplant
  - Linda Meaux
- Cancer Genomics
  - Lincoln Nadauld
- Cardiovascular
  - Patti Spencer
- Central Lab
  - Bruce Middleton
- Communications
  - Susan Gagnier
- Contracts
  - Ahsen Khan
- Critical Care
  - Tom Graydon
- DNA Lab
  - John Carlquist
- Foundation
  - Becky Lloyd
- General Specimen Collection
  - Patti Spencer
- Genetics
  - Steven Bleyl
- Grant Accounting
  - Rebecca Nielsen
- Grants Submission
  - Shauna Bruun
- Hyperbaric
  - Lindell Weaver

Intermountain Leadership Institute
  - Brent James
  - Lucy Savitz
Imaging
  - Keith White
Infectious Diseases
  - Bert Lopansri
Invention Management
  - Mike Mayer
Institutional Review Board (IRB)
  - Shelby Moench
Medical Informatics
  - Kathryn Kuttler
  - Sid Thornton
Medical Librarians
  - Dave Castelli
  - Emily Eresuma
  - Shawn Steidinger
Nursing
  - Linda Hofmann
Oncology Clinical Trials
  - Julie Ballard
Organ Transplant
  - Kandis Schwartz
Orthopedic Research
  - Tyler Barker
Pediatrics
  - Jonell Murray
  - Carolyn Reynolds
Physical Therapy
  - Gerard Brennan
Primary Care
  - Wayne Cannon
Project Management & Proposal Development
  - Brad Isaacson
Pulmonary
  - Tom Graydon
Sleep Disorders
  - Robert Farney
Sports Science
  - James Walker
Statistical Data Center
  - Greg Snow
Surgical Services
  - Shelly Stinson
Transformation Lab
  - Katherina Holzhauser
Trauma
  - Tom Graydon
Women & Newborns Research
  - Peggy Reed
INTERMOUNTAIN HEALTHCARE RESEARCH

Principal Investigator (PI)
Roles & Responsibilities
Qualifications to perform research are based on prior experience in the conduct of research, training and education.

Principal Investigator Assurances
As a researcher, you are required to make sure the following scientific and administrative needs are met:

Scientific:
- Provide adequate study design and methodology
- Demonstrate the potential value to patient care, or future patient care
- Conduct research in accordance with protocol
- Ensure subjects have access to care at all times

Administrative:
- Demonstrate expertise related to research curriculum vitae
- Obtain approvals to conduct the research (department, facility, accounting, IRB/Privacy, and clinical program)
- Receive adequate training
- Participate in site visits, monitoring visits and audit the study
- Research management – oversee research personnel, manage budgets and costs
- Provide disclosure and protection of Intermountain assets and intellectual property
- Report progress and results as required and appropriate (to IRB & sponsors)
- Provide record and sample protections, retention and destruction (as may be required)
- Manage a data-sharing plan as required by NIH (if applicable)

INTERMOUNTAIN FACILITY ROLE/RESPONSIBILITY

Institutional Assurances
The institution is responsible to ensure the following needs are met:

- Provide resources and personnel for the design and conduct of research
- Assure and maintain research policies and infrastructure for institutional compliance in:
  - Human subjects and privacy
  - Conflict of interest and research misconduct
  - Financial and legal compliance
  - Research education and training programs

For more detailed information and requirements see: Principal Investigator Responsibilities Research Guideline.
OVERVIEW OF WHAT WE DO

OFFICE OF RESEARCH

Grants
We provide grant application assistance (federal and non-federal). We review agency requirements, assure application business information is accurate and complete, review/approve budgets, assist with literature reviews, provide scientific consultation, and submit grants on behalf of Intermountain researchers. We maintain passwords and institutional profile/registration(s) including the System for Award Management (SAM). We also coordinate applications with partnering institutions (such as the University of Utah), as well as providing help with letters of support.

Award Acceptance & Contracting
- Receive grant awards centrally (federal and non-federal).
- Negotiate contracts for research with legal and coordinate contract execution.
- Develop and issue contracts for research as needed.
- Work closely with the Invention Management Office on contracts with industry and also issue Data Sharing Agreements and Material Transfer Agreements when needed (refer to Intermountain contract policy).

Grant Accounting
We are responsible for account management (income and expense management), invoicing and financial reporting required from sponsored awards and contracts.

Clinical Research Billing
We manage compliance with Centers for Medicaid and Medicare Services (CMS) rules related to patient billing and research.

Statistical Data Center
We provide biostatistician support on research projects. We offer expertise in study design; data collection, management and analysis; and provide statistical support on grant applications and publications.

Clinical Study Management
The Departments of Women and Newborns Research and Oncology Clinical Trials report through the Office of Research. These departments support multi-site studies throughout the system. Cardiovascular research and pulmonary research at Intermountain Medical Center can also provide clinical study management services.

BioRepository
Intermountain BioRepository is a centralized resource for research involving biologic samples and linked clinical data.

Research Education
Online and classroom courses are available and described later in this Guidebook. The Office of Research coordinates research lectures and the Annual Research Summit.

Project Management Services
We offer expert project management services for seeing research through from start to finish.

Research Communications Services
We offer professional writing and communication support for assistance with journal publications, internal/external public relations initiatives, social media promotions, grant applications, and more.

Graphic Design Services
We offer graphic design services for both print and web projects. We can assist you with research presentations, abstract poster displays, logos, web visuals, videos, infographics, and much more.
Intermountain has an IRB that reviews research involving human subjects before the research is conducted to ensure human subjects’ rights and welfare are protected, potential risks are minimized and that there are benefits to participants and our community.

The IRB is responsible for:

- The review and approval of applications to conduct research involving human subjects
- Continuing review of approved protocols
- Monitoring safety information
- Assuring and facilitating the ethical conduct of research

IRB applications are accepted online in iRIS at: https://iris.intermountain-healthcare.org.

For access to iRIS please call the IRB Office at 801.408.1991 option1 or send an email to IRB@imail.org.

IRB Meeting Schedules and Committee Rosters are available online at: https://m.intermountain.net/Research/IRB/Pages/Home.aspx.

Do you need IRB approval?

All research projects must be submitted to the IRB for an official research determination. The IRB, not the researcher or department manager, determines the appropriate review categorization of each study. When determining whether the project needs IRB approval, the IRB considers the following:

1. Is the project considered “research”?
2. Is the project a “systematic investigation”? A “systematic investigation” means that you will use a predetermined method or a plan for studying your specific topic, answer a specific research question(s), and test a specific research hypothesis. A systematic investigation may also incorporate collection of data (quantitative or qualitative), specimens, and/or analysis of data.
3. Does the project include research development, testing, and/or evaluation, designed to develop or contribute to generalizable knowledge?

Projects “designed to develop or contribute to generalizable knowledge” are projects designed so you may draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.

The purpose of the IRB is to assure and facilitate the ethical conduct of biomedical research involving human subjects (focus is on patient safety).

Is the project a “human subjects research” project?

- Does the research include a study of living individuals (or can the research impact living individuals)?
- Does the research involve intervention or interactions with “human subjects”? Will the project require use of or need access to identifiable private information from the participants?
- Will the project collect or access data or specimens with identifiable private information? (Examples include initials, ages, zip codes, dates of collection.)
- Are the data/specimen(s) coded such that a link exists that could allow the data/specimen(s) to be re-identified?
- Is the project federally sponsored/funded (grant monies) for the project?

Following initial review, the IRB will notify the researcher of whether the research qualifies as exempt or if further IRB review is required.
The Research Series is a collaborative effort of the Office of Research and the Intermountain Leadership Institute and is presented in an electronic format for convenience.

In conducting research, education is somewhat dependent on the role a person has related to the research project and a person’s professional development interests. Research courses are specifically designed and recommended (if not required) for Intermountain Principal Investigators, researchers, regulatory and clinical coordinators and involved staff. The courses are developed to teach principles of research compliance, study design and methodology, and study management.

We have provided a summary of research courses available: Intermountain subscribes to online research education through the CITI Program at www.citiprogram.org, which provides comprehensive web-based research training courses. The following chart is a listing of the recommended CITI courses and the recommended audience:

<table>
<thead>
<tr>
<th>CITI COURSE NAME</th>
<th>PRINCIPAL INVESTIGATORS (PI)</th>
<th>RESEARCHERS</th>
<th>STUDY COORDINATORS</th>
<th>REGULATORY COORDINATORS</th>
<th>INVOLVED STAFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human Subjects Research (HSR) HHS &amp; Intermountain</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td>Responsible Conduct of Research (RCR) HHS for many NIH Grants</td>
<td>Required for PI role on federal grants/contracts</td>
<td>Recommended for federal grants/contracts</td>
<td>Recommended for federal grants/contracts</td>
<td>Recommended for federal grants/contracts</td>
<td>Optional</td>
</tr>
<tr>
<td>Conflicts of Interest (COI) FDA; HHS</td>
<td>Required every 4 years for federal grants/contracts</td>
<td>Required every 4 years for federal grants/contracts</td>
<td>Required every 4 years for federal grants/contracts</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Good Clinical Practice (GCP) (Delegation Logs/Protocol Training) FDA Guidance</td>
<td>Required if clinical studies with human subjects (non-data studies)</td>
<td>Required if clinical studies with human subjects (non-data studies)</td>
<td>Required if clinical studies with human subjects (non-data studies)</td>
<td>Required if clinical studies with human subjects (non-data studies)</td>
<td>Optional</td>
</tr>
<tr>
<td>Biosafety and Biosecurity (BSS) International Health Regulations; HHS for NIH funding</td>
<td>Required if study involves Recombinant DNA</td>
<td>Required if study involves Recombinant DNA</td>
<td>Required if study involves Recombinant DNA</td>
<td>Required if study involves Recombinant DNA</td>
<td>Optional</td>
</tr>
</tbody>
</table>

Note: The notation in RED is the federal source requirement.

Intermountain considers the CITI training a baseline of required and recommended training. In order to adequately ensure safety and compliance in research the chart on page 13 identifies recommended supplemental research courses and the recommended audience.
## RECOMMENDED SUPPLEMENTAL RESEARCH COURSES AND THE RECOMMENDED AUDIENCE

<table>
<thead>
<tr>
<th>INTERMOUNTAIN COURSE NAME AND LOCATION</th>
<th>PRINCIPAL INVESTIGATORS (PI)</th>
<th>RESEARCHERS</th>
<th>STUDY COORDINATORS</th>
<th>REGULATORY COORDINATORS</th>
<th>INVOLVED STAFF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator Responsibilities – located at the Office of Research intranet page under “multimedia content”</td>
<td>Required</td>
<td>Recommended</td>
<td>Required</td>
<td>Required</td>
<td>Recommended</td>
</tr>
<tr>
<td>Intermountain Policy; FDA Guidance</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
</tr>
<tr>
<td>Research Financial Rules and Grant Accounting – located at the Office of Research intranet page under “multimedia content”</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
<td>Optional for federal grants and contracts</td>
</tr>
<tr>
<td>Does My Project Need IRB Approval? – located at the Office of Research intranet page under “multimedia content”</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Introduction to Epidemiologic Methods – located at the Office of Research intranet page under “multimedia content”</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Study Design – located at the Office of Research intranet page under “multimedia content”</td>
<td>Required</td>
<td>Required/Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Beyond GCP Good Study Oversight and Compliance for You – located at the Office of Research intranet page under “multimedia content”</td>
<td>Optional</td>
<td>Optional</td>
<td>Required if consenting human subjects</td>
<td>Recommended for QA purposes</td>
<td>Optional</td>
</tr>
<tr>
<td>Mastering the Informed Consent Process and Documentation (including Non-English Speaking) – located at the Office of Research intranet page under “multimedia content”</td>
<td>Required if consenting human subjects</td>
<td>Optional/Required if consenting human subjects</td>
<td>Required if consenting human subjects</td>
<td>Recommended for QA purposes</td>
<td>Optional</td>
</tr>
<tr>
<td>Scientific Posters: A How To – located at the Office of Research intranet page under “multimedia content”</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
<td>Optional</td>
</tr>
<tr>
<td>Research Orientation – available 2016 at the Office of Research intranet page under “multimedia content”</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Recommended</td>
<td>Optional</td>
</tr>
</tbody>
</table>
**RESEARCH EDUCATION**

**AUDIENCES**

**Principal Investigators (PI)**

PIs are responsible for the overall scientific and administrative oversight of the study. Refer to the Intermountain Principal Investigator Responsibilities Guideline for more information in the Intermountain Policy Library.

Researchers can be PIs but may also be involved in research studies in other capacities, such as: conducting literature searches, developing study plans and protocols, preparing applications to IRB and to granting agencies, recommending study design and data requirements, accessing data for research, preparing research records, storing research records, analyzing research records, generating research reports, publications and presentations about research and research results.

Research Clinical Coordinators are trained on Good Clinical Practices (GCP) in conducting clinical research; must be competent to GCP and departmental Standard Operating Procedures (SOP) for conducting clinical studies with PIs; involved in enrolling research subjects and performing informed consent interviews and documentation; collecting and submitting study data; and involved in all phases of clinical studies through closeout and auditing.

Research Regulatory Coordinators are trained on Human Subject regulatory requirements as well as agency and sponsor requirements in conducting clinical studies and the FDA guideline for Good Clinical Practices.

Involved Research Staff depends on their role in the organization. Examples include department managers, accountants, office staff, compliance, and risk management.

**ASSIGNMENT TYPE**

(Education is Optional, Recommended, Required, or Mandatory per Intermountain Education Policy):

**Optional Education:** Education activities that support learning for professional and personal development. Optional education is available for self-enrollment, but does not have a required due date that triggers employee sanctions.

**Recommended Education:** Professional education activities that contribute to an employee’s success in their current or future role. This education is assigned, but does not have a required due date that triggers employee sanctions.

**Required Education:** Professional education activities that directly support orientation, equipment, systems, policies, procedures or external requirements of the organization. It is assigned with a specific due date and may be subject to audit at any time. Completion of this education by the due date is necessary to maintain competency, safety, compliance, or credentialing requirements.

**Mandatory Education:** Professional education activities that have the highest level of personal and organizational accountability, in addition to all attributes of required education. Mandatory education is defined by the Education Steering Committee and only assigned by the Central LMS team.
RESEARCH PROCESSES

PROJECT APPROVALS
Research studies are initiated by independent researchers (physicians, nurses, staff) who then get approval to conduct research within their own department. Researchers must also make sure that departments that are impacted by the research also approve. For example, if a study is to be conducted that will impact surgery or endoscopy, surgical services should be consulted in advance and approve the study. At a minimum, the departments should review for adequate study resources and impact to budgets when approving research to be conducted. Sponsored studies also need to be approved by a researcher’s department and impacted departments prior to submission for funding.

External Research Collaboration Committee (ERCC) — Chaired by Brad Isaacson. Established under the Research Guidance Council in 2010, the purpose of the External Research Collaboration Committee (ERCC) is to assure integrity and consistency in the use of Intermountain data and materials (patient samples) on research projects and activities with external entities per the External Research Relationship Guideline.

The ERCC triages and reviews external research projects involving data and/or material for which there is no internal Intermountain advocate and/or the study has not received an internal review and approval through a clinical program or department (what might be referred to as a “business owner”).

The ERCC maintains criteria and processes to approve projects and activities with external entities that involve the transfer of Intermountain data and/or materials (patient samples) for: compliance with Intermountain policies, compensation and/or financial support, contractual requirements and compatibility with Intermountain’s research mission.

Literature Searches
Intermountain Medical Librarians can identify appropriate information resources to support evidence-based practice, clinical decision making, or research, and facilitate the development of search strategies, as well as plan the literature review. For a more complete list of services, please refer to the section, “Research Resources” in this guidebook and look under “Medical Librarians.” To contact Intermountain Healthcare’s network of libraries and librarians, visit https://my.intermountain.net/mlibraries or the Help2 eResources page and look for the “Email Librarian” links.

Study Design
If you require assistance in assuring adequate sample size/statistical power, consult an expert statistician. The mission and purpose of the Statistical Data Center is to assure proper study design and analysis.
PRIVACY & SECURITY OF HEALTH INFORMATION (HIPAA)

Certain laws and regulations require that practitioners and health plans maintain the privacy of health information. In August of 1996, the U.S. Congress passed the Health Insurance Portability and Accountability Act - the privacy legislation we simply refer to as HIPAA. In general, privacy is about who has the right to access personally identifiable health information. The rule covers all individually identifiable health information in the hands of practitioners, providers, health plans, and health-care clearinghouses. Intermountain facilities take HIPAA regulations very seriously.

Identifiable Information:
The following is considered identifiable information by HIPAA and requires approval from the IRB and Privacy Board to access for research:

1. Names;
2. All geographical subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
3. All elements of dates (except year) for dates directly related to an individual, including birthdate, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
4. Phone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social Security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and
18. Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data).

PRICING AND BUDGET PREPARATION

Costs of doing research need to be accounted for. There are often options and opportunities that should be explored in sponsored funding to support research. It is recommended that a budget is prepared for all research studies to be conducted, and that departments and facilities are aware and approve of costs incurred in performing research.

Common direct costs associated with research are:

- Personnel costs: you will need to decide who will be required to work on the project and provide an estimate of effort (expressed as a percentage of their time). A calculation can then be made based on hourly rates and the percentage of time needed. You will also need to add amounts for employee benefits (variable per facility by year).
- Equipment: Intermountain defines capital equipment as any item costing $5,000 or more with a useful life greater than one year. Anything less than $5,000 is not equipment and should be budgeted as a supply item (e.g., computers).
- Travel costs need to be identified with a cost estimate. Contact the travel department if you need assistance. If traveling by car, the standard Intermountain mileage should be used.
- Other items that should be identified and budgeted are student involvement, materials/supplies, communication costs, service expenses, publication costs, consultant and independent contractor services, and patient care costs.

Indirect Costs

Indirect Costs (a.k.a. Facilities and Administrative Costs) apply to sponsored activity and by policy require that we apply for and request reimbursement based on our current negotiated rate(s) for all federal projects and for non-federal projects (consult Intermountain’s Sponsored Activity Policy for more information).
PATIENT CARE COSTS & COVERAGE ANALYSIS

CMS and the ACA allow billing of the routine costs of clinical trials. However, there are complex laws governing what can be billed to insurance and what must be paid for by the study. Please reach out to Shanna Ford, shanna.ford@imail.org or for Primary Children’s Hospital, Ricardo Curletto, ricardo.curletto@imail.org, to obtain research pricing for patient care as well as assistance with creating the required billing plan and performing a coverage analysis. Shanna and Ricardo are also responsible for training research staff on how to manage patient care charges to ensure compliance with federal billing regulations and Intermountain’s Billing Clinical Research Policy. Some studies, like investigational devices, may have special billing requirements and require authorization from our Medicare Administrator Contractor. Getting Shanna and Ricardo involved early in the process will help prevent delays in study start up and minimize risk to Intermountain.

ACCESSING DATA, HUMAN MATERIAL, AND SAMPLES FOR RESEARCH

Subject also to IRB and Privacy Board approval, accessing data for research purposes is dependent on Access and Steward approval as described in Intermountain’s Information Systems Access Control Procedure. If the researcher is not an Intermountain employee, data access may be requested through an Intermountain workforce member, but this person should be a collaborator on the research study. Data access for non-employees requires compliance with the Information Systems Access Control Procedure and execution of an Individual Research Agreement facilitated by the Office of Research with the Legal Department.

Subject also to IRB and Privacy Board approval, acquiring biologic materials as part of a research project is usually coordinated with Intermountain workforce members. Studies that include transferring or sharing data beyond Intermountain requires a Material Transfer Agreement facilitated by the Invention Management Office.

FUNDING SEARCHES AND GRANT APPLICATIONS

The Office of Research assists researchers in searching for funding opportunities. Generally these searches are performed based on keywords and research interests. Once a viable funding opportunity is recognized it is highly recommended that the researcher read application preparation instructions and contact the Pre-Award Office at officeofresearch@imail.org when a decision has been made to prepare and submit an application for funding. Coordination of the preparation and submission of grant applications requires an understanding of “who does what.” The researcher and Pre-Award Office will work together to prepare the grant application and review the business portions and budget for correctness prior to submission.

Grant preparation:
There are many external sources and classes for acquiring grant application preparation skills. Consider the agency reviewers when preparing the grant application, especially the scientific portion. Funding for research is competitive and subject to peer review. The Pre-Award Office encourages you to work with the advisors on the scientific portion. It is recommended to have experts and colleagues review and edit for content and grammar. Once the submission is completed you will have to wait while the agency makes a decision to fund. If the agency does not fund, you will likely receive feedback from the peer review. Use the peer reviewers’ suggestions, as you can always choose to re-submit with revisions or submit to an alternate agency for their consideration.
RESEARCH PROCESSES

GRANT AWARD
Grant awards for research and other sponsored activities should be directed to the Office of Research. It is important that all parties understand the terms and conditions (financial and programmatic) of the award. The Office of Research will make the award available to the Grant Accounting department for financial management. A unique project will be established for each award which will be used for tracking. The Office of Research will provide updates for compliance.

Researchers need to pay attention to their responsibilities in expending the funds specifically in support of the project for which the funds were requested and preparing and submitting required progress reports. At the conclusion of a study and an award there are specific requirements to be followed, usually submission of a final financial report (completed by Grant Accounting) and submission of a final technical report (completed by the Principal Investigator/researcher).

Principal Investigators are also responsible for maintaining IRB oversight during the life of the project and retaining research records as required by Intermountain and the sponsor.

CLINICAL TRIALS AND CONTRACTING IN RESEARCH
Research is dynamic and collaborative and involves contracting with third parties from Intermountain, or Intermountain being contracted to conduct or collaborate in research.

The Office of Research follows Intermountain’s Contract Review and Execution Policy and Procedure in administering all contracts for research. Our Research Contract Manager, Ahsen Khan, is the facilitator of this activity.

The startup of a clinical trial usually begins with a feasibility assessment to determine if there is sufficient clinical interest and patient needs/volumes to support the conduct of the clinical trial. This feasibility can also include the cost of conducting the trial. If feasibility and costs are satisfied, we’ll usually ask the department to complete a site readiness survey (this can also happen prior to feasibility). Industry sponsors, prior to receiving the study protocol, require a Confidentiality Agreement or a Non-Disclosure Agreement. These are directed to ahsen.khan@imail.org, who is responsible for research agreements. If the sponsor and researcher decide to go forward, the sponsor will usually provide a Clinical Trial Agreement for negotiation and execution.

FINANCIAL AWARD MANAGEMENT
The Principal Investigator, or designee, is responsible for making sure that research costs and research staff time are charged to and/or allocated to the correct research project. Patient care costs are managed either in our STAGES program or, if your site is live on iCentra, in Powertrials. The Grant Accounting department will review charges to the research project, invoice the sponsor for payment, manage receipt of payments, prepare required financial reports, and maintain General Ledger information.

PRESENTATION AND PUBLICATION OF RESEARCH

Presentations: Select a conference to which you are interested in submitting your abstract for consideration (this can sometimes be 9-12 months prior to a conference). Review the guidelines and format instructions. After you draft the presentation, have a colleague or resource review and edit prior to submission. Some conferences require that you choose a category (e.g., clinical innovations, best practice, etc.). Once selected, prepare the presentation in the appropriate format. If a poster will be used, please work with the Office of Research if you need assistance.

Publications: Select a professional journal to which you are interested in submitting a manuscript for

For assistance with financial award management of research, contact grantaccounting@imail.org

Direct research agreements to: Ahsen Khan at ahsen.khan@imail.org
consideration. Intermountain’s Medical Librarians can help with this process. Always consider the journal audience when preparing the manuscript. Review the authorship guidelines and format instructions. After your first draft, it is recommended that you have several colleagues or resources review and edit. Once completed, submit to selected journal with a cover letter to the editor. Most journal editors can receive emails and prefer electronic submission. The difficult part is waiting while journal reviewers make a decision to accept, accept with changes, or reject your manuscript. If you receive a rejection letter there are still options. You can choose to re-review, add more data, change focus, or resubmit to another journal. Use the peer-reviewers suggestions whenever possible and appropriate. For additional assistance with submissions, please contact the Office of Research.

**SCIENTIFIC POSTERS**

Most conferences include scientific poster presentations in their events. Scientific posters summarize research information concisely and attractively to help publicize and generate discussion. It is important to follow Intermountain brand guidelines to build brand recognition and value for Intermountain research.

For assistance with presentations, publication of research, or scientific posters, contact Office of Research at officeofresearch@imail.org

**3RD PARTY ACCESS**

From time to time, depending on the study, access for external investigators, clinical research coordinators, study personnel, and study monitors is required. Access to Intermountain facilities is described in the Intermountain Vendor Access Policy. Badge requirements are described in the Intermountain Identification Badge Policy, and if information system access is required, refer to requirements in the Intermountain Information Systems Access Control Procedure.

**MANAGING INTELLECTUAL PROPERTY**

Institutions that engage in research are allowed to retain intellectual property rights for their inventions and patents associated with research. Researchers should be aware of Intermountain’s Intellectual Property Policy and disclosure requirements.

Researchers should also be cautious of not infringing others’ patents. For more information, contact the Invention Management Office at imo@imail.org
RESEARCH RESOURCES

MEDICAL LIBRARIANS

Intermountain’s Medical Librarians are information professionals who can provide you, the researcher, with a host of research support options.

Research support services can be tailored to meet your specific needs:

- To learn to search and/or manage your own literature searches and collections of citations efficiently through a one-on-one free research consultation session
- To have a customized professional search performed for you

Training and orientation

- Personalized orientation to the library, its services and resources
- Individualized training in the use of electronic databases and research portals such as PubMed, Cochrane Database of Systematic Reviews, Google Scholar, etc.
- Guidance to improve your online research profile with resources such as ResearchGate, Google Scholar Citations, and My NCBI’s sciENcv

Assistance with literature searching – Medical Librarians are your “Ultimate Search Engine”

- Identification of information resources to support evidence-based practice, clinical decision making, research or education
- Developing general search strategies
- Planning the literature review and developing the search strategies for meta-analyses and systematic reviews
- Creating database Auto Alerts (SDI) for your research projects
- Citation verification for bibliographies
- Professional searches from a variety of biomedical databases

Technical and web support

- Troubleshooting technical problems related to accessing the library’s resources
- Copyright compliance questions

Visit Intermountain Healthcare’s network of libraries and librarians or the Help2 eResources page and look for the “Email Librarian” links.

Document Delivery

- Get full-text resources sent directly to your inbox
- Intermountain’s Librarians can also obtain, at low- to no-cost, access to resources not held in our institution’s collections.

DATA AND ANALYTIC

Enterprise Data Warehouse (EDW)

The Enterprise Data Warehouse plays a critical role at Intermountain Healthcare. It is the primary source for analytics and business intelligence activity for the enterprise. The EDW is a centrally-managed and easily-accessible copy of data collected from Intermountain’s systems, including financial, clinical, laboratory, pharmacy, and other departmental systems. The data is aggregated, organized, structured and cataloged to facilitate population-based analyses, queries, and research.

EDW Data and Support Staff:

- Help determine sufficiency of patient data needed for planned research projects
- Determine initial numbers of patients available that meet certain research criteria (if it can be determined with EDW data)
- Assist in writing queries to extract data from the EDW and deliver the data in an appropriate and compliant method
- Assist a researcher in gaining direct access to the EDW if deemed appropriate and provide appropriate training

- Pull new data sources into the EDW that may be needed for research
- Create automated reports
- Provide statistical support if needed by EDW analysts (masters trained statisticians)
- Train on use of tools such as metadata to know what data is available in the EDW and SANbox for creating their own datasets in EDW
- Help to triage data requests to appropriate analytic group

Process for Requesting Data from the EDW

1. Define the patient sample or population
   a. List of specific patients (EMPIs), patients with certain conditions, or patients who meet certain criteria
2. Define facilities (if necessary), and date range
3. As specifically as possible, define which data elements are needed
4. Submit an Analytic Request
   a. Visit: https://projects.intermountain.net/AnalyticRequest and then click on the “new request” button to fill out the online form
   b. The Data Architect or Business Intelligence (BI) Developer from the data subject area will get in touch with the requestor within a couple days
   c. At this time, the requestor would speak with this person to further define the request and go from there.

EDW contact:
Lee Pierce at 801.442.3734 or lee.pierce@imail.org

HOMER WARNER CENTER FOR INFORMATICS RESEARCH (HWCIR)

The HWCIR is a department of informatics where independent research is conducted and assistance is available to researchers where
value added models (including natural language processing tools) are required.

**They can assist with:**

- Identifying available study populations (stratified by site/clinical characteristics/providers)
- Identifying required samples sizes
- Automated screening and subject identification (inclusion/exclusion criteria)
- Tools to expedite subject review for study coordinators
- Computerized protocols
- Tracking tools
- Data acquisition tools
- Research databases and tools to automate data capture
- Modeling clinical and care delivery processes
- Utilization of existing databases to develop hypotheses and project future research

**INTERMOUNTAIN LEADERSHIP INSTITUTE**

The “Institute” is known for training healthcare providers in quality improvement. Additionally, the Institute offers a series of short courses through its Data and Research Series for Intermountain staff (class registration available in TalentLink).

The Institute analysts directly support Clinical Programs, offering research support and consulting services in the following:

- Development, definition and measurement requirements that describe key processes specific to existing Clinical Program
- Implementation of appropriate risk adjustment/assessment stratification as it relates to Clinical Program outcomes
- Forecasting future measure requirements
- Employing advanced working knowledge of statistical analysis as applied to clinical outcomes (this includes in-depth knowledge of database construction, risk and severity adjustment methodology, and reporting systems)
- Conducting quality measurement planning and implementation across the care continuum; including system regions, facilities, practice groups and physician clinics
- Assessing/supporting clinical performance and patient safety objectives; developing, tracking, and disseminating quality improvement measures; ongoing assessment and implementation of new quality measures; periodic data mining of existing data as they relate to Intermountain Clinical Programs
- Tracking cost, charges, length-of-stay, readmission, survival, utilization and customer satisfaction/perception of quality metrics

**A senior scientist in the Institute is also available to provide:**

- Investigative services/consultation on implementation science, program evaluation, cost-benefit, and comparative effectiveness analyses using mixed methods approaches and observational study designs
- Identification of, and strategies for, external funding opportunities
- Research mentorship
- Mock study section reviews of near-final, draft proposals

**STATISTICAL DATA CENTER (SDC)**

The SDC is a department of trained statisticians who are available to assist researchers with:

- Training personnel on the basics of clinical trials
- Refining research questions
- Study design
- Power/sample size calculation
- Randomization strategies
- Designing data collection protocols
- Analysis and interpretation of results including preparation of graphs/charts/tables
- Writing/reviewing statistical portion of grant proposals, publications and presentations

**SDC contact:**
Greg Snow at 801.408.8111 or greg.snow@imail.org

**HWCIR contacts:**
Kathryn Kuttler at 801.507.5592 or kathryn.kuttler@imail.org

Sid Thornton at 801.507.9250 or sid.thornton@imail.org
REDCap™

REDCap (Research Electronic Data Capture) is a web-based program for entering and managing data for research projects. REDCap was developed at Vanderbilt University and is used by many different research institutions (including the University of Utah). REDCap is a central location where a research group can enter and store the data securely for a project, controlling access to the data while making it easily accessible to the research team. REDCap also has survey functionality that allows research subjects outside of the Intermountain firewall to answer the surveys without need of a login. Survey invitations can be automated to be sent out at given times and under given conditions.

You can gain access to REDCap using the AccessWeb tool available from Intermountain.net. Once access has been granted (usually within 2 days of the request) go to: https://intermountainhealthcare.org/redcapsurveys/ and log in using your standard Intermountain username and password. The first time that you log in you will need to answer a couple of questions. Once logged in there is a tab labeled “Training Resources” that has several introductory videos that will help you get started.

ResearchDoc contact:
Office of Research at officeofresearch@imail.org

ResearchDoc

ResearchDoc is internally developed software used to collect data for clinical trials and quality improvement projects within Intermountain Healthcare. It was built by the Homer Warner Center in collaboration with the Intermountain Heart Institute and the Office of Research. More than 100 projects are active or under construction in ResearchDoc and it is used across a number of clinical departments and subject areas. The core functionality is a flexible web-based forms tool that you can use on your own to set up a project and includes the ability to pull in data from the Intermountain Enterprise Data Warehouse (EDW). Having an in-house development and support team, we can enhance the tool to meet your research and other data collection needs. Please contact researchdoc@imail.org for a personalized demo and for information on accessing the tool.

ResearchDoc contact:
David Taylor at david.taylor2@imail.org

INTERMOUNTAIN RESEARCH AND MEDICAL FOUNDATION

The Intermountain Research and Medical Foundation offers grant opportunities to employed physicians, scientists, nurses, and other personnel. There are four funding cycles each year. A researcher starts the process by submitting a letter of intent to the Foundation by the announced due date. Letters are reviewed for guideline compliance, after which researchers may be asked to submit a full application. Grants are up to $60,000 and may be awarded for a two-year period. The Foundation is located at Intermountain Healthcare, Central Office, 36 South State, Salt Lake City, UT. Contact the Foundation to obtain letter of intent forms, funding guidelines and the funding cycle calendar.

Foundation contact:
Becky Lloyd at becky.lloyd@imail.org

BIOSPECIMENS

Intermountain BioRepository

The BioRepository is a centralized resource for research involving biologic samples and linked clinical data that can be utilized for research, test development, and validation studies. The team members at the BioRepository are experts in tissue microarray construction.

The key functions of the BioRepository include:
- Coordination of research projects that utilize biologic samples from start to finish, including data collection and de-identification.
- Facilitation of Material Transfer Agreements (MTA) and IRB approvals when assistance is needed
- Management of a paraffin repository which includes samples from all Intermountain facilities
• Coordination with pathology departments when needed for specific research studies
• Central resource to coordinate collection and storage of biologic samples systemwide
• Fulfillment of requests for patient materials needed for consented clinical trials and other research studies

Additionally, our research histology laboratory is a resource for sample preparation for research and validation studies.

The paraffin repository includes nearly 4 million archival formalin-fixed paraffin embedded tissue blocks, most of which are older than 10 years and no longer required for clinical management. These blocks are linked to clinical data in the EDW and also to the Utah Populations Database and represent a valuable resource for medical discovery. The paraffin blocks can be utilized for research meeting Intermountain’s Research Mission, Vision and Values with appropriate approvals. The Intermountain BioRepository coordinates these studies and functions as the Honest Broker.

Looking Ahead
The Intermountain BioRepository has recently received IRB approval for the collection of consented tissue for the purpose of furthering the development of pharmaceutical products and new diagnostic tools. Intermountain BioRepository will finalize consolidation of paraffin tissue storage from all medical facilities currently storing tissue, and will begin the collection and storage of consented tissue.

BioRepository contacts:
Patti Spencer at 801.507.4778 or patti.spencer@imail.org
John Carlquist at 801.408.1028 or john.carlquist@imail.org

Intermountain DNA Repository/Registry
The purpose of the DNA Repository/Registry is to study genetic and plasma biomarkers in relationship to coronary disease. The project has been underway since 1994, as well as the development of a multiple of other disease registries since then. Services available include extracting and storing samples, and genotyping services (GWAS, Gene expression Micro-RNA, sequencing).

DNA Repository/Registry contact:
John Carlquist at 801.408.1028 or john.carlquist@imail.org

HEALTH INFORMATION MANAGEMENT
Inpatient Medical Records and Working with Health Information Management
When paper medical records are required to complete a research study, the request to pull and provide these records to you must be coordinated with the Director of the Health Information Management (HIM)/Medical Records Department. They will determine when the records will be ready for review and provide the workspace for record review. The HIM Directors at each facility will support research as much as possible and may accommodate the request based on workloads.

Review of Medical Records
It is assumed that the records required as part of your research study will be reviewed retrospectively. If you are planning to perform a con-current review of records, please provide this in the study materials.

Access to Paper Medical Records
1. The research manager or designee contacts the HIM Director in advance of the scheduled visit with a list of records needed for the review.
   
2. The research manager or designee provides the HIM Director a copy of the approved IRB project.

Medical records which are stored at our central retention center should be reviewed at the retention center whenever possible. A review request for greater than 30 records from a single facility at a single time should always be reviewed at the central retention center. The following facilities store all of their medical records at the central retention center:

- McKay-Dee Hospital
- LDS Hospital
- Primary Children’s Hospital
- Intermountain Medical Center
- TOSH
- Alta View Hospital
RESEARCH RESOURCES

The HIM Director will work directly with the retention center staff, providing them with the listing of records to be pulled and giving them the names of the individuals who will actually be performing the record review. The reviewers must check in with the retention center staff to have them unlock the review room, giving you access to the records.

Cost of Pulling Medical Records
It is very important to have an estimated number of records in a study. This helps to determine where the actual record review will need to take place. There is a fixed fee of five dollars ($5.00) per medical record requested for pulling and re-filing each medical record paper chart. You will need to coordinate payment of these records with the HIM Director from each facility. Payment should be made before the conclusion of your record review.

Facilities who do not store records at the retention center will provide requested records at the location where service was provided. Please coordinate with the location providing the records if you need to have more records pulled, or if you need to keep records available for a longer period of time than anticipated.

For a complete listing of HIM Directors, please contact Carrie Dunne at carrie.dunne@imail.org

The address of the central retention center:
1136 South 3600 West
Salt Lake City, Utah
Phone number: 801.442.7200

PHARMACY
Research that requires the use of an investigational drug, agent, or biologic must be reviewed and approved, preferably prior to application made to external agencies or to Intermountain’s IRB, by the department of pharmacy in each facility where the research will be conducted; including hospitals, outpatient hospital clinics, medical group clinics, and home care services.

Drugs to be administered to a patient must be dispensed by the Department of Pharmacy unless the pharmacy dispensing the study drug would not be feasible, as dictated by the study protocol. All drugs, agents, or biologics involved in a research project must be under the Principal Investigator’s personal supervision or under the supervision of physicians who are directly responsible to the study’s Principal Investigator.

For more information, see the Intermountain Investigational Drugs Agents Biologics Research Policy and implementing procedure.

STUDENT RESEARCH

Academic Research Student Rotation & Student Placement Process

The Student Placement Coordinator will:
- Coordinate/verify placement request with Intermountain department manager
- Determine if the student is sponsored by an affiliated institution and recognized school program
- Coordinate the following with student:
  - Negotiate contractual relationship if not sponsored by an affiliated institution and recognized school program
  - Provide student forms packet and verify completion
  - Provide ID badge in accordance with ID Badge Policy
  - Ensure completion of, and compliance with, TJC requirements and CDC immunization requirements (as noted in agreement)
  - Provide systems access if required/requested by department manager
  - If necessary, coordinate student stipend with central office Student Programs Manager (in accordance with terms noted in the Individual Student Rotation Agreement (ISRA) or Letter of Agreement (LOA))
The department manager, mentor or designee, will ensure:

- Students do not work independent of an Intermountain supervisor
- Students do not provide services unrelated to the objectives defined in the research project

All students need to be aware of Intermountain Healthcare’s Student Education Experience Policy and Procedure, which outlines employee-as-student requirements as follows:

Students are not considered employees while functioning in a student role, students must meet all student requirements (student ID badge, student-related forms and orientation must be completed, drug and background screening may be waived if employee status is active and hired after April 1, 1996, not perform employee duties while functioning as student or vice versa. Worker compensation is not in effect while employee is acting as a student. Students work with the regional student placement coordinators to make sure they are in compliance.

For approval requirements refer to the Project Approvals Section of this Guide.
It is our hope that this guidebook will help you as you get started in research at Intermountain Healthcare. If you have any questions please don't hesitate to contact the Office of Research.