**CLINICAL RESEARCH QUICK GUIDE**

**RESEARCH ROLES & RESPONSIBILITIES**

**MEDICAL RESEARCHER**
- Develop the research protocol
- Complete human subjects research training (CITI Program) and other applicable training
- If not an Intermountain employee, identify an Intermountain investigator
- Obtain written approvals as needed
- Complete the IRB application
- Obtain IRB approval prior to beginning the project
- Maintain IRB approval (renewals, amendments, adverse event reports)
- Submit the final project report when the study is complete
- Prepare scientific reports, presentations & posters
- If the Researcher is an affiliated physician*

**INSTITUTIONAL REVIEW BOARD (IRB)**
- Provide access to the online IRB application (IRIS)
- Educate investigators about requirements for conducting research at Intermountain
- Provide assistance with the IRB application and guidance for using IRIS
- Inform the researcher through the IRB review process
- Responsible for reviewing the research projects for regulatory compliance and ethical conduct of research

**RESEARCHER & DEPARTMENT MANAGER**
- Identify and approve the department resources required for conduct of the project
- Provide written department approval for the project to be conducted
- Oversee conduct of the project
- Ensure compliance with Intermountain policies and procedures
- Review research roles & competency training

**OFFICE OF RESEARCH**
- AVP of Research approves and endorses research
- Grant submission
- Award acceptance
- Contracts & agreements for research
- Research education
- Research communications
- Research strategy & operations
- Provides research resources to researchers

**RESEARCH PROCESS**

**DESIGN STUDY**
- If not an Intermountain employee, identify an Intermountain investigator
- Obtain approval from all the impacted departments
- Begin human subject training
- Contact the Pre-Award Office
- Define the project
- Get Medical Librarian support for literature searches, training, and full-text resource delivery
- Write the study
- Begin the draft of consent documents and other study documentation (as applicable)

**START IRB APPLICATION**
- Contact the IRB for access to IRIS
- Complete the IRB application
- Upload the required documents (consent, protocol, etc.)
- Researcher must complete human subjects research training prior to receiving IRB approval

**IRB REVIEW & APPROVAL**
- IRB coordinator will pre-review the application
- IRIS will inform the researcher of review determination (non-human subjects research, exempt, expedited or convened board)
- IRB coordinator will forward the application to the expedited reviewer or place on the next available IRB agenda
- The IRB will review to ensure the project meets ethical and regulatory requirements for approval
- The IRB status & approval is communicated to the researcher

**ACTIVE PROJECT**
- For data studies:
  - Gather the data (survey, EDW, or patient charts) or screen and enroll the study subjects
  - Follow the study plans and the IRB approvals for data authorizations
  - Use best practices for data compliance and/or conduct of the research (i.e., GCP)
  - If funded, charge the study costs to established project per allowable charges and oversee the study funds
  - Submit progress reports as outlined by the sponsor

- For clinical studies:
  - Researcher and department in accordance with the IRB
  - Study supplies — return the supplies (if applicable)
  - Study data — destroy after the retention period
  - Financial closeout — researcher and department manager assure all costs have been charged to the study account
  - Final scientific report to the sponsor (if required)

**STUDY CLOSEOUT**
- Final reports to the IRB when access to the data is no longer needed
- Data record retention — researcher and department in accordance with the Intermountain policy and sponsor’s requirements
- Study supplies — return the supplies (if applicable)
- Data study — destroy after the retention period
- Financial closeout — researcher and department manager assure all costs have been charged to the study account
- Final scientific report to the sponsor (if required)

**PUBLICATION & PR**
- Determine a medical journal for submission
- Manuscript preparation assistance may be provided by the Office of Research
  - Proofing and editing to meet journal guidelines
  - Navigate the submissions process
- The researcher is responsible for any publication costs associated with the journal

**PUBLIC RELATIONS (PR)**
- Prepare and submit the publication announcement (add to Research CV)
- Develop and execute a communication plan to disseminate research findings through various internal and external communication channels including, web, email, social media, conferences, traditional media, Stories, and etc.

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* Intermountain affiliated physicians and research engagement — affiliated physicians and physician groups occasionally engage in research that impacts and/or involves Intermountain. Intermountain wants to support research that furthers its research objectives. Affiliated physicians should first meet with their Intermountain Operations Officer. The Operations Officer should evaluate the research for resources involved and impact to the physician contract. A contract addendum is often required to include research that Intermountain will also support as part of the physician contract. Data studies and studies involving patients can incur different resources, some of which may need to be reimbursed. Contact the Office of Research for assistance as needed at officeofresearch@imail.org.

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INSTITUTIONAL REVIEW BOARD (IRB)
The IRB is responsible for assuring studies are safe for patients by reviewing protocols per regulatory requirements and providing IRB and Privacy Board approval. The IRB is a resource for researchers to know about human subject protections, privacy, regulatory requirements and by policy make the determination if a study requires Intermountain IRB approval or not.

RESEARCH TRAINING
Intermountain subscribes to the CITI Program for its core research training (www.citiprogram.org). This training is supplemented through the recorded Research Colloquia and research courses that can be found on the Office of Research .net page. The program is designed to provide individuals with the information they need to know based on their individual role and the type of research.

MEDICAL LIBRARIANS
Intermountain’s Medical Librarians are information professionals who can provide a host of research support options, including literature searches, library usage training, document delivery, and more. Visit Intermountain.net medical library services or eResources page for librarian information.

PROJECT ASSISTANCE
The Pre-Award Office within the Office of Research offers assistance with literature searches, study and protocol development, study design, and research methods, grant application preparation assistance, study coordination assistance, data access assistance, report generation and research presentation assistance. We become part of your research team or supplement your team based on research needs.

GRANT PROPOSALS
The Office of Research provides grant application assistance (federal and non-federal). We review agency requirements, assure application business information is accurate and complete, review/approve budgets, and submit grants on behalf of Intermountain researchers. We also coordinate applications with partnering institutions (such as the University of Utah), as well as providing help with letters of support.

CONTRACTING
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.

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.

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.

GRANT ACCOUNTING AND PATIENT BILLING
Grant accounting is responsible for account management (income and expense management), invoicing, and financial reporting required from sponsored awards and contracts. We coordinate external annual federal grant audits for research (OMB- A133) (refer to Intermountain grant financial policies and procedures).

INTERMOUNTAIN LEADERSHIP INSTITUTE
The Institute is known for training healthcare providers in quality improvement. Institute analysts directly support clinical programs, offer research assistance, and consulting services.

DATA AND ANALYTIC
Enterprise Data Warehouse (EDW)
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.

STATISTICAL DATA CENTER (SDC)
The SDC is a department of trained statisticians who are available to assist researchers with study design, data, and statistical analysis.

INTERMOUNTAIN RESEARCH AND MEDICAL FOUNDATION (Formally known as The Deseret Foundation)
The Foundation offers grant opportunities to employed physicians, scientists, nurses, and other personnel.

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.

HEALTH INFORMATION MANAGEMENT
Access to inpatient medical records can be coordinated with the Director of Health Information Management/Medical Records.

PHARMACY
The department of pharmacy in each facility where the research will be conducted must review and approve the use of investigational drugs, agents, or biologics used in the research, preferably prior to IRB application.

STUDENT RESEARCH
Academic Research Student Rotation & Student Placement Process. The process includes a coordinator to verify placement and a department manager, mentor, or designee to ensure students do not work independent of the Intermountain supervisor and aligns with the objectives of the research project.

PUBLICATIONS & PR
The Office of Research offers professional writing, graphic design, and communication support for assistance with journal publications, internal/external public relations initiatives, social media promotions, grant applications and more.

For more detailed information please refer to the Intermountain Healthcare Research Guide located online at https://intermountainhealthcare.org/research/research-resources/