Intermountain® Healthcare Research

INTERMOUNTAIN HEALTHCARE HUMAN RESEARCH PROTECTIONS PROGRAM PLAN

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Purpose

The purpose of this document provides an overview and summary of the Intermountain Healthcare Human Research Protections Program (HRPP).

Contents

Definitions

Agent

An agent is a party who has express (oral or written) or implied authority to act on behalf of IHC Health Services, Inc. so as to bind IHC Health Services, Inc. into contractual relationship, engage in Human Subjects Research or other obligations

Clinical Trial

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Engaged in Human Research

In general, Intermountain Healthcare is considered engaged in Human Research when its employees or agents, for the purposes of Human Research, obtain:

1) Data about the participants of the research through intervention or interaction with them
2) Identifiable private information about the participants of the research
3) The informed consent of human participants for the research

The Intermountain HRPP follows the guidance on "Engagement of Institutions in Research" provided by the Office of Human Research Protections (OHRP).

Human Research

Human research is considered any activity that either:

- Is "research" as defined by Department of Health and Human Services (DHHS) and involves "Human Subjects" as Defined by DHHS; or
- Is "Research" as defined by the Food and Drug Administration (FDA) and involves "Human Subjects" as defined by the FDA.

Human Subject as defined by DHHS

A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information.

Human Subject as defined by FDA

An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen (identified or unidentified) a medical device is used.

Investigator

The person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a site, the investigator is the responsible leader of the team and may be called the Principal Investigator (PI).

Key Study Personnel

All individuals that are part of the research team that are involved with identifying, consenting, and treating potential research participants or interacting with personally identifiable data, and those involved with applying to and interacting with the IRB (i.e. study coordinators, study nurses, etc.).

Research (DHHS)

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research (FDA)

Any experiment that involves a test article and one or more human subjects, and that meets any one of the following:

- Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR

- Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Research Misconduct

Is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results:

- Fabrication - Making up data or results and recording or reporting them.
- Falsification - Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism - The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Purpose

Intermountain Healthcare Research uses our model healthcare system to advance clinical investigation and improve patient outcomes and healthcare quality through innovation, discovery and implementation science.

The Human Research Protections Program protects the rights and welfare of human participants in research being conducted at Intermountain Healthcare. Intermountain aims to promote a culture of compliance with the highest ethical and legal standards for the conduct of human research. Intermountain Healthcare is also committed to education of the research community.

The purpose of this document is to describe Intermountain's plan to comply with ethical and legal requirements to ensure the protection of the rights and welfare of participants in Human Research.

Intermountain's Human Research Protection Program (HRPP) is comprised of institutional leadership, the Office of Research, Institutional Review Board, Privacy Board, Research Guidance Council, Research Conflict of Interest Committee, Compliance, Legal Services, Pharmacy, Information Technology, and other teams who are responsible for the ethical conduct of research at Intermountain Healthcare.

The HRPP promotes high quality, ethical research by:

- Requiring IRB review and approval for all research involving human subjects prior to initiating any research at Intermountain Healthcare
- Monitoring, evaluating and continually improving the protection of human subjects
- Promoting compliance with research regulations, institutional policies and professional and ethical standards
- Responding to concerns of research participants
- Responding to needs and concerns from researchers and research teams
- Educating researchers and research teams of their responsibilities to protect research participants

Scope

The Intermountain HRPP oversees the conduct of all Human Research at IHC Health Services, Inc., including all Intermountain Healthcare facilities and Select Health. For the purposes of this document, "Intermountain Healthcare" will be used to denote all research activities throughout the organization unless specifically noted.

Requirements

Ethical Requirements

Intermountain Healthcare follows the principles of the April 18, 1979 report of The National Commission for the Protection of Human Subjects of Biomedical and Behavior Research titled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" also known as the "Belmont Report". The principles are:

- Respect for Persons
- Beneficence
- Justice

Legal Requirements

Intermountain Healthcare commits to applying the above ethical standards to all research conducted at Intermountain Healthcare regardless of funding.

When Intermountain is engaged in Department of Health and Human Services (DHHS) Research that is conducted, funded or otherwise subject to regulations by a federal department or agency, who is signatory of the Common Rule, Intermountain commits to apply the regulation of that agency relevant to the protection of Human Subjects.

When Intermountain is engaged in FDA Human Research, Intermountain commits to apply the FDA regulations.

Intermountain applies the standards of the HIPAA Privacy Rule to research that involves the use of Protected Health Information (PHI).

Other Requirements

ICH Good Clinical Practice (GCP) Guidelines

National Institutes of Health (NIH)

Additionally, Intermountain adheres to the Department of Defense directives as applicable to specific research projects.

Human Research Protection Program Policies and Procedures

Policies, Procedures and Guidelines are available online in the Intermountain Policy Library at https://m.intermountain.net/policy/Pages/Home.aspx#.

Program Components

Institutional Official

The Assistant Vice President of Research is designated as the Institutional Official (IO) for Intermountain Healthcare. The IO and the Research Guidance Council are responsible for the approval of Intermountain's Human Subjects Protection Program Plan.

The IO has authority to make or delegate the following actions:

- Sign federal assurances
- Appoint and remove IRB Members and IRB Chairs
- Place limitations or conditions on a researcher or research staff's ability to conduct Human Research

The IO is responsible to:

- Approve the Human Research Protections Plan for Intermountain Healthcare
- Ensure the HRPP has sufficient resources, considering the volume and types of Research conducted

HRPP Manager

The Program Manager has overall responsibility for the Intermountain Healthcare HRPP.

The HRPP Manager is responsible to:

- Develop and implement policies and procedures governing Human Research at Intermountain
- Establish policies and procedures to increase the likelihood that Human Research will be conducted in accordance with ethical and legal requirements
- Oversee the review and conduct of Human Research under the jurisdiction of Intermountain
- Manage budget
- Manage staff and resources
- Periodically review this plan to assess whether it is providing the desired results and recommend amendments as needed
- Institute regular, effective education and training programs
- Ensure that the research review process is independent and free of coercion or undue influence, and ensure that Intermountain officials cannot approve research that has not been approved by Intermountain's IRB (or an IRB designated to review on behalf of Intermountain)
- Implement a process to receive and act on complaints and allegations regarding the HRPP

- Investigate and remediate identified systemic problem areas and when necessary (with the IO and Research Operations Director) remove individuals from involvement in the HRPP
- Report unanticipated problems to institutional officials, federal agencies, etc. as required

Investigators and Research Staff

The individual investigator is the ultimate protector of the rights and welfare of research participants. They are responsible for carrying out sound ethical research consistent with the plans approved by the IRB; and for the ongoing requirements of approved research.

All individuals within the research community have the responsibility to:

- Consult with the IRB when there is uncertainty regarding whether an activity is Human Research
- Not conduct Human Research or allow Human Research without review
- Report allegations of undue influence regarding the oversight of HRPP or concerns about the HRPP to the HRPP Manager or IO
- Report allegations or findings of non-compliance with the requirements of the HRPP to the IRB and/or Compliance
- Follow Intermountain Research Policies and Procedures
- Comply with all determinations and additional requirements of the IRB, the IRB Chairs, the HRPP Manager and the Institutional Official
- Also see **the Researcher Responsibility Policy**

Individuals who are responsible for business development are prohibited from carrying day-to-day operations of the review process.

Institutional Review Board (IRB)

The purpose of the Intermountain IRB is to assure and facilitate the ethical conduct of research involving human subjects. The IRB reviews all Intermountain 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 also responsible to ensure human subjects research complies with local, state and federal regulations.

The IRB has authority to:

- Determine whether an activity is Human Subjects Research
- Determine whether Human Subjects Research is exempt
- Approve, require modification, and disapprove all Human Subjects Research conducted at Intermountain. All Human Subjects Research must be approved by an IRB approved to review research at Intermountain Healthcare. Intermountain officials may not approve research that has not been approved by the IRB
- Suspend or terminate previously approved research not being conducted in accordance with the IRB's requirements or that has been associated with harm to participants
- Observe, or request a third party to observe, the consent process and the conduct of research

- Evaluate financial interests of researchers and research staff and have the final authority to decide whether the financial interest and the management plan, if any, allow the research to be approved
- Make a final determination as to when an event or non-compliance represents an unanticipated problem involving risks to subjects or others (reportable to federal agencies)

External IRBs may be relied upon as outlined in the External IRB Reliance Procedure.

IRB Chairs, members and staff are responsible to follow applicable Intermountain policies and procedures.

IRB Chairs and members are appointed by the HRPP Manager and Assistant Vice President for Research.

Privacy Board

The Intermountain Privacy Board reviews requests for waiver or alteration of the Authorization requirements under the HIPAA Privacy Rule for uses and disclosures of PHI for research. The Privacy Board has authority to waive or alter all or part of the Authorization requirements for a specified research project or protocol.

The Privacy Board is a sub-committee of the Intermountain IRB.

Conflict of Interest Committee

The HRPP Office coordinates conflict of interest disclosures for individual researchers. The Research Conflict of Interest Committee reviews disclosures that report an outside interest or activity to determine whether the interest could affect the design, conduct, or reporting of research. If a potential or actual conflict of interest related to the research is found, the committee is responsible to work with the individual to eliminate, minimize, or manage the conflict. Refer to the Research Conflict of Interest Policy for further information.

Institutional Conflicts of Interest in research are conflicts where Intermountain Healthcare receives royalties from the sale of a product under investigation at Intermountain, holds any equity interest in a non-publicly traded sponsor of any active Intermountain research, or holds equity in a publicly traded sponsor of any active Intermountain research. To assure research integrity Intermountain maintains a program that identifies and addresses institutional conflict of interest. The Research Conflict of Interest Committee will require appropriate disclosures be made to potential research participants and the scientific community. See the Institutional Conflict of Interest in Research Policy and Procedure.

Compliance Program

Intermountain Healthcare is fully committed to conducting its activities in compliance with all federal and state laws and regulations and in conformance with the highest ethical, medical, and legal standards. The Intermountain Healthcare Compliance Department oversees Intermountain Healthcare Research compliance activities. The Intermountain Compliance Department is designed to help every individual or entity affiliated with Intermountain Healthcare Research achieve these objectives by establishing a general overall framework for conducting activities with integrity and accountability for a shared set of ethical and legal principles. The Compliance Department activities overseeing

Intermountain Healthcare Research will also follow the elements of an effective compliance program as established by the Office of the Inspector General (OIG).

Institutional Biosafety Officer and Institutional Biosafety Committee (IBC)

The IBC has the responsibility to review all research involving recombinant DNA. The Institutional Biosafety Officer is responsible to consult research teams on safe microbiological practices, procedures, and proper use of containment equipment and facilities. The Institutional Biosafety Officer (or designee) will conduct walkthroughs to ensure safe and appropriate practices are in place and being followed.

IBC approval is required before final IRB approval is granted.

Research Guidance Council

The Research Guidance Council serves as the governance structure and sets expectations for research at Intermountain Healthcare. Under the leadership of the Assistant Vice President of Research, the Research Guidance Council is responsible to set the strategic plan for research and set goals for research. The work of the Research Guidance Council will be ongoing to address the research needs of different clinical areas and how the Office of Research can best support them. The Research Guidance Council membership is formed of research leaders from the different departments and divisions that conduct research at Intermountain.

Research Integrity Officer

The Vice President of Compliance is the Research Integrity Officer (RIO) for Intermountain Healthcare. The RIO is responsible for the evaluations of allegations of research misconduct. The Intermountain policy for research misconduct is consistent with federal policy. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

See the Research Ethical Conduct Policy and Procedure for further information.

Intermountain Legal Services

- The Intermountain legal office is responsible to provide advice to the Office of Research Leadership, IRB Chairs, Institutional Officials, and other individuals involved with the Human Research Protection Program
- Assist in determining whether someone is acting as an agent of Intermountain Healthcare (IHC Health Services, Inc.)
- Assist in determining who meets the definition of “legally authorized representative” and “children” when Human Research is conducted in jurisdictions not covered by policies and procedures
- Assist in the resolution of conflicts among applicable laws

Office of Research Contracts Department

The Contracts Department is responsible to review contracts and funding agreements, and assists in compliance with HRPP policies and procedures.

Intellectual Property Office

The Intellectual Property Office is responsible to negotiate and advise on intellectual property issues in Clinical Trial and Sponsored Research Agreements.

Radiation Safety Committee

The Radiation Safety Committee has the responsibility to review research procedures or activities that involve the use of radiation sources at Intermountain Healthcare facilities and act upon the procedures or activities to meet regulatory requirements as deemed appropriate by the Radiation Safety Officer or designee. Radiation sources include: ionizing and non-ionizing radiation sources or devices, e.g., radioactive materials; lasers; x-rays.

Upon receipt of a new application, the IRB will notify the Radiation Safety. The Radiation Safety Officer or designee will determine if the procedure/activity requires Radiation Safety Committee approval or action. The Radiation Safety Officer or designee shall notify the Radiation Safety Committee when approval or action is required. NOTE: Not all research procedures or activities require Radiation Safety Committee approval/action.

Management of Investigational Products

Investigational Drugs, Agents and Biologics

Intermountain Healthcare Institutional Review Board shall review and approve the use of investigational drugs, agents, and/or biologics for use in accordance with federal regulations. The Department of Pharmacy assesses and monitors investigational drug handling in each facility where the research is conducted, including hospitals, outpatient hospital clinics, Medical Group Clinics, Homecare Services, and research involving Intermountain Healthcare employed personnel.

Investigational Devices

Intermountain Healthcare Institutional Review Boards (IRBs) shall review and approve all investigational device use in accordance with applicable laws and regulations. Researchers and Research Staff members are responsible to ensure that all investigational devices are handled according to legal and regulatory requirements. Researchers are also responsible to maintain appropriate records and to use the device as specified in the study protocol.

Scientific Review

The scientific review process evaluates the soundness of research, the ability of the research to answer the proposed questions, alignment with Intermountain Healthcare mission and values, and ensures procedures are consistent with sound research design and risks to subjects are minimized and reasonable in consideration of anticipated benefits. All human research studies that involve more than minimal risk must undergo scientific review and all research proposals undergo an operational review. Scientific/Operations review must be conducted by a sub-committee of the Research Guidance Council or a departmental committee which has been approved by the Research Guidance Council. Scientific reviews will utilize a standardized assessment and scorecard, which will be provided to the IRB as part of the initial IRB submission packet.

Information Technology - Cybersecurity

Cybersecurity is responsible to prevent the exposure, loss or breach of sensitive and critical information, which if exposed, could result in negative impacts to patients, employees and business partners. Cybersecurity is also responsible to review proposed research projects in order to ensure that all hardware and devices are configured to appropriately protect the data and Intermountain systems. Cybersecurity reviews all research projects where any of the following apply:

- data is exchanged with external partners
- medical devices, laptops, tablets or computing equipment is provided by external partners
- non-approved software is required to be installed on Intermountain systems
- use of electronic data capture (EDC) or other websites not managed by Intermountain Healthcare

Cybersecurity approval is required before IRB approval is final.

Monitoring and Auditing

The Intermountain Compliance Department will perform periodic review of research studies. Directed (for-cause) audits will focus on areas of concern that have been identified by any entity (i.e., regulatory body, sponsor, IRB).

To ensure reviewer objectivity, the Intermountain Compliance Department is responsible for internal regulatory and quality assurance reviews. Internal quality assurance reviews may be requested by contacting the Intermountain Compliance Department.

Research departmental quality reviews will identify educational/training opportunities and ensure compliance with Federal regulations, industry standard and Intermountain policies. The objective of an internal research quality assurance review is to protect the rights and welfare of human subjects, and to ensure research data integrity and regulatory compliance for research activities.

Internal reviews and audits for compliance with industry standards, government laws and regulations, and Intermountain policies may be conducted for any research activities, including those identified in the IRB Jurisdiction Policy.

In addition, the HRPP participates in external monitoring activities and utilizes these outcomes toward improving overall compliance and protections of human subjects. External monitoring may be conducted by (but is not limited to):

- Office of Human Research Protections (OHRP)
- Food and Drug Administration (FDA)
- National Institute of Health (NIH)

Education and Training

Researchers, Research Staff and IRB members are to review this plan as part of their initial orientation. The HRPP will provide education opportunities on a regular basis and upon request by Researchers or Departments.

Key study personnel must complete the following Collaborative IRB Training Initiative (CITI) modules as applicable to the type of research being conducted:

Course Title	**Renewal Cycle**
Human Subjects Training Biomedical Social/Behavioral Research Research with Data and Specimens Only IRB Members	5 years
Good Clinical Practices	3 years
Conflict of Interest	4 years

Reporting and Management of Concerns

Questions, concerns, complaints, allegations of undue influence, allegations or findings of noncompliance, or input regarding the Human Research Protection Program may be reported orally or in writing. Employees may report concerns on an anonymous basis. The Intermountain Compliance Department maintains a compliance hotline and email system 24 hours a day, 7 days a week to report noncompliance (compliancehotline@imail.org or 1-800-442-4845). Each report or allegation of noncompliance will be assessed and appropriate actions taken as indicated.

Concerns may be reported to the IRB, HRPP Manager, Institutional Official, Compliance, and Intermountain Legal Services. Compliance has the responsibility to investigate allegations of noncompliance when requested by the IRB and HRPP Manager. The IRB and HRPP Manager will evaluate and manage all allegations and findings of non-compliance.

Employees who report possible compliance issues in good faith will not be subjected to retaliation or harassment as a result of the reporting. Concerns about possible retaliation should be immediately reported to the Compliance Office, HRPP Manager or Institutional Official. Employees and agents of Intermountain Healthcare are strongly encouraged to report concerns. Retaliation will not be tolerated. Refer to the Intermountain Code of Ethics for further information.

To make such reports, contact information is as follows:

Intermountain Compliance Department

Phone: 1-800-442-4845
Email: compliance.hotline@imail.org

Mailing Address: Intermountain Compliance Department
36 South State Street, 10th floor
Salt Lake City, UT 84111

HRPP Manager

Name: Shelby Moench
Phone: 801-507-9401
Email: shelby.moench@imail.org
Mailing Address: Institutional Review Board
5171 S. Cottonwood Street, Suite 400
Murray UT 84107

Institutional Official

Name: Raj Srivastava, MD, MPH
Phone: 801-442-3817
Mailing Address: Intermountain Office of Research
36 South State Street, 16th floor
Salt Lake City, UT 84111

Disciplinary Actions

The Institutional Official for Research may place limitations or conditions on an investigator or research staff member's privilege to conduct Human Research whenever in the opinion of the Institutional Official (in consultation with the Research Guidance Council and the Vice President of Compliance as appropriate) such actions are required to maintain the Human Research Protection Program.

Approval and Revisions to HRPP Plan

Human Research Protection Program Plan is to be approved by the Institutional Official and the Research Guidance Council. This plan is intended to be flexible and readily adaptable to changes in regulatory requirements. The HRPP Manager has the responsibility to review this plan to assess whether it is providing the desired results. At the request of the HRPP Manager, the Institutional Official for Research and Research Guidance Council have the authority to amend this plan as deemed necessary.

Attachments

Attachment A - Organizational Chart