

Spectrum Health Human Research Protection Program

Overview

Overview and Purpose

Spectrum Health is a West Michigan-based health care system dedicated to improving the health and well-being of the communities it serves. Spectrum Health was created in 1997 as a not-for-profit health care system, bringing together Blodgett Memorial Medical Center and Butterworth Health Corporation. Today, Spectrum Health is composed of a health plan (Priority Health), a network of quaternary care and community hospitals (Spectrum Health Hospital Group), and a physician group (Spectrum Health Medical Group). Spectrum Health provides a continuum of care including inpatient, outpatient, and post-acute care. Spectrum Health also includes the Lemmen-Holton Cancer Pavilion, West Michigan's most comprehensive outpatient cancer center, and Helen DeVos Children's Hospital, a state-of-the-art pediatric hospital.

The mission of Spectrum Health is to be the nation's leader for health care by the year 2020. In reaching this mission, Spectrum Health is committed to promoting creative, innovative and cutting-edge research that is conducted within a culture of integrity and ethical accountability and can be translated into improved standards of care for those within our community, state, and nation.

Description of the Components

The Spectrum Health President & CEO and the Senior Vice President of Public Affairs & Research have delegated responsibility for oversight of human research protection activities to Leah Voigt, JD, MPH, Chief Privacy & Research Integrity Officer for Spectrum Health System. She also serves as the Institutional Official for Spectrum Health's Federalwide Assurance (FWA00000058). Leah Voigt has delegated the day-to-day operational activities of the human research protection program to Wendy Parrish, Compliance Manager for the Office of Research Integrity.

The Spectrum Health Institutional Review Board (IRB) serves as the cornerstone for the Spectrum Health Human Research Protection Program. The IRB is, in turn, part of the Office of Research Integrity, which assumes responsibility for research compliance activities and oversight, coordinates and facilitates research policy and education, and provides ethical guidance to individuals engaged in research at Spectrum Health. Staff support is provided to facilitate all efforts related to an effective research compliance and integrity program and, specifically, to support an effective Human Research Protection Program. As of July 1, 2016, the Office of Research Integrity reports up and through the Vice President, Chief Risk/Compliance Officer, who in turn reports through Spectrum Health's Chief Legal Officer.

Previously, research compliance activities were shared by the Office of Organizational Integrity & Compliance (Corporate Compliance) and the Office of the HRPP/IRB. Those two functions and programs have consolidated under the Office of Research Integrity.

The Spectrum Health Office of Research Integrity, including the Human Research Protection Program/IRB, works closely with the Spectrum Health Office of Research Administration to assure human subject research conducted at Spectrum Health complies with all applicable ethical principles, state and federal laws, federal regulations and guidances, and Spectrum Health policies and procedures. The Spectrum Health HRPP applies FDA Good Clinical Practice Guidelines, when applicable, as required by the Sponsor/Agreement. The HRPP, in collaboration with other stakeholders, coordinates policy development and implementation, coordinates educational opportunities, communicates pertinent and timely information about human subject research to members of the research community, and plans

program enhancements. The HRPP/IRB and the Office of Research Integrity, along with other stakeholders, continuously assesses methods to improve operational efficiencies and enhance the quality of the program.

Spectrum Health investigators include physicians employed by the Spectrum Health Medical Group and physicians who are not employed by Spectrum Health, but who are members of the Spectrum Health medical staff (independent physicians who practice at a Spectrum Health hospital facility).

The majority of inpatient research takes place at Spectrum Health Grand Rapids Campus (Blodgett, Butterworth, and Helen DeVos Children's Hospital). Regardless of the type of research, or where it is taking place, the HRPP has been designed to offer the equivalent protections to Spectrum Health patients regardless of where they are receiving care.

The Spectrum Health IRB provides oversight for more than 700 research projects. The IRB meets on the first and third Tuesday of each month. In addition to the leadership of the Office of Research Integrity, the Office of the IRB includes a Lead Compliance Analyst and seven (7) Analysts. Two (2) additional analysts support the Research Integrity education and monitoring and auditing programs.

Spectrum Health's HRPP has the support of a dedicated legal team, including internal and external resources, to assist in identifying applicable laws at the federal, national, and local levels.

Key Representatives

- Tina Freese-Decker, Executive Vice President and COO, Spectrum Health System
- David Leonard, JD, Senior Vice President and Chief Legal Officer, Spectrum Health
- Kim McCoy, Senior Vice President and Chief Risk/Compliance Officer for Spectrum Health
- Leah A. Voigt, JD, MPH, Chief Privacy & Research Integrity Officer
- Christopher Chambers, MD, PhD, Vice President, Research
- Jeff Jones, MD, CIP, IRB Chair
- Steve Pastyrnak, PhD., IRB Vice Chair
- Jodi Bohnhorst, MPA, Manager, Office of Sponsored Programs
- Abrianna (Abby) Dalman, PharmD, Investigational Drug Pharmacist
- Dave Chesla, PA-ASCP, Manager, Spectrum Health Universal Biorepository
- Shanta Layton, Director of Research, Helen DeVos Children's Hospital
- Megan Hausler, BSN, RN, CCRP, Director of Research and Education, Frederik Meijer Heart and Vascular Institute
- Heather Zak, CPA, MBA, Director of Research Finance

Type of Human Research Conducted at Spectrum Health

The Spectrum Health IRB reviews primarily biomedical research but also reviews a small percentage of social and behavioral studies. Research at Spectrum Health is primarily sponsored by industry. A small percentage of research is federal/state funded or supported by non-profit organizations. Numbers of initial protocols reviewed by review category are shown below:

April 2016 to March 2017	Biomedical & Social Behavioral Research	Total (%)
Initial Review via Full Board	52	17%
Initial Review via Expedited	134	44%
Reviewed to Determine if Exempt or Not Human Subject Research	82	27%
Initial reviews ceded to other IRBs	35	12%
Total Initial Reviews for this one year period	303	100%

The Spectrum Health legal team and the Director for the Office of Sponsored Programs are responsible for the final review, negotiation, and submission of all grant and contract applications and for the negotiation of agreements for Spectrum Health owned entities. The Research Finance team provides financial and other administrative assistance by preparing financial reports, submitting invoices, processing payments, and addressing other items.

Other Human Research Protection Support Units

The Spectrum Health Office of Research Administration houses a robust clinical research staff that partner with Principal Investigators to carry out research. This group often partners with the HRPP/IRB on initiatives to ensure and improve human research protections. The HRPP/IRB gains important feedback from Principal Investigators and Spectrum Health's clinical research teams.

The clinical research teams consist of approximately forty (40) staff that support industry-sponsored Phase I, II, III, and IV clinical trials, government-funded clinical research, privately funded research, and investigator-initiated research. The clinical research teams represent the following four sub-specialty areas:

- Oncology Research
- Cardiovascular Research
- Medical/Surgical Research
- Pediatric Research

The clinical research teams coordinate administrative and operational aspects of clinical investigations, including:

- Experienced research coordinator support
- Facilitation of contract review and negotiation
- Budget development and maintenance
- Facilitation of IRB submissions
- Informed consent development

- Preparation and maintenance of regulatory documentation
- Collection, documentation, and review of study data
- Performance of quality assurance
- Education of clinical research staff
- Grant writing support as needed
- Investigator-initiated research support

The Spectrum Health Pharmacy provides an **Investigational Drug Service (IDS)** which is a dedicated research service within Spectrum Health. The primary responsibilities of the IDS are to assure oversight of investigational drug use in human research subjects enrolled in clinical drug trials at Spectrum Health and to ensure that the implementation of investigational drug protocols comply with the Spectrum Health medication use system and all other institutional policies related to medication administration and investigational drug management.

Spectrum Health Laboratory and Pathology Services reviews protocols that utilize either laboratory and/or pathology services to perform research procedures. These efforts provide assurance that the appropriate resources and communication channels have been established to support the conduct of the research.

The **Nursing Research Committee** reviews all requests for nursing research related tasks as they relate to standard of care. They also review research projects for feasibility and validity before IRB submission.

Other Organizations

Cancer Research Consortium of West Michigan (CRCWM) is a consortium of 11 members (participating) hospitals and health systems. It is funded by the National Cancer Institute's National Community Oncology Research Program grant, and its primary focus is cooperative group oncology research. CRCWM offers national adult and pediatric cancer control and cancer treatment protocols to West Michigan. The Spectrum Health IRB serves as the IRB of record for the CRCWM; as required by the terms of the NCI grant, the Spectrum Health IRB relies on NIH's Central IRB for review of CRCWM trials. The CRCWM partners with approximately 110 West Michigan physician investigators to provide access to approximately 190 research studies.

Spectrum Health Helen DeVos Children's Hospital also serves as the lead organization for the Neuroblastoma & Medulloblastoma Translational Research Consortium (NMTRC), an international consortium of hospitals, health systems and academic centers engaged in primarily investigator-initiated research. Over twenty (20) institutions throughout the United States participate in NMTRC. Western IRB serves as the IRB of record for NMTRC, and currently each participating site, including Helen DeVos Children's Hospital, is permitted to conduct its own local IRB review.

Spectrum Health has partnered with the Michigan State University (MSU) College of Human Medicine, which recently opened a four-year medical school in Grand Rapids. Spectrum Health serves as a training ground – and our investigators as faculty preceptors – for approximately 140 students from MSU and other medical schools nationwide. Additionally, sixteen residency programs are active at our hospitals and approximately 300 medical residents train with us each year.

Spectrum Health has developed relationships with other research programs in the community, to enhance human subjects protections through efficiencies such as co-coordination and standardization of training. In order to enhance the level of collaboration and quality of care, Spectrum Health has fostered several

research related partnerships and alliances within the health care community in West Michigan. Spectrum Health researchers work closely with scientists at the **Van Andel Institute (VAI)** as well as **Michigan State University (MSU)** to facilitate advancement of research discovery and translational research.