Clinical Research Center

The Clinical Research Center, largest of the five centers at Marshfield Clinic Research Foundation, provides centralized comprehensive services ensuring quality and efficiency in conduct of primarily Phase II and III clinical trials of drugs, devices and biotechnology. The Clinical Research Center aligns resources from grant development to study completion through publication for industry and investigator initiated, Federal and non-Federal funded foundation grants and contracts.

The mission of the Clinical Research Center is to support basic and translational biomedical research to improve human health by continually advancing disease knowledge as well as availability of new therapies.

Steven H. Yale, M.D., FACP
Director, Clinical Research

Dr. Steven Yale received his Medical Degree from Albany Medical College and completed an Internal Medicine Residency and General Internal Medicine Fellowship at Mayo Clinic, Rochester Minnesota. He serves as Director of Clinical Research at the Marshfield Clinic Research Foundation, Assistant Program Director Internal Medicine Program and Clinical Associate Professor of Medicine, University of Wisconsin School of Medicine and Public Health.
WHY MARSHFIELD CLINIC?

Marshfield Clinic is the largest private group medical practice in Wisconsin and one of the largest in the United States. Experience developing innovative procedures, advancing treatments and conducting clinical trials make Marshfield Clinic’s Clinical Research Center an ideal site for clinical research.

Collaborative Resources
When you choose Marshfield Clinic’s Clinical Research Center for pre-pilot and pilot projects, you enlist our expertise and services with access to 54 clinics, affiliated hospitals and other collaborative organizations.

Infrastructure
Marshfield Clinic has state of the art electronic infrastructure to successfully address the important challenge of decision support at point-of-care.

Integrated Support Services
Marshfield Clinic supports preliminary studies and clinical trials, primarily Phase II and III, of drug, device and biotechnological innovations. We provide administrative, laboratory testing, biostatistical and scientific writing services.

Large Representative Stable Patient Population
Marshfield Clinic serves over 375,000 unique patients with over 4 million patient encounters annually. Historically, patients value and are supportive of medical research with studies achieving participation rates greater than 60 percent. Access to a stable population (less than 3 percent attrition) spanning up to 5 generations with success in recruiting and retaining patients in clinical trials make Marshfield Clinic an ideal environment in which to conduct longitudinal studies and research on inherited diseases.
CLINICAL TRIALS
The Clinical Research Center Director and Administrator work closely with Investigators and Clinical Trial Management to facilitate high-quality good clinical practice research. Our dedicated team of research coordinators and nurses are nationally certified by the Association of Clinical Research Professionals (ACRP), the Society of Clinical Research Associates (SoCRA) or Oncology Certified Nurse (OCN). Our physicians and staff have experience in Phase II, III and IV trials as well as multi-center trials encompassing adult and pediatric populations, drug and device trials, prevention trials, biotechnology, specimen banking and genetics.

RESOURCES

TeleHealth
Marshfield Clinic TeleHealth video technology bridges the gap between resources and remote based populations providing rural patients access to clinical trials.

Electronic Protocol Books
Clinical Research Center electronic protocol books provide access to clinical trial information facilitating enrollment and accrual of patients.

Clinical Trial Management System (CTMS)
CTMS provides a full scale solution to all aspects of Marshfield Clinic Research Foundation study management ensuring efficient incorporation of research with clinical practice. Features include:
- Feasibility
- Detailed protocol implementation with patient calendaring
- Auditing
- Integration with collaborative institutions

Investigational Drug Pharmacy (IDP)
IDP coordinates the procurement, storage, accountability, preparation, dispensation, drug information dissemination and return of all sponsor-supply (commercial and/or investigational) agents used in human subject research.

Core Laboratory
A service laboratory staffed by an experienced team with broad-based expertise assist in the design and execution of laboratory-based testing for research projects. The laboratory supports tissue culture, bacteriology, virology, molecular microbiology and general molecular biology research.

SUPPORT SERVICES

Office of Research Integrity and Protection (ORIP)
The Institutional Review Board (IRB) meets bi-weekly resulting in rapid turnaround from application submission to date of IRB review. ORIP is a founding member of the Wisconsin Institutional Review Board Consortium (WIC).

Research Committee
The Research Committee determines scientific merit and internal funds approval.

Office of Scientific Writing and Publication (OSWP)
OSWP supports Marshfield Clinic scientists and clinician investigators writing external and internal grants and in publication of medical research results.

Sponsored Programs and Fiscal Affairs
The Sponsored Programs and Fiscal Affairs office provides assistance with all pre-award, post-award and accounting functions related to the management of research grants and contracts.

Quality Management Program
The Clinical Research Center’s Quality Management Program assures compliance with federal, international, local and state human subject protection standards.

Clinical Medicine & Research (CM&R) and Journal of Agromedicine
These Marshfield Clinic publications are nationally and internationally indexed professional journals.

Biostatistical and Informatics Analytics
A Biomedical Informatics Research Center team of biostatisticians and program analysts assist with project planning, data analysis and interpretation. These experts provide programming and information systems support, biostatistics and data management, as well as assistance in study design, feasibility and sample size estimation.

Physician-Scientist Emeritus
The program actively engages the expertise of retired physicians and scientists for direct contribution to institutional research and education endeavors.
Marshfield Clinic CCOP is overseen by Dr. Matthias Weiss, Principal Investigator. CCOP Investigators provide leadership in each of Marshfield Clinic’s primary divisions.

CCOP provides state-of the art cancer research in community based healthcare facilities in central, western and northern Wisconsin. Marshfield Clinic CCOP, one of two in the State of Wisconsin, is in its third decade of sustained funding.

Adult and pediatric cancer patients have access to over 140 clinical treatment, symptom management and cancer prevention trials at any given time. It has consistently contributed to successful clinical trials that exceed accrual goals and facilitate the development of interventions that prevent and treat cancer. CCOP protocols are available through a broad network of cancer groups and projects.
MARSHFIELD MEDICAL COMPLEX

The Marshfield medical complex consists of Marshfield Clinic, Marshfield Clinic Research Foundation, Affiliated Hospitals, Marshfield Labs and Applied Sciences.

Marshfield Clinic
Marshfield Clinic employs approximately 780 physicians representing 86 different specialties and 6,500 additional staff working on the main campus in Marshfield or one of 54 regional clinics serving the population of central, western and northern Wisconsin; and the Upper Peninsula of Michigan.

Marshfield Clinic Research Foundation (MCRF)
The mission of MCRF is to discover and communicate scientific knowledge that substantially improves human health and well being.

Marshfield Clinic’s Research Program has three guiding principles:
1) Integration of Medical Research into Clinical Practice
2) Beneficial Collaboration
3) Excellence in Translational Research

MCRF is organized into five research Centers: Marshfield Epidemiology Research Center (MERC), Biomedical Informatics Research Center (BIRC), Center for Human Genetics (CHG), Clinical Research Center (CRC) and National Farm Medicine Center (NFMC).

Research discoveries by MCRF scientists and physicians have expanded knowledge in multiple fields of human health and reduced the burden of disease and disability.

Marshfield Clinic’s research program is an essential component of its status as a nationally recognized academic medical center and as an affiliate campus of the University of Wisconsin School of Medicine and Public Health.

Affiliated Hospitals
Marshfield Clinic partners with a number of affiliated hospitals:
- St. Joseph’s Hospital (Member of Ministry Health Care) is a 500+ bed tertiary care teaching institution located in Marshfield. It is the only major rural referral medical center in Wisconsin and shares a combined electronic medical record with Marshfield Clinic.
- Saint Clare’s Hospital (Member of Ministry Health Care) is a 110-bed provider located in Weston. This all-digital hospital is completely chartless with patient data instantly updated in an electronic medical records system.
- Lakeview Medical Center is a 75-bed acute care hospital located in Rice Lake and serves the medical needs of northwest Wisconsin.
- Sacred Heart Hospital is a 344-licensed bed acute care hospital located in Eau Claire with a level three trauma center and Regional Cancer Center services.
Marshfield Labs
Marshfield Labs performs over 2.4 million diagnostic clinical laboratory tests and reports over 22 million results annually. Marshfield Labs holds accreditation and deemed status from the Clinical Laboratory Improvement Act (CLIA), the College of American Pathologists (CAP) and Joint Commissions for Accreditation of Healthcare Organizations (JCAHO).

Technology Transfer
Marshfield Clinic partners with WiSys Technology Foundation, Inc., the patenting and licensing organization of the University of Wisconsin (UW) System, with the goal to strengthen collaborations in research and technology transfer, share resources, promote joint development and protect intellectual property. WiSys, a wholly-owned subsidiary of the Wisconsin Alumni Research Foundation (WARF) is the nation's pre-eminent technology transfer organization and provides patenting and licensing services to Marshfield Clinic physicians and scientists and facilitates collaborations between University and Clinic researchers, through the Clinic’s Applied Sciences Division.
Database Support

Data Warehouse (DW)
Marshfield Clinic's sophisticated DW is intended to be the sole reporting source for high quality integrated information related to patient care, research and Clinic operations. DW is a data repository that has been optimized for data analysis and reporting to support research activities, quality assurance and decision support at Marshfield Clinic. DW utilizes existing Marshfield Databases and other data sources to store key information central to defining patient phenotypes. Electronic Medical Record (EMR) data is transferred to DW, where it is linked accurately and completely as longitudinal continuums of care, ensuring that virtually no records are lost. DW serves as an essential resource for the development of research databases. As data is moved from clinical applications into DW, data models and coding standards are normalized, algorithms are applied that insure data quality and data is transformed into a data model that supports population based research.

Electronic Medical Record (EMR)
Marshfield Clinic was one of the first institutions to establish a Combined Medical Record (CMR), which it shares with St. Joseph's Hospital, Marshfield. Through its Windows-based EMR viewer, CMR supports the viewing of all transcribed documents, laboratory results, vitals and other observations, patient demographics, encounter history, special conditions, alerts, immunization history, problems list, medications, diagnostic images, image forms and insurance information. Medical information is comprehensive and readily available. Diagnostic codes for each patient have been computerized since 1960 and medical procedure codes have been archived since 1985. Individual patient records have been maintained in an extensive electronic medical system since the early 1990s. A dental component, the Oral-System Research Project (OSRP), is also being built as a parallel resource to The Personalized Medicine Research Project (PMRP) which incorporates electronic health and dental records plus additional environmental data (microbiome characterization).

Medical Event Charting and Code Acquisition (MECCA)
MECCA database stores point of care applications between patients and providers. MECCA captures the detail of visits, providers, diagnoses, procedures and vitals. It uses a clinically relevant lexicon developed by Marshfield Clinic physician specialists.

Clinical Registries
The Clinical Registry systems support the evaluation of clinical practice and health outcomes in targeted clinical populations, benchmarking, accreditation, or management reporting. The clinical registries contain either data that is collected at the time of patient care or data retrospectively collected by abstracting the CMR.
The Marshfield Epidemiologic Study Area consists of two geographically separate areas:

- **MESA North**
  (10 zip codes around the northern Ladysmith and Phillips Centers)
- **MESA Central**
  (14 zip codes clustered around the main clinic campus in Marshfield)

MESA North and MESA Central combined are home to about 80,000 people who get all or most of their health care from one or more of Marshfield Clinic’s 54 regional locations or from affiliated hospitals. Linking this research resource with the Clinic’s comprehensive electronic medical record system provides the capacity to conduct population-based clinical and epidemiologic research.

**Population Cohorts**

**Marshfield Epidemiologic Study Area (MESA)**
MESA is a geographic region defined by zip codes where the great majority of residents choose to receive medical care at Marshfield Clinic, its regional centers and affiliated hospitals. Most of MESA meets the federal definition of “rural”. Since MESA was launched by Marshfield Epidemiology Research Center staff in July 1991, the resulting dynamic cohort has grown to include individual follow-up time on more than 150,000 people. Linking MESA with the Marshfield Clinic Electronic Medical Record and archived Data Warehouse health data enables population based, health-related research to be conducted.

**Personalized Medicine Research Project (PMRP)**
PMRP is the largest population-based genetic research project in the United States involving more than 20,000 central Wisconsin residents. Subjects provided blood from which DNA was extracted and plasma and serum stored, and allowed access to their Marshfield Clinic medical records. The PMRP was designed to be a national resource for research in the areas of genetic epidemiology, pharmacogenetics and population genetics. Researchers work closely with colleagues in Information Systems to develop electronic algorithms to define phenotype using the electronic medical records.
Wisconsin Network for Health Research (WINHR)
WINHR is a collaborative effort involving the UW School of Medicine and Public Health, Marshfield Clinic Research Foundation, Aurora Health Care and Gundersen Lutheran Medical Foundation. WINHR was established to promote greater interinstitutional cooperation in research and to move research results to the bedside more efficiently and effectively. WINHR, established in 2005, provides researchers with: 1) an expanded geographic reach and ethnically diverse study populations; 2) potential access to the electronic medical records of the 3-4 million residents served by the partner sites; 3) specialty and primary care collaborators from WINHR partner institutions; and 4) increased efficiency in conducting research and meeting accrual goals.

Wisconsin Research & Education Network (WREN)
WREN is a statewide practice-based research network of over 130 primary care clinicians and academic researchers. The mission of WREN is to improve health outcomes for the people of Wisconsin through education, and through promoting and conducting primary care research in partnership with primary care clinicians and the communities they serve. WREN members conduct high-quality translational research projects in “real-world” family practices across Wisconsin.

Wisconsin Genomics Initiative (WGI)
WGI is a historic collaboration among Marshfield Clinic, Medical College of Wisconsin, University of Wisconsin School of Medicine and Public Health and University of Wisconsin-Milwaukee. The WGI vision is to be able to predict for individual patients in a clinical setting the risks of disease susceptibility and treatment response using the combined power of cutting edge genetic, phenotypic, and environmental analysis.
WON was established to allow community health centers to enroll patients in select cancer clinical trials that are open to the UWCCC. WON conducts National Cancer Institute (NCI) or industry supported multi-institution trials (Phase I and II therapeutic involving Investigational New Drug and non-IND compounds) encompassing a broad range of disease sites, including solid tumors and hematologic malignancies, as well as protocols evaluating interventions in the supportive and psychosocial care of patients with cancer.

Health Maintenance Organization Research Network (HMORN)
Marshfield Clinic Research Foundation is a member of the HMORN; a consortium of 16 HMO organizations that have formal, recognized research capabilities and whose mission is to use their collective scientific capabilities to integrate research and practice for the improvement of health and health care among diverse populations. Marshfield Clinic Research Foundation participates in the Cancer Research Network (CRN), Cardiovascular Research Network (CVRN), Center for Education and Research on Therapeutics (CERT), Developing Evidence to Improve Decisions about Effectiveness Network (DEcIDE) and Vaccine Safety Datalink (VSD).

Institute for Clinical and Translational Research (ICTR)
Marshfield Clinic Research Foundation’s devotion to improving the health of Wisconsin residents is further reflected in it’s collaborative partnership with the University of Wisconsin School of Medicine and Public Health. In 2007 ICTR was jointly founded and subsequently received a prestigious multi-year, multi-million dollar Clinical and Translational Science Award from the National Institutes of Health (NIH). The goal of ICTR is to create an environment that transforms research into a continuum from investigation through discovery to translation into real-life community practice, thereby linking even the most basic research to practical improvements in human health.
Clinical Research Center

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