UWHealth

Administrative Policy

Location: Wisconsin
Chapter: Legal/Business Integrity

Policy Title: **Clinical Research Conducted within UW Health Facilities**
Policy Number: **4.24**
Effective Date: June 20, 2023

I. PERSONS AFFECTED

Note: If an individual fits into any checked box, that individual is subject to this policy.

X	UWHC or UWMF employees		Non-employed contracted individuals (consultants, independent contractors, or agency staff) doing business remotely
X	UWHC or UWMF remote employees		Vendors
	UWHC or UWMF employees, not including trainees	X	Individuals involved in research (e.g., study coordinators, research nurses, etc.)
X	Advanced practice providers and other non-physicians credentialed by the UW Health Medical Staff Administration Office		Volunteers and Patient and Family Advisors
X	SMPH-employed attending and faculty physicians and GME physicians		Non-employed students or visiting GME physicians
X	SMPH-employed non-physician providers		Observers and those job shadowing
	SMPH-employed GME physicians in a UW Health sponsored program		Patients
X	GME physicians (residents and fellows in ACGME-accredited programs) and employed by UW Health		Visitors
X	GME physicians not employed by either UW Health or SMPH		Any individual present in UW Health clinical space
	Non-employed contracted individuals (consultants, independent contractors, or agency staff) doing business on UW Health property		Any individual present in UW Health non-clinical space

II. PURPOSE

To provide a University of Wisconsin Hospitals and Clinics Authority (UWHCA) and the University of Wisconsin Medical Foundation (UWMF) (together referred to as UW Health) policy and related procedures to support the protection of human subjects and research integrity for clinical research conducted within UW Health facilities.

III. DEFINITIONS

A. Clinical Research: as defined by the National Institutes of Health (NIH), is research in which people, or data or samples of tissue from people, are studied to understand health and disease. Clinical research helps find new and better ways to detect, diagnose, treat, and prevent disease.

B. Clinical Trial: as defined by the NIH, is 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.

IV. POLICY KEY ELEMENTS

A. In alignment with the UW Health's mission to sponsor and support "research in the delivery of health care to further the welfare of the patients treated" and apply "the advances in health knowledge to alleviate human suffering, promote health and prevent disease" UW Health's staff members will conduct, coordinate, support and/or promote scientific research.

B. This policy is guided by the general principle that the University of Wisconsin - Madison Campus (UW-Madison) and UW Health are committed to research data integrity and to the protection of the safety, rights and welfare of human participants taking part in clinical research. Furthermore, these protections are maintained as required by applicable federal and state regulations, accreditation standards, and as outlined by applicable UW-Madison, School of Medicine and Public Health (SMPH), and UW Health policies and professional standards.

C. This policy applies to all clinical research and clinical trials (see NIH definitions above) conducted within UW Health facilities, and includes research with patients, patients' specimens or data, using UW Health network and software applications, and/or requests for UW Health workforce participation in said research.

D. Clinical research that falls under this policy must also follow:

1. Any UW Health policies that apply to UW Health facility spaces and resources (e.g., designated clinical and non-clinical spaces), network and software applications (e.g., Health Link accessed from a remote location), and
2. UW-Madison Human Research Protection Program (HRPP) policies and procedures in the HRPP Toolkit Library.

E. The University of Wisconsin Hospitals and Clinics Authority (UWHCA) and the University of Wisconsin Medical Foundation (UWMF) designates UW-Madison as their Institutional Review Board (IRB) of record on their respective Federal-wide Assurances (FWA) and have entered into an IRB Authorization Agreement with UW-Madison.

1. Clinical research conducted under this policy must be reviewed by the UW-Madison IRB, or another UW-Madison ~~a~~approved IRB.

F. The oversight of the operations and quality/compliance roles of clinical research within UW Health is shared between UW Health and UW-Madison through alignment of both organizations' policies, procedures, and infrastructure applicable to clinical research and clinical trials. UW Health uses UW-Madison infrastructure for the following key administrative functions:

1. Study contract signature and budget development,
2. Studies Fiscal Management,
3. Ongoing qualified clinical research workforce activities,
4. Research records
5. Research records management,
6. Ensuring qualified clinical research staff,
7. HRPP, including IRB review & oversight, Reliance review, Scientific review, and study monitoring and audit.

G. Researchers in UW Health clinical space must apply for and be granted clinical privileges per the UW Health Bylaws and Rules and Regulations of the Medical Staff and any other ~~All~~ decisions concerning the use of UW Health facilities, employees, non-employees in UW Health sponsored GME programs, and material resources are made by UW Health administrators and professional staff members.

H. UW Health Graduate Medical Education (GME) physicians participating in clinical research and/or clinical trials require:
   1. A first sign off/attestation from the Principal Investigator (PI);
   2. The second by the residency/fellowship director; and
   3. The final sign off should be from the department chair (who may rely on input from their division chief or associate chair in deciding whether to sign off).

I. Clinical research involving Human Subjects as defined by the Department of Health and Human Services (DHHS) that is conducted, supported, or otherwise subject to regulations by a Federal department or agency that has adopted the Common Rule, shall follow 45 CFR Part 46 Subpart A for the protection of human participants as applied by UW-Madison HRPP and UW Health.
   1. Such research conducted or supported by DHHS, the Veterans Administration (VA), the Department of Homeland Security (DHS), Department of Defense (DOD) or other federal agencies, as applicable, shall comply with all subparts of 45 CFR Part 46.
   2. Regardless of the source of support and/or funding, such research shall follow the ethical principles described in the report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" also known as "The Belmont Report."
   3. Such research shall be directed by guidelines established by the Office for Human Research Protections (OHRP) within DHHS.

J. Clinical research involving Human Subjects as defined by US Food and Drug Administration (FDA), shall follow 21 CFR Parts 50, 54, 56, 312, 314, 812, as applicable, and all other applicable FDA regulations as applied by UW-Madison HRPP and UW Health policies.
   1. Such research shall be guided by current "International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use" (ICH)-Good Clinical Practice (GCP) (E6) as adopted by the FDA and the guidance of ethical principles stated in the "Declaration of Helsinki", unless other requirements are stated in clinical agreements, contracts, or grants.
   2. Such research also shall be informed by FDA guidelines pertaining to Good Clinical Practice and Clinical Trials.

K. UW Health and the UW-Madison HRPP, including the University of Wisconsin Clinical Trials Institute (UW CTI), are responsible for communicating new or revised policies, procedures or other written clinical research-related materials to all stakeholders through their websites, newsletters, email and other communication channels (see Reference section for more information). Training will be supplied, as appropriate.

V. POLICY DETAILS

Quality and operational documents and forms will be developed as needed to communicate, implement, and guide the conduct of clinical research and/or clinical trials covered by this policy.

VI. REFERENCES

UW Health Administrative Policies

A. 1.49 - Access to Enterprise Data for Reporting and Analytics
B. 2.13 - Charges for Patients in Research Studies
C. 4.11 - Investigational and Study Drug Control
D. 4.27 - Compassionate Use of an Investigational Agent or Use of an Investigational Agent from a Second Institution
E. 9.85 - Training and Competency Verification for RNs Engaged in Clinical Research at UW Health Who are Not Employed by UW Health
F. 12.10 - Research Safety Committee Authority and Function

UW Health Departmental Policies/Guidelines

A. Nursing Administration 3.11 - Research: Obtaining Nursing Resources and Support
B. Nursing Administration 3.23 - Research: Conducting Nursing Research at UW Health (Nursing Administration)
C. Pharmaceutical Research Center 10.4 - Distribution of Research Drugs/Supplies

UW-Madison Policies

A. UW-Madison HRPP Toolkit Library - https://irb.wisc.edu/toolkit-library
B. UW-Madison Human Research Protection Program Plan - https://research.wisc.edu/compliance-policy/human-research-protection-program
C. UW-Madison Conflict of Interest Policy - https://policy.wisc.edu/library/UW-4001
D. UW-Madison Misconduct in Scholarly Research - https://policy.wisc.edu/library/UW-869

External References

A. Food and Drug Administration (FDA) regulations - 21 CFR Parts 50, 54, 56, 312, 812, and all other regulations of that agency relevant to the protection of human subjects - https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials
B. Office of Human Research Protections (OHRP) regulations - 45 CFR Part 46, Subparts A-D - https://www.hhs.gov/ohrp/index.html
C. Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979 - http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
D. World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013 - http://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
E. Current International Conference on Harmonization (ICH) Guideline for Good Clinical Practice (GCP) E6 (R2), FDA, United States, Published in the Federal Register, March 1, 2018, Vol. 83, No. 41, p. 8882-3 - https://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html
F. NIH definition of clinical research - https://www.nih.gov/health-information/nih-clinical-research-trials-you/what-is-clinical-research
G. NIH definition of clinical trial - https://grants.nih.gov/policy/clinical-trials/definition.htm

VII. COORDINATION

Sr. Management Sponsor: Chief Clinical Officer

Primary Owner: Senior Director, Chief Clinical Research Officer

Stakeholders: UW Clinical Trials Institute
Research Medical Director
Director, Clinical Trials Quality
Sr. Director, Clinical Trials Integration and Medical Science Liaison

University of Wisconsin
Director, Office of Research Compliance
Director, Institutional Review Board
Senior Legal Counsel, Office of Legal Affairs

UW Carbone Cancer Center
Manager, Compliance and Quality Assurance

UW Health
System VP, Business Integrity
Corporate Counsel
Nurse Scientist, Magnet and Nursing Excellence
Manager, Pharmaceutical Research Center

Approval Committee: UW Health Administrative Policy Committee

VIII. APPROVAL

Elizabeth Bolt
UW Health Chief Administrative Officer