What is Marshall University's Human Research Protection Program?

The Marshall University Human Research Protection Program (HRPP) exists to protect the rights and welfare of persons who voluntarily participate in research studies conducted by Marshall faculty and staff and is administered by the Office of Research Integrity (ORI).

The HRPP includes the responsibility to monitor all aspects of the institution's research activities, to include the informed consent process, as well as to provide education to investigators, potential investigators and Institutional Review Board (IRB) members concerning the ethical principles involved in human subjects research.

MARSHALL UNIVERSITY®

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MARSHALL

OFFICE OF
RESEARCH INTEGRITY

Human Research Protection Program

What you need to know about conducting human research at Marshall University

Association for the Accreditation of Human Research Protection Programs, Inc.
Full AAHRPP Accreditation

What is an Institutional Review Board (IRB)?

The Institutional Review Boards (both the Medical IRB #1 and the Social/Behavioral/Educational Sciences IRB #2) are the university's mechanism to review, approve, disapprove or request changes to research projects that involve human subjects, regardless of funding source. The institution has an approved Federal-wide Assurance from the U.S. Department of Health and Human Services (FWA00002704).

The Board members ensure that the proposed research protects the rights and welfare of human subjects and that the study has undergone a thorough review of the ethical considerations of Respect for Persons, Beneficence and Justice.

What is research?

Under DHHS regulations, research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Under FDA regulations, research is any experiment that involves a test article and one or more human subjects, and that either is subject to requirements for prior submission to the FDA.

What is a human subject?

Under DHHS regulations, a human subject is defined as a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual; or (2) identifiable private information.

What is considered human subject research?

Activities are human subject research under U.S. Department of Health and Human Services (DHHS) or U.S. Food and Drug Administration (FDA) regulations when they meet the DHHS or FDA definition of **"research"** and involve a **"subject"** as defined in DHHS or FDA regulations.

Under FDA regulations a human subject is defined as an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A participant may either be a healthy human or a patient.

When must I submit my human subject protocol to the Office of Research Integrity?

IRB approval must **precede** any research involving human subjects, including the recruitment of subjects.

It is often of assistance to the researcher to review the IRB Protocol Application Form as he or she is writing the research protocol so that all appropriate ethical considerations are included in both the protocol and informed consent.

www.marshall.edu/research/ori

For more information, to voice concerns or complaints, or to offer input, please contact the Office of Research Integrity at **304.696.4303** or **www.marshall.edu/research/ori**.