MERITUS MEDICAL CENTER INSTITUTIONAL REVIEW BOARD

Our primary goal is to facilitate the institutional Review Board (IRB) review process, provide support to investigators to assure compliance with all applicable federal, state, and local regulations, institutional policies, and procedures which aim to protect human subjects, all while providing timely expert care close to home.

The board is comprised of at least 5 members from the following backgrounds physicians, pharmacists, statisticians, nurses, and community members in order to provide complete and adequate review. This Board will consist of at least one member that is not affiliated with the institution and one member who is not a scientist. This IRB has several consultants in various disciplines who advise the Board periodically in the protocol review.

HOW DOES THE INSTITUTIONAL REVIEW BOARD PROTECT PEOPLE IN RESEARCH?

The Meritus Medical Center Institutional Review Board's (MMCIRB) is primary responsibility is to review and monitor research studies to ensure the protections of rights, privacy and welfare of all human participants who are the subjects of research at Meritus Medical Center by applying the ethical principles of respect for persons, beneficence, and justice.

This is accomplished by a rigorous review by this group of professionals with various backgrounds to ensure the following are explained in accurate terms that are understandable: 1) complete explanation of the study; 2) benefits and risks in the study, 3) what is expected of you, 4) the time commitment, 5) your right as a research participant and the ability to ask as many questions as needed to help you make an informed decision to participate.

The Meritus Medical Center IRB operates in accordance with Federal Drug Administration and HHS regulations for the protection of human subjects in research. In addition to complying with federal regulations, all research at Meritus Medical Center must comply with our mission and values.

As part of the human subject research oversight process, the IRB will review and respond to research participant's questions, concerns or complaints. If you are a research participant and have a research question or concern, contact the Office for the Protection of Human Subjects. The contact information is located in your consent form. All inquiries are held in the strictest confidence unless otherwise instructed. We will do everything to review and respond to your inquiry in a timely manner.

If you have any questions or would like assistance, contact the Office of Human Subjects Protection at 301-790-8825 or email <u>Christine.Fornwalt@meritushealth.com</u>

HELPFUL LINKS

- <u>CITI Training Program</u>
- Office for Human Research Protection
- U.S. Food and Drug Administration
- <u>Clinical Trials.gov</u>
- HIPAA and Research