



**Statement of Compliance
with International Conference on Harmonization guidelines
for Good Clinical Practice**

Good clinical practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety, and wellbeing of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The Medical College of Wisconsin/Froedtert Hospital IRBs comply with the Responsibilities, Composition, Functions and Operations, Procedures, and Record-keeping as stated in the International Conference on Harmonization (ICH) Guidelines for Good Clinical Practice E6 Section 3.

The Medical College of Wisconsin/Froedtert Hospital IRBs are established and constituted in accordance with the Federal Food, Drug and Cosmetic Act 21 CFR 50 and 56.