



**CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE**

To: External sponsors of clinical research & trials at
University of Massachusetts Medical School and UMass Memorial Medical Center

Re: Statement of Compliance

HHS Regulations

The University of Massachusetts Medical School (UMMS) holds a federal-wide assurance (FWA 00004009) from the Office for Human Research Protection (OHRP). Under this HHS assurance, all human research review and approval at UMMS and its clinical partner, UMass Memorial Medical Center, complies with 45CFR46, including all subparts B, C and D.

Institutional Review Board

The Institutional Review Board (IRB) for University of Massachusetts Medical School comprises two committees (IRB #1 00000269 and IRB #2 00000270), registered with HHS as the *Committee for the Protection of Human Subjects in Research*, and operates in compliance with FDA and HHS regulation.

Belmont Report

The University of Massachusetts Medical School adheres to the ethical principles for the protection of human subjects in research, including respect for persons, beneficence and justice as set forth in the Belmont Report.

FDA Regulations

The University of Massachusetts Medical School participates in clinical research and trials which fall within jurisdiction of the Food and Drug Administration (FDA). The institution complies with 21CFR50 and all subparts, 21CFR56, 21CFR312 and 21CFR812.

ICH/GCP Guidelines

The University of Massachusetts Medical School complies with Guidelines of the International Conference on Harmonization (ICH) for Good Clinical Practice where they are consistent with FDA and HHS regulations.

Sincerely,

Katherine Luzuriaga, M.D.
UMass Memorial Health Care Endowed Chair in Biomedical Research
Director, UMass Center for Clinical and Translational Science
Vice Provost, Clinical and Translational Science
Professor, Molecular Medicine, Pediatrics, and Medicine
University of Massachusetts Medical School
Email: Katherine.Luzuriaga@umassmed.edu

Assistant: Donna Peart (508) 856-1952