



**CENTER FOR CLINICAL AND
TRANSLATIONAL SCIENCE**

Date: January 19, 2022

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

Re: Statement of Compliance

HHS Regulations

The UMass Chan Medical School 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 UMass Chan 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 UMass Chan 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 UMass Chan 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 UMass Chan 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,

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