

Health Sciences Campus Institutional Review Board

Andreas Klein, MD
Chair

Julie Morelli Novak 
Director of IRB Operations

Subject: Tufts Health Sciences IRB Statement of Compliance

The Tufts Health Sciences IRB provides services to two institutions, Tufts Medical Center and Tufts University Health Sciences. All research involving human subjects reviewed by the Tufts Health Sciences IRB is guided by the ethical principles in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research prepared by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Tufts Health Sciences IRB panels are duly constituted, fulfilling Federal requirements for membership; have written procedures for initial and continuing review for human subjects research; prepare written minutes of convened meetings; and retain records pertaining to the review and approval process all in compliance with the requirements for IRBs defined in DHHS 45 Code of Federal Regulations (CFR) Part 46, Food and Drug Administration (FDA) 21 CFR Parts 50 and 56, and Guidelines of the International Conference on Harmonization relating to Good Clinical Practices (GCPs) to the extent that those guidelines mirror the regulations and guidance set forth by the FDA regulations.

The **IORG** (*IRB Organization*) Number for the Tufts University Health Sciences and Tufts Medical Center is:
IORG0000435

The two review panels registered under this IORG are associated with the Tufts Health Sciences Human Research Protection Program:

The IRB # for **IRB-RED** is **IRB00000577**

The IRB # for **IRB-BLUE** is **IRB00001236**

Tufts University Health Sciences and Tufts Medical Center hold the following Federalwide Assurance (FWA) numbers:

Institution: **Tufts U Hlth Sciences**

FWA #: **FWA00004517**

Institution: **Tufts Med Ctr, Inc. (previously Tufts-New England Med Ctr)**

FWA #: **FWA00004449**

Refer to the Office of Human Research Protections (OHRP) website: <http://ohrp.cit.nih.gov>

The Tufts Health Sciences Human Research Protection Program has received full Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation. For more information, refer to the AAHRPP website at: <http://www.aahrpp.org/learn/find-an-accredited-organization>.

The Tufts Health Sciences Human Research Protection Program does not release IRB member rosters or membership lists. Any IRB member who is an Investigator, Co-Investigator, or has any other conflict of interest with a study under review by the Tufts Health Sciences IRB will not participate in the deliberation or vote of that study, although he or she may be called upon to answer questions during the review.

Current forms and templates are publicly available on the Tufts Health Sciences IRB website: <http://viceprovost.tufts.edu/HSIRB/>

If you have questions or need further information, please do not hesitate to contact us.