

The University of Kansas Medical Center

Human Research Protection Program

January 7, 2019

TO: Research sponsors

FROM: Karen Blackwell, MS, CIP
Director, Human Research Protection Program

RE: Regulatory assurance statement

All research involving human subjects at the University of Kansas Medical Center (KUMC) is governed by the ethical principles outlined in the Belmont Report, specifically, the three key concepts: respect for persons, beneficence and justice. The Human Research Protection Program operates under Federalwide Assurance # FWA00003411, which is valid until January 17, 2023. Our number IORG0000100 is valid until January 4, 2022.

The following IRBs are covered by our assurance:

IRB00000161 - U of Kansas Med Ctr IRB #1 – Kansas City campus
IRB00006196 - U of Kansas Med Ctr IRB #3 – Kansas City campus

The HRPP administers 2 institutional review boards (IRBs) that oversee all human subjects research on the Kansas City, Wichita and Salina campuses.

KUMC research may be under the authority of external IRBs, provided the reliance agreement has been approved the HRPP and by the university's legal counsel.

KUMC applies the federal Common Rule (45 CFR 45, Subpart A) to all non-exempt human subjects research conducted or supported by any federal department or agency that has adopted the Common Rule. KUMC also applies Subparts B through D of the federal Common Rule to non-exempt human subjects research funded by the U.S. Department of Health and Human Services ("DHHS research").

Research under the oversight of the U.S. Food and Drug Administration (FDA) also must comply with 21 CFR Parts 50, 56, 312 and 812. KUMC follows Good Clinical Practice guidelines to the extent they are otherwise contained within the FDA regulations. Research involving protected health information must comply with HIPAA regulations on privacy and security at 45 CFR Parts 160 and 164.

The KUMC IRBs are duly constituted to meet the membership requirements of 45 CFR 46.107 and 21 CFR 56.107. Members include scientific, non-scientific and community members who fulfill federal requirements for expertise and diversity. When necessary, consultants with

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additional expertise provide information to the board. KUMC does not provide the IRB membership list to sponsors or collaborators.

No member may participate in an IRB review in which they have a conflict of interest. The conflicted member may provide information requested by the IRB. Conflicted members leave the room during discussion and voting on the project.

State laws governing research at KUMC include those related to the definition of minors, reporting of infectious diseases, reporting of abuse, and the designation of legally authorized representatives for surrogate consent.

IRB approval letters are generated after the investigator has fulfilled all compliance and institutional requirements related to human research. These include IRB review and approval, management of any conflict of interests (if applicable), HIPAA, Radiation Safety approval (if applicable) and Biosafety approval (if applicable). The date of approval is the date an IRB administrator confirms that all HRPP requirements have been satisfied. The approval letter will have the typed name of the HRPP Director or administrator. The typed signature from the electronic system is equivalent to a hand-written signature and is evidence of approval.

All institutional policies and procedures related to human research protections are developed and implemented to align with the Belmont principles and regulatory standards cited above. The KUMC Human Research Protection Program was granted Full Accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) in September 2007 and was fully re-accredited in December 2010 and December 2015.

The Standard Operating Procedures of the KUMC IRB are publicly available on the IRB's website.

Kam Blackwell 1/7/2019