DukeHealth

Institutional Review Board

To: DUHS Research Community, Sponsors, and Collaborators
From: DUHS Institutional Review Board
Date: March 1, 2026
RE: Duke University Health System Statement of Compliance and Assurance

Duke University Health System (DUHS) and all registered components conduct human subject research in compliance with all applicable regulations and laws governing the protection of human participants. DUHS maintains a current Federalwide Assurance (FWA00009025) with the U.S. Department of Health and Human Services (HHS) Office of Human Research Protection (OHRP).
DUHS operates 10 Institutional Review Boards (IRBs) that are registered with the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA), as applicable; specifically,

1. IRB00004122 Duke U Hlth System, Inc. IRB #1-DUMC
2. IRB00000125 Duke U Hlth System, Inc. IRB #2-DUMC
3. IRB00000723 Duke U Hlth System, Inc. IRB #3-DUMC
4. IRB00000126 Duke U Hlth System, Inc. IRB #4-DUMC
5. IRB00000724 Duke U Hlth System, Inc. IRB #5-DUMC
6. IRB00000744 Duke U Hlth System, Inc. IRB #6-DUMC
7. IRB00004989 Duke U Hlth System, Inc. IRB #7-DUMC
8. IRB00004990 Duke U Hlth System, Inc. IRB #8-DUMC
9. IRB00012400 Duke U Health System, Inc. IRB #9
10. IRB00004992 Duke U Hlth System, Inc. IRB #10-Rapid Response

IRB review and oversight are conducted in accordance with applicable regulations, including but not limited to:

- 45 CFR Part 46 (DHHS/Common Rule);
- 21 CFR Parts 50 and 56 (FDA);
- 32 CFR 219 and DoD Instruction 3216.02 (Department of Defense);
- 28 CFR 46 (Department of Justice);
- DUHS institutional policies and procedures for the protection of human subjects.

DUHS maintains IRB rosters and related regulatory records in accordance with institutional policy and applicable federal and state regulations. IRB rosters will no longer be publicly posted as of March 01, 2026 and will not be shared with sponsors, commercial entities, or individuals without regulatory oversight authority. Rosters and related documentation will be disclosed only as required for audits or inspections by regulatory authorities, accreditation activities, or as otherwise required by applicable laws or institutional policies. This approach applies to any previously posted historical IRB rosters; such records will be retained internally in accordance with applicable record retention requirements but will not be publicly available.

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DUHS maintains institutional conflict of interest (COI) policies applicable to all individuals involved in the conduct, review, and oversight of human subjects research. IRB members are required to disclose any financial or other interests that could reasonably affect, or appear to affect, their objectivity in the review of research. Members with a conflicting interest are recused from the review, discussion, and vote on the affected protocol in accordance with federal regulations and DUHS policy, except as permitted to provide information requested by the IRB.

DUHS may enter into IRB reliance agreements when appropriate and will ensure that human subjects research conducted under such agreements complies with all applicable regulatory requirements and institutional policies.

Sharon Ellison, PharmD

Sharon L. Ellison, Pharm. D.
Executive Director
DUHS Institutional Review Board

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