Duke University

OFFICE OF THE CHANCELLOR

POLICY STATEMENT REGARDING THE INSTITUTIONAL OVERSIGHT OF HUMAN RESEARCH

Assurances

Duke University Health System (DUHS) maintains a Federalwide Assurance (FWA), number FWA00009025, which is approved by the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP). Components included in the DUHS FWA are:

- Duke University School of Medicine
- Duke University School of Nursing
- Duke University Hospital
- Duke Regional Hospital
- Duke Raleigh Hospital
- Duke HomeCare & Hospice
- Duke Primary Care
- Duke University (e.g., biomedical engineering)

The FWA has been signed by the Institutional Official (IO), who is the individual authorized to represent the institution and all components listed on the DUHS FWA on matters related to human research.

All components included in the DUHS FWA are subject to DUHS policies and procedures for all activities related to research involving human participants.

The Principles for Assuring that the Rights and Welfare of Subjects are Protected

For all activities related to research involving human participants, the Duke University Health System (DUHS) is guided by the ethical principles outlined in the Belmont Report.

DUHS assures that whenever it engages in human research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, DUHS will comply with the terms set forth in the Code of Federal Regulations at 45 CFR 46 (including Subparts A, B, C, and D), unless the research is otherwise exempt from these requirements, or the department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

For clinical investigations regulated by FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U. S. 6. 355(i)), DUHS will apply FDA human subjects regulations.

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These regulations include, but are not limited to Protection of Human Subjects (21 CFR 50), Institutional Review Boards (21 CFR 56), Investigational Drugs (21 CFR 312), Investigational Devices (21 CFR 812), and Application for FDA Approval to Market a New Drug (21 CFR 340).

DUHS applies the International Conference on Harmonization (ICH) Good Clinical Practice Consolidated (E6) Guidelines as adopted by the FDA to clinical investigations regulated by the FDA and to other research as applicable.

Human subject research that is supported by the Department of Defense (DoD) or one of its components (e.g., Departments of the Army, Air Force, and Navy and Marine Corps) through a contract, grant, cooperative agreement, or other arrangement must comply with DoD Regulations. Regulations and directives that address the protection of human subjects in research include DoD Directive 3216.02; 32 CFR 219; Section 980 of title 10, USC; and DoD Directive 6200.04. Other DoD component-specific requirements may also apply depending on the particular study.

For all other research involving human participants DUHS is guided by the Code of Federal Regulations at 45 CFR 46.

Institutional Review Board Designation

DUHS designates one or more institutional review boards (IRB) for review of human participant research under its FWA.

DUHS maintains one or more institutional review boards. The DUHS IRBs serve as the primary IRBs of record for DUHS. This policy vests the appropriate authority in each IRB appointed under this policy to review and approve (or not approve) any proposed human subject research conducted by any employees, students, or agents of DUHS, when acting in their DUHS role (performing institutionally designated activities or exercising institutionally delegated authority or responsibility).

DUHS may rely on the IRB of another institution or organization, or an independent IRB for review and approval of human research. Reliance on the IRB of another institution or organization, or an independent IRB must be documented by a written authorization agreement or memorandum of understanding, signed by the DUHS Institutional Official or his/her designee. Such IRBs must be registered with OHRP.

All IRBs designated on the DUHS FWA must comply with the DHHS regulations for the Protection of Human Subjects (45 CFR 46) when considering human research conducted or supported by any federal department or agency that has adopted the Federal Policy for the

Protection of Human Subjects, known as the Common Rule and FDA regulations for Institutional Review Boards (21 CFR 56) when considering clinical investigations regulated by FDA under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U. S. 6. 355(i)), and meet DUHS institutional standards.

Authority and Independence of the Institutional Review Board

DUHS grants, recognizes and safeguards the independent authority of the IRB as required under federal regulations. DUHS grants IRBs designated under the DUHS FWA the authority:

- To approve, require modifications to secure approval, or disapprove all research activities overseen and conducted by DUHS
- To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants
- To observe, or have a third party observe, the consent process
- To observe, or have a third party observe, the conduct of the research
- To conduct continuing review of research requiring review by the convened IRB annually or more often when appropriate

DUHS personnel may not approve research involving human participants if it has not been approved by an IRB designated under the DUHS FWA or through the external IRB mechanism. However, research that has been approved by an IRB may be subject to further review and approval or disapproval by DUHS officials. [45 CFR 46.112 and 21 CFR 56.112]

IRB Jurisdiction

All human participant research, and all other activities, which wholly or in part involve human research, regardless of sponsorship, must be reviewed and approved by the DUHS IRB or other IRB consistent with DUHS policy regarding reliance on an external IRB.

No intervention or interaction with human research participants, including advertising, recruitment, and/or screening may begin until IRB approval has been obtained.

Employees, students, or agents of DUHS should refer to the following policies for guidance in determining which activities require DUHS HRPP/IRB review and oversight: *Research for Which Review by the DUHS HRPP Is Required*, and *Duke Trainees Engaged in Research Involving Human Subjects at a Site Other Than Within DUHS.*

Employees, students, or agents of DUHS include all individuals performing institutionally (DUHS) designated activities or exercising institutionally delegated authority or responsibility.

It is the responsibility of the DUHS IRB Chairperson(s), their designee(s), or the full DUHS IRB to determine whether an activity is exempt from the federal regulations. Investigators may not independently determine whether an activity is exempt from the federal regulations.

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