Duke University School of Medicine

Policy Statement Regarding the Institutional Official
Issued: May 22, 2025

The Executive Vice Dean for Clinical Sciences & Research Administration, Duke University School of Medicine, is designated as the Institutional Official (IO) for the Duke University Health System (DUHS) Human Research Protection Program. The IO is delegated the legal authority to represent DUHS and all components listed on the DUHS Federalwide Assurance submission (FWA) on matters related to human research.

The IO:

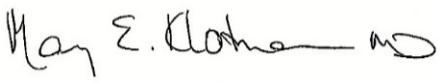
- Understands the institution's responsibilities under the FWA (FWA00009025)
- Has the authority to ensure that:
    - The safety, rights, and welfare of human research subjects are protected,
    - Members of the designated Institutional Review Boards (IRBs) are
        - Knowledgeable about the local research context and
        - Comply with the terms of the FWA,
    - All components of the human research protection program are functioning satisfactorily,
    - The DUHS FWA is updated as necessary and sent to the Office for Human Research Protections within the Department of Health and Human Services (OHRP) for approval;
- Supports the independent authority of the IRB as required under federal regulations.

The IO is responsible for:

- Setting the "tone" for an institutional culture of respect for human subjects;
- Overseeing compliance with all applicable federal regulations and guidance, state law and institutional policies;
- Being the signatory authority for the FWA submitted by DUHS to OHRP;
- Serving as a knowledgeable point of contact for OHRP, FDA and other governmental and nongovernmental agencies regarding human research protections;
- Ensuring effective institution-wide communication and guidance on human subject protection issues;
- Overseeing processes to ensure that investigators fulfill their

responsibilities under applicable regulations;
- Investigating allegations of potential undue influence and taking corrective actions as appropriate;
- Facilitating participation by the Duke research community in human subject protection educational activities;
- Designating one or more IRBs that will review research covered by the DUHS FWA;
- Arranging for sufficient resources, space, and staff to support the IRB's review and record keeping duties;
- Appointing, either directly or through his/her designee, the IRB Chairpersons; and
- Conducting an annual review of the Human Research Protection Program.

At the IO's discretion, the IO may designate other individuals to act on the IO's behalf; however, the IO retains overall responsibility for the Human Research Protection Program.



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