

DUHS PRINCIPAL INVESTIGATOR AGREEMENT
*Commitment of a Duke University Health System Principal Investigator
or Co-Principal Investigator to Institutional Human Subject Protection Policies
and IRB Oversight Under Federal-Wide Assurance, FWA# 00009025*

Name of DUHS Investigator: _____

Department/CRU Affiliation: _____

If you are a Principal Investigator or a Co-Principal Investigator, please read and sign the agreement below.

I intend to participate in research for which initial and continuing review will be provided by the Duke University Health System (DUHS) Institutional Review Board (IRB), or by another IRB that the DUHS IRB has agreed upon. I understand that one of the conditions of my participation in such research is my acceptance of my responsibilities under this Agreement to comply with institutional policies, applicable federal, state, and local laws and regulations, ethical guidelines, and other policies and principles as described below.

- (1) I am familiar with, and will comply with, applicable federal regulations and guidance for the protection of human subjects: HHS regulations at 45 CFR 46 and associated guidance; FDA regulations at 21 CFR Parts 50, 54, 56, 312, 314, 601, 812, and 814 and associated guidance; the HIPAA privacy regulations at 45 CFR Parts 160 and 164 and associated guidance; the DUHS Federal-Wide Assurance; and relevant institutional policies and procedures for the protection of human research subjects.
- (2) I recognize the authority of the DUHS IRB to oversee human subject research, as described in the Federal-Wide Assurance, and I will abide by all decisions of the IRB.
- (3) I will assume overall administrative responsibilities for all aspects of each research study approved under this Agreement. I will conduct the research according to the IRB-approved protocol, maintain appropriate oversight of the research study and supervision of my research staff, and appropriately delegate research responsibilities.
- (4) I will ensure that all members of my research staff, and all others directly involved in the conduct of the study, are qualified by education, training, and experience to perform their research responsibilities. I will inform my staff of any pertinent changes during the course of a study, and arrange for education or additional training of staff as needed.
- (5) If I arrange with a source outside of DUHS to provide information critical to the study, I will take steps to ensure that the outside source can verify the integrity of data and records provided to me.
- (6) I will employ sound research design in accordance with the standards of my discipline.
- (7) I will recruit subjects in a fair and equitable manner, weighing the potential benefits of the research to the subjects against their vulnerability and the risks to them.
- (8) If the research involves more than minimal risk to research subjects, I will provide the IRB with an adequate data and safety monitoring plan for promptly detecting harm and mitigating potential injuries.

- (9) I will have determined, before initiating a research study, that the necessary resources are present to conduct the study, including access to a sufficient number of potential subjects, adequate time to conduct the research, an adequate number of qualified staff, adequate facilities, and the availability of needed medical and psychological resources that subjects may require as a consequence of research participation.
- (10) I agree to maintain an accurate Research Data Storage Plan.
- (11) I will comply with the IRB's prompt reporting requirements.
- (12) I will seek, document, and maintain records of informed consent and HIPAA authorization from each research subject or the subject's legally authorized representative as required under applicable regulations and requirements of the IRB. I will develop an informed consent process emphasizing the importance of subject comprehension and voluntary participation.
- (13) I will ensure that the informed consent process is led only by individuals who have appropriate training and knowledge of the research, including any investigational product involved, in order to discuss the risks and benefits of the study with prospective subjects. Only appropriate staff listed as "Key Personnel" in my IRB submission will be authorized by me to conduct the consent process with prospective subjects.
- (14) I agree to cooperate with the IRB as it conducts initial and continuing review, including providing required information, records, reports, and certifications. I will ensure that the periodic continuing review of my research will occur within the time frame stipulated by the IRB, and no research will continue beyond the designated approval period.
- (15) If I conduct research involving an FDA-regulated product under an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application, I will comply with all applicable FDA regulations and fulfill all investigator responsibilities [or investigator-sponsor responsibilities, where appropriate], including those described on Form FDA 1572, and at 21 CFR 312 and 812. And I will be familiar with the information in the Investigator's Brochure, including the potential risks and side effects of the investigational product.
- (16) I will not enroll subjects in research prior to receiving final approval of the research by the IRB. I will report promptly to the IRB proposed changes in the research. I will not initiate changes in research activities without prior review and approval by the IRB, except when necessary to eliminate immediate hazards to the research subjects.
- (17) I understand that emergency medical care may be delivered to a research subject without IRB review and approval to the extent permitted under applicable Federal regulations and State law. I will provide, or arrange to provide, a reasonable standard of medical care to study subjects for medical problems arising during their participation in the research.
- (18) My research staff and I will respond in a timely manner to any subject's complaints, suggestions or requests for information. If I am unable to resolve a complaint satisfactorily, then I will report the complaint to the IRB. In addition, I will respond promptly to IRB queries regarding a subject complaint.
- (19) I will generally be available (by phone or other electronic communication) to subjects during the study. If I will be unavailable during the study, I will delegate study responsibility to a specific qualified person who will be available in my absence. I will inform the IRB of this delegation of authority, via a protocol amendment, as a change in the research activity requiring IRB review. This includes such extended periods of time when I am off-campus for personal leave, Family Medical Leave Act (FMLA), maternity/paternity leave, or sabbatical.

- (20) If I am unable to meet my responsibilities as principal investigator (PI) or co-principal investigator (Co-PI), I will inform the IRB of the change and seek IRB approval for a new PI or Co-PI to continue the study, or request closure of the study.
- (21) I will cooperate with any inquiry by the Duke University Compliance Program, including audit functions at the CRU level, concerning any research with humans in which I participate. In the event that institutional officials determine that I have failed to comply with this Agreement, I agree to take recommended action(s), including, but not limited to, termination of my participation in designated research activities.
- (22) In the event I am found to have failed to comply with any of these requirements and, as a result, the convened IRB has made a recommendation of serious and/or continuing noncompliance with the DUHS Institutional Official's subsequent concurrence, the IRB will report the event(s) to institutional officials, the Office for Human Research Protections (OHRP), and/or the FDA, as appropriate.
- (23) I acknowledge that my primary responsibility as a principal investigator or co-principal investigator is to safeguard the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.