POLICY: Research Involving Human Subjects	Issue Date: February 2019 Supersedes: January 2014; June 2010 Page: 1 of 2

Purpose:

Kennedy Krieger Institute is committed to the protection of research participants.

Policy:

Kennedy Krieger Institute strives to ensure the ethical conduct of all research, consistent with established ethical principles, legal and regulatory requirements, and institutional policies and procedures. In any research involving human subjects, procedures are in place to protect the rights of research participants and to minimize risks to the fullest possible extent.

Kennedy Krieger makes every effort to protect the privacy and confidentiality of all research participants. Research participants receive information about the research purpose and procedures, possible benefits, risks and side effects, discomforts, options for alternative care, and any other important details to help them make an informed decision about participation. Participation in research is voluntary. Refusal by an individual to join a research study or discontinuing participation in a research study at any time shall not affect the individual's access to care, treatment, and services unrelated to the research. Kennedy Krieger employees and trainees are also allowed to participate in research at the Institute if they choose. Refusal by an employee or trainee to join a research study or discontinuing participation in a research study at any time shall not affect the individual's employment and training at Kennedy Krieger.

The Hugo W. Moser Research Institute at Kennedy Krieger, Inc. has its own Federal-wide Assurance Number (FWA00005719) for research involving human subjects, issued by the U.S. Department of Health & Human Services Office of Human Research Protections (OHRP). The Johns Hopkins Medicine Institutional Review Board (JHM IRB) serves as the IRB of record for Kennedy Krieger. Accordingly, Kennedy Krieger adheres to the JHM IRB institutional policies and guidelines for the conduct of research.

The Federal-wide Assurances associated with each of the organizations linked to the JHM IRBs are as follows:

- The Johns Hopkins University School of Medicine, FWA00005752-expires 10/1/2023
- The Johns Hopkins Hospital and Johns Hopkins Health Systems, FWA00006087-expires 12/13/2023
- The Johns Hopkins University Applied Physics Laboratory, FWA00018613 - expires 3/6/2022
- Hugo W. Moser Research Institute at Kennedy Krieger, Inc., FWA00005719-expires 10/15/2023

To fulfill the agreement underlying the Federal-wide Assurances and to satisfy institutional policy, all faculty and staff must submit for JHM IRB review any human subject research project, regardless of funding source (or lack thereof) and/or location at which the research will be conducted.

In some multi-site non-exempt human research studies, Kennedy Krieger administration may approve reliance on an external IRB other than Johns Hopkins as the single IRB of record. However, a JHM IRB local context application submission with review and approval is still required for these single IRB studies with external reliance.

Formal review and approval by the JHM IRB or designated single IRB of record is required prior to the initiation of all research activities at Kennedy Krieger, including but not limited to recruitment and enrollment of subjects, administration of research procedures, and collection and use of research data. IRB review and approval is also required for changes in research, including but not limited to changes to the study team, study population, protocol, recruitment, and consent. The Principal Investigator is responsible for the research application submission and conduct of the research, as well as any follow-up activities upon the application's approval, such as Continuing Review applications and reporting of protocol deviations and adverse events.

The research application review process consists of (1) the researcher's preparation and submission of a new application, (2) pre-review of the application at Kennedy Krieger, and (3) review of the application by the JHM IRB or a designated single IRB of record. All new applications requiring review by the JHM IRB are submitted electronically via the eIRB system and are subsequently pre-reviewed by the Office of Human Research Administration (OHRA) at Kennedy Krieger.

The pre-review process consists of checking for application completion and inclusion of all required elements, as well as a risk and safety review assessment. As of 1/21/19, all new applications are subject to the requirements of the revised Federal Policy for the Protection of Human Subjects (commonly referred to as the "Revised Common Rule") (45 CFR 46). When necessary, the Principal Investigator is asked by the pre-reviewer to provide additional information and make application revisions. OHRA ancillary committees may also be consulted during the pre-review process in special circumstances, such as conflict of interests in research, high risk research, or data security concerns.

Following approval by the KKI OHRA pre-reviewer, all new applications are reviewed by the JHM IRB or designated single IRB of record. Before final IRB approval, the application is routed to any additional required ancillary committees (i.e., F.M Kirby Center, clinical radiation research committee) for review and approval. The JHM IRB or designated single IRB of record has the ultimate authority to either approve or disapprove the research application.

Research studies at Kennedy Krieger may by audited and monitored internally by OHRA's Compliance and Quality Assurance Team to ensure adherence to federal and state regulations and IRB guidelines, to determine that the rights and safety of human subjects have been properly protected, and to identify areas in need of improvement and monitor improvement efforts. The OHRA team also provides regulatory guidance and education to Kennedy Krieger faculty and research staff.