REQUIREMENTS OF STUDY PERSONNEL CONDUCTING THE CONSENT PROCESS

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This document describes the requirements for a study team member to conduct the consent process in a research study over which the DUHS Institutional Review Board (IRB) serves as the IRB-of-Record. The requirements described in this policy also apply to any study conducted by a Duke investigator that has external IRB oversight.

The DUHS IRB requires that only appropriately trained and qualified personnel conduct the consent process for research studies. Appropriately trained and qualified personnel are those study team members who have met the following criteria:

(i) Completed all institutional training, including CITI training, Responsible Conduct of Research (RCR) training, Annual HIPAA Privacy and Security training, required for individuals conducting research with human subjects; and
(ii) Completed all specific DOCR training involving the consent process; and
(iii) Possess sufficient knowledge of the study, as determined by the Principal Investigator (PI), to be able to adequately address all questions from a potential subject; and
(iv) Are listed on both Key Personnel and the Delegation of Authority Log for the study

The most appropriate individuals for this role on the study include the PI, co-PI, clinical research coordinator, clinical research nurse coordinator, and regulatory coordinator; however, this does not preclude others on the study team from assuming this role provided the criteria described in this document are met. This is also consistent with the DOCR Policy: Consenting for Research Studies Approved by the DUHS IRB.

Ideally, all individuals who are designated to conduct the consent process will possess prior experience in this role. For those individuals who do not possess prior experience, the PI must implement a plan by which the individual is observed conducting consent at least the first two times by an individual experienced in the process ("Observer"), and the Observer will provide immediate feedback, including corrective actions. Documentation of successful completion of informed consent observation must be maintained in accordance with individual CRU policies, e.g., personnel files, study regulatory binder, etc. This is appropriate for clinical research specialists (CRS) for minimal risk studies, and senior clinical research specialist for simple studies (such as survey or observational studies).

Individuals who are considered by the DUHS IRB as <u>not</u> qualified to conduct the consent process under any circumstances include:

(i) Volunteers
(ii) Minors
(iii) Administrative support personnel
(iv) Study team members with limiting conflicts-of-interest

Graduate students, medical students, residents, and fellows at Duke may conduct the consent process if the four criteria above are met, and the observation period described above is completed. Undergraduate students may be allowed to conduct the consent process in accordance with the policy entitled “Duke Undergraduates Engaged in the Consent Process on DUHS IRB Protocols” and completion of the DUHS IRB Duke Undergraduate Student Agreement for Consent through ORC.

The PI is ultimately responsible for selecting appropriately trained and qualified individuals to conduct the consent process.

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