PERMISSIBLE RESEARCH-RELATED ACTIVITIES
PRIOR TO IRB AND INSTITUTIONAL APPROVALS
8/3/2016

Scope
This policy applies to all research involving human participants that is reviewed by the Duke University Health System (DUHS) Institutional Review Board (IRB). The requirements described in this policy also apply to any study conducted by a Duke investigator that has external IRB oversight.

Purpose
The purpose of this policy is to define the research-related activities that are permissible under DUHS policies and applicable federal regulations prior to IRB approval and during the period between IRB approval and institutional approval.

Definitions
“Interim period” means the time between the issuance of DUHS IRB approval and the issuance of institutional approval for the research study.

“Institutional approval” means that all institutional reviews required for a research study subject to this policy have been completed. Examples of required institutional reviewers for applicable protocols include the Duke Office of Clinical Research (DOCR), Office of Corporate Research Collaborations (OCRC), Radiation Safety Review, and Pediatric Risk Assessment.

“IRB approval” means the written notice of approval issued by the DUHS IRB or an external IRB for a research study subject to this policy.

“Research-related activities” means all activities undertaken by the study team that are directly related to the research study whether those activities are described in the IRB-approved protocol or are required by DUHS policies and procedures.

Permissible Activities
The following research-related activities may occur prior to IRB approval:
• Reviews Preparatory to Research (RPRs)
• Site qualification visits (SQVs)
• Investigator meetings
• ClinicalTrials.gov registration

The following research-related activity may occur after the date of IRB review and before IRB approval is issued:
• Site initiation visit (SIV)

The following research-related activities may occur in the interim period:
• Ascertainment of potential subjects through chart reviews, DEDUCE queries, patient lists, etc. (NO recruitment and NO prospective screening)
• Study-related training without patient contact
(CRF/database entries, device manipulation, in-service for affected clinical staff, etc.)

- Set-up of regulatory binders
- Set-up of IDE billing framework
- Drug/device shipment to IDS (or equivalent drug services) and/or investigators
- MaestroCare order sets
- Willow and Beacon builds
- Site initiation visits (SIV) may also occur in the interim period.

**Prohibited Activities**

The following activities are expressly **NOT** permitted during the interim period:

- Recruitment (including advertisement of any kind)
- Contact or communication with potential subjects
- Conduct of the consent process

No amendments to a study are allowed in the interim period between the issuance of IRB approval and issuance of institutional approval.

**eIRB**

The eIRB has been modified to provide two possible notifications to study teams: (i) notice of pending final approval containing a link to this policy; and (ii) notice of final approval. How many, and which, notices a study team receives will depend upon the sequence of approvals. Receipt of the pending approval notice means that IRB approval has been issued and interim activities may proceed.

Previous Version Date(s): 3/14/2014