



PERMISSIBLE RESEARCH-RELATED ACTIVITIES PRIOR TO IRB AND INSTITUTIONAL APPROVALS

1/8/2024

Scope

This policy applies to all research involving human participants that is reviewed by the Duke University Health System (DUHS) Institutional Review Board (IRB). This policy also applies to intermediate-size expanded access submissions reviewed by the DUHS 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 Research Contracts (ORC), Radiation Safety Review, and Institutional Biosafety Committee (IBC). Institutional approval is issued via a notification sent out of the OnCore system.

“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)
- Set-up of regulatory binders
- Investigator meetings
- *ClinicalTrials.gov* registration
- Set-up of IDE billing framework
- MaestroCare order sets and Beacon builds

The following research-related activity may occur **after the date of IRB review and before IRB approval is issued**:

- Site initiation visit (SIV)

No amendments to a study are allowed in the interim period between the date of IRB review and before IRB approval.

Please note: The **date of IRB review** is the date the convened board meets. As long as the study has cleared the date of IRB review without a disapproval, the SIV can occur, even if modifications sent by the IRB are still being addressed.

The following research-related activities may occur **in the interim period (after DUHS IRB approval is issued, but before Institutional Approval is issued)**:

- Ascertainment of potential participants 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.*)
- Drug/device shipment to IDS (or equivalent drug services) and/or investigators
- 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 participants
- Conduct of the consent process

Previous Version Date(s): 3/14/2014, 8/3/2016, 8/28/2020, 3/11/2021, 9/20/2021, 11/20/2023