Durham Regional Hospital
DUKE UNIVERSITY HEALTH SYSTEM

Policy Deployment

Policy Name:	Investigational Research (Clinical Trials)	Institution:	Duke University Health System
Supersedes:		Division:	Durham Regional Hospital
Policy Level:	Hospital Wide	Department:	
Owner(s)	Lynn Whitt L. Sellers John Legge	Contributing Departments:	Finance, Compliance, PRMO, Risk Management
Approved by:	Executive Leadership Team	Manual Name:	Administrative
Original Effective Date:	02/25/2008	Manual Chapter:	Finance, Patient Rights
Revision Date:	10/21/11		
Scheduled Review Date:	10/21/14	Scheduled Review Interval:	36 months

Applicable Standards JCAHO RI.2.180, RI.2.180 2, RI.2.180 3, RI.2.180 3, RI.2.180 4, RI.2.180 5, RI.2.180 6, RI.2.180 7.

DEFINITIONS

POLICY

Durham Regional Hospital (DRH) is guided by the ethical principles regarding research involving humans as set forth in the report of the National Commission for the Protections of Human Subjects of Biomedical and Behavioral Research (“Ethical Principles and Guidelines for the Protection of Human Subjects of Research” or “The "Belmont Report"). The involvement of Durham Regional patients in research will not be permitted until informed consent has been obtained from the subject or the subject’s legal representative.

Prior to implementation of a research protocol at Durham Regional, the study will be reviewed and approved by the DUHS Institutional Review Board, which will review the study to assure:

1. Risks to subjects are minimized;
2. Risks to subjects are reasonable in relationship to anticipated benefits;
3. Selection of subjects is equitable;

4. Informed consent will meet all requirements as set forth by CFR 46.116 and be appropriately documented;
5. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects;
6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data, and;
7. When some or all subjects fit the criteria for a potentially vulnerable population, additional safeguards are included to protect the rights and welfare of these subjects.

Durham Regional Hospital will have processes in place that ensure the safe delivery of patient care and proper billing of services to any patient participating in clinical research. These processes apply to patients participating in clinical trials approved for Durham Regional Hospital and to patients who present for services on clinical trials approved by other institutions. The following guidelines have been developed for Durham Regional Hospital.

PROCEDURE

DRH Application and Approval Process

This section applies to studies being approved at Durham Regional Hospital.

- The DUHS Investigational Review Board (IRB) shall approve all clinical research prior to Durham Regional Hospital granting final site approval.

- Investigators conducting research at DRH must complete and submit the required Site Approval Form along with the Clinical Research Support Office (CRSO) approved GRID. Investigators may obtain the Durham Regional Hospital form from the Duke University IRB website (http://irb.mc.duke.edu/). The Site Approval Formis attached to the policy.

- Once Durham Regional has received the completed Site Approval Form, the Investigator or Clinical Research Coordinator (CRC) shall be notified in writing that Durham Regional has begun the review process.

- The hospital departments impacted by the research study along with Durham Regional Finance and the DUHS Compliance Office shall review the study information.

- After all departments have reviewed the study, the CRC and/or Investigator shall meet with department managers and DRH Hospital Administration, as necessary, prior to final approval.

- Final approval or rejection is granted by DRH Hospital Administration

- Final approval or rejection shall be communicated in writing to the Investigator and/or CRC. Final approval shall be communicated to department managers impacted by the research study.

Information and Consent Process for All Patients

- Clinical Trials conducted at Durham Regional Hospital will be required to provide patients who are potential subjects in research and investigational studies with adequate information regarding participation or refusal to participate in research. The information provided to the patients must include an explanation of the purpose of the research and expected duration of the subject's participation; a description of expected benefits, potential discomforts, and risks; alternative services that might prove advantageous to the individual; and a full explanation of the procedures to be followed.

- Patients must be informed that refusing to participate or discontinuing participation at any time will not compromise their access to care, treatment, and services unrelated to the research.

- The consent form must address the information listed under Consent Process in this policy; indicate the name of the person who provided the information and the date the consent form was signed; and address the participant's right to privacy, confidentiality, and safety.

- Subjects must be informed of the extent to which their personally identifiable private information will be held in confidence.

- All information given to subjects will be kept in either their medical record or research file along with their consent forms.

- If a research-related injury (that is physical, psychological, social, financial or otherwise) occurs, the principal investigator must attempt to address any harmful consequences the subject may have experienced as a result of research related procedures and notify the Duke University IRB and Durham Regional Hospital Administration in accordance with their adverse events policies.

Patient Identification Process

This section applies to patients in clinical trials approved at Durham Regional Hospital or other institutions.

- All subjects consented into a clinical trial at Durham Regional Hospital will be entered into the CRSO Subject Registry within 24 hours of consent by the Clinical Research Coordinator, the Principle Investigator, or designated trial staff member.

Trial Staff (Clinical Research Coordinators / Principle Investigators

- All Clinical Research Coordinators and appropriate Trial Staff involved in clinical research at Durham Regional Hospital are required to attend the Clinical Research Support Office training program. This training program will provide instructions pertaining to new subject entry into the CRSO Subject Registry within 24 hours. This will ensure that the PRMO will receive the appropriate patient information and automatically place accounts on hold for further charge review. Refer to DUHS CRSO policy and procedures.

- Durham Regional Hospital will assure both the Principle Investigator and the Clinical Research Coordinator are aware of the mandate to attend the CRSO training program prior to subject enrollment.

- All Trial staff performing patient related procedures will be credentialed in accordance with the Durham Regional Hospital Medical Staff Services credentialing policies and procedures. Non-physician credentialing will be at the discretion of the individual Durham Regional Hospital departments in conjunction with the Chief Medical Officer and Human Resource Office.

Billing / Compliance Process

This section applies to all clinical trials approved by DRH.

- Once the Patient / Subject has been entered into the CRSO Subject Registry, any DRH accounts generated by that patient will be identified and those accounts will be placed on hold for a complete charge review. The PRMO Clinical Trials Billing Office will review charges to determine routine and non-routine charges in accordance with the CRSO approved GRID. See PRMO Clinical Trial Billing Policy.

CROSS REFERENCES PRMO Clinical Trial Billing Policy
DUHS Clinical Investigations
CRSO Policies and Procedures
Patient Rights and Responsibilities