Policy Name: Contract and Informed Consent Guidelines for Clinical Trials

Policy #: RSCH -01
Effective Date: 01/01/2009

GENERAL

Background

The Contracts Office in the Department of Research is responsible for contract negotiations, obtaining signatures and routing of the executed contract to all parties. A clinical trial agreement (CTA) is a legally binding document between the Medical Center and the sponsor that defines the scope of the work required by the protocol. The CTA is also known as a contract, statement of work, letter of agreement and clinical research agreement.

Purpose

The purpose of this procedure is to outline the Medical Center's policy on the contract review and approval process. This policy should also be utilized for other research related contracts, i.e. confidentiality agreements, amendments, subcontracts and collaboration agreements.

Policy

All research studies conducted at the Medical Center must have a fully executed contract in effect prior to trial commencement.

Administration

The Chairman for the Department of Research is responsible for the administration and subsequent revisions to the procedure.

PROCEDURE

CONTRACT AND INFORMED CONSENT REVIEW PROCESS

1. The study team provides the Contracts Office with a copy of the contract, and sponsor contact information upon receipt. (sponsor may be a pharmaceutical company, device company, contract research organization [CRO] or another institution who has been awarded funds for research and would like to engage the Medical Center in their research) IRB review and budget negotiations will begin simultaneously at their respective offices during the contract review process.

2. If the principal investigator is an independent contractor/non-employee of the Medical Center a three-way agreement naming the private physician as a party to the agreement will be required.

3. The injury section of patient informed consent should be consistent with the terms agreed upon in the contract for the particular study.

4. The Contracts Office will negotiate the terms of the contract with the sponsor and modify the contract as necessary to ensure all regulatory and institutional requirements are met. When necessary the Contracts Office will coordinate with the Medical Center's appropriate auxiliary offices, i.e. Corporate Compliance and General Counsel.

5. When negotiations are complete the principal investigator will review, approve and execute the contract. The Chairman of the Department of Research will subsequently review and execute the contract on behalf of the Medical Center. The principal investigator does not have the institutional authority to sign on behalf of the Medical Center. The department of research will retain the original contract and provide a copy to the principal investigator.

Initial Review
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Medical Advisory Board

Revised
12/2012-abatel