
2103 ADMINISTRATION OF CLINICAL TRIALS

Subject: SPONSORED PROJECTS
Effective: August, 1998
Last Reviewed: April 2016
Last Revision: December 2014
Resp. Office: Research Services
Approval: Research Services

PURPOSE:

To ensure that funds received for the clinical testing of pharmaceuticals and medical devices (“clinical trials”) are administered in accordance with University policies, sponsor requirements and federal regulations.

POLICY:

1. All externally funded clinical trials must be approved in accordance with Sponsored Projects Policy No. 2102, as well as by the University’s Institutional Review Board, and performed under the terms of a formal clinical trial agreement or grant which has been executed or accepted on behalf of the University by Research Services or Office of Clinical Research.
2. All externally funded clinical trials will be accounted for in a sponsored project fund established by Research Services.
3. The Principal Investigator is responsible for managing the clinical trial in accordance with the terms of the clinical trial agreement or grant and protocol, University policies and applicable Federal laws and regulations. It is also the Principal Investigator’s responsibility to submit required reports and other appropriate information to the sponsor and to enable his or her Business Administrator to invoice sponsor as required to ensure timely payment.
4. If not restricted by the terms of the clinical trial agreement, funds remaining at the end of a clinical trial, after all appropriate expenses have been charged to the clinical trial account, may be transferred to a non-sponsored project account for use by the Principal Investigator or his/her department or school for research and/or educational purposes only.

ROLES AND RESPONSIBILITIES:

PRINCIPAL INVESTIGATOR

- Manage clinical trial
- Submit reports and invoices, as required by the contract

OFFICE OF CLINICAL RESEARCH

- **Negotiate and execute clinical trial contracts with industry sponsors**

OFFICE OF RESEARCH SERVICES

- **Negotiate and execute/accept clinical trial contracts or grants with public sector or not-for-profit sponsors. Establish a sponsored project fund**
- **Deposit cash as received**

PENN CENTER FOR INNOVATION

- **Advise as needed regarding on intellectual property issues**

The source of this document is Research Services.