

New York University

UNIVERSITY POLICIES

Title:	Clinical Trials Financial Management Policy for Sponsored Programs
Effective Date:	December 1, 2017
Supersedes:	September 1, 2013
Issuing Authority:	Sponsored Programs Administration
Responsible Officer:	Assistant Vice President for Post-Award Administration

Policy

It is the policy of New York University (NYU, “the University”) that all clinical trials shall be performed in accordance with generally accepted standards of good clinical practice, in compliance with the protocol and with all applicable local, state and Federal laws and regulations governing the performance of clinical investigations.

Purpose of this Policy

The purpose of this policy is to set forth the financial management requirements for Clinical Trials in accordance with Federal and sponsor requirements.

Scope of this Policy

This policy is applicable to all schools, departments, units and personnel of the University involved in administering sponsored awards.

Procedures for Implementation

Sponsored Programs Administration (SPA) Responsibilities:

Invoices – SPA will review all Clinical Trials invoices prepared by the school or department prior to submission to ensure compliance with sponsor terms and conditions.

Submission of Reports – SPA will follow-up and ensure the timely submission of interim and final financial reporting to Federal sponsors.

Department / Principal Investigator (PI) Responsibilities:

Clinical Trials Terms and Conditions – Upon receiving Institutional Animal Care and Use Committee (IACUC) and/or Institutional Review Board (IRB) approval and the fully executed

agreement, the PI may start the Clinical Trial. The PI should abide by all clauses of the agreement. The PI is responsible for the performance of the scientific, technical, and administrative duties normally associated with the Clinical Trial. The PI is responsible for administering the trial in accordance with the signed agreement terms and conditions and the approved clinical research protocol as well as in compliance with University policies.

Budget Expenditures –The budget included in a clinical trial agreement is part of the agreement. PIs should closely monitor the budget in the performance of the clinical trial.

Billing/Payments to Subjects –The department tracks milestones and performs timely billing of study activities for the appropriate Clinical Trial. The department must submit all invoices to SPA for review and approval prior to submission to the Sponsor. The department also coordinates appropriate and timely payments to participants.

Project Closeout – The PI and Department Administrator (DA) should ensure the submission of accurate and timely closeout documents to applicable Federal agencies, University entities, and the sponsor. The study documentation must be maintained in files in accordance with sponsor requirements and University policies and procedures.

Audits – The departments should notify SPA of any external audits associated with Clinical Trials. See the [*Internal and External Audits Policy of Sponsored Programs*](#).

Policy Definitions

Clinical Trials	A form of clinical research that involves researcher(s) who directly observe a person or people, and/or who collect data to answer a scientific or medical question about the safety or potential benefit of an intervention such as a medication, device or behavioral change.
Institutional Animal Care and Use Committee (IACUC)	A committee that provides oversight for use of animals in research. Institutions that use animals for Federally funded laboratory research must have an Institutional Animal Care and Use Committee (IACUC). At NYU, this is known as the University Animal Welfare Committee (UAWC). The UAWC reviews research protocols and conducts evaluations of the institution’s animal care and use, which includes the results of inspections of facilities as required by law.

Institutional Review Board (IRB)

A committee that has been formally designated to approve, monitor, and review research involving human subjects. Also, known at NYU as the University Committee on Activities Involving Human Subjects (UCAIHS).

Related Policies

- Award Closeout Policy for Sponsored Programs
<http://www.nyu.edu/about/policies-guidelines-compliance/policies-and-guidelines/award-closeout-policy-for-sponsored-programs.html>
- Internal and External Audit Policy for Sponsored Programs
<http://www.nyu.edu/about/policies-guidelines-compliance/policies-and-guidelines/internal-and-external-audit-policy-for-sponsored-programs.html>
- Prior Approvals Policy
<http://www.nyu.edu/about/policies-guidelines-compliance/policies-and-guidelines/prior-approvals-policy-for-sponsored-programs.html>

Federal Regulations

N/A