

Principal Investigator Effort on Industry Supported Clinical Research

Category: Research

Responsible Office: Clinical Research Office

Responsible Executive: Vice President for Research, Vice President for Health Sciences

Date Established: to be determined

Date Last Updated 03-10-2021

Summary

University faculty and staff working on industry-sponsored clinical research must include some effort in the budget to be charged to the project, if awarded.

Policy Statement

Principal investigators (PI), with a paid University at Buffalo (UB, university) appointment, working on industry-sponsored clinical research are required to reflect PI oversight of clinical activity with an appropriate charge of at least 1% of the individual's university appointment (up to the National Institutes of Health (NIH) salary cap) on each agreement. The balance of effort spent on the project beyond this amount will be voluntary uncommitted time, unless otherwise negotiated with the sponsor. The effort will be charged over a maximum of one year or over the total life of the project for projects less than one year in duration.

Principal investigators may seek an exception through their department chair and dean. However, if an exception is granted, the effort must be charged to the award prior to account closure if funds are available.

Non-compliance

The university will take corrective action in the event of non-compliance with this policy. Non-compliance may also lead to other disciplinary actions in accordance with university policies.

Background

Federal regulations require that compensation and effort devoted to clinical trials is appropriately documented and supported by a system of internal controls that provides reasonable assurance that the charges are accurate, allowable, and properly allocated. UB must be consistent with how it tracks faculty and staff effort on federal and non-federal awards. Salary charges to clinical research are initially made based upon the planned or estimated workload of faculty and others; the actual effort of each individual working on sponsored projects must be monitored, with charges modified, as necessary based, on variances between the estimated and actual effort.

Applicability

This policy applies to all faculty and staff who provide effort in support of the industry-sponsored clinical research mission at the university. Federal awards will be managed per federal regulations and policies.

Definitions

Clinical Research

Research based mainly on observation of the patient rather than on laboratory work. It is often used to determine the safety and effectiveness of treatments, the natural history of disease, or the conditions that predispose to illness.

Effort

The amount of time spent on an activity, expressed as a percentage of the individual's total activity for the university. University effort includes all activities for which an employee is compensated by the university and includes research, instruction, other sponsored activities, administration, non-sponsored and departmental research, university service, proposal preparation, and clinical activities. For the purpose of effort reporting and certification, university effort totals 100%, regardless of the number of hours worked or the individual's appointment percentage. Practice Plan or other university affiliate compensation is not included.

Responsibility

Departments

- Manage and oversee effort allocation on sponsored projects, including processing payroll, in conjunction with PIs, as required based on school and departmental policies.

Principal Investigator

- Understand their own as well as their staff members' levels of effort committed, charged, and reported on all applicable clinical research.
- Estimate (during trial budget and proposal development) the amount of effort that will be required by each faculty and staff member on the clinical research project and determine whether or not actual effort or the 1% effort minimum, will be charged.
- Track their own effort and that of others' working on their clinical research, and ensure charges are applied, per the negotiated budget
- Seek an exception, with proper justification, to this policy at the time the budget for an award is negotiated.

Chairs, Deans

- Review and approve, as appropriate, exceptions to this policy.

Clinical Research Office

- Negotiate budgets for industry-sponsored clinical research that include applicable PI oversight effort or verify that an exception to this policy has been granted.
- Work with PIs to ensure that effort is charged appropriately by notifying Sponsored Projects Services of the required charges.

Sponsored Projects Services

- Charge awards for PI effort based on negotiated budgets.

Contact Information

Contact	Phone	Email
Clinical Research Office	716-888-4841	Pka2@buffalo.edu

Related Information

University Links

[Clinical Research](#)
[Prepare and Submit Your Grant Proposal](#)
[Sponsored Projects Services](#)

Forms**Related Links**

[Uniform Guidance Subpart E – Cost Principles](#)