RUTGERS
BIOMEDICAL AND
HEALTH SCIENCES

**Policy Name:** Indirect Costs: Clinical Trials

**Approval Authority:** Presidential

**Originally Issued:** 9/21/2011, 7/1/2013

**Revisions:**

## 1. Who Should Read This Policy

All Rutgers University research faculty, staff, principal investigators, and co-investigators within Robert Wood Johnson Medical School, School of Health Related Professions, Rutgers School of Dental Medicine, New Jersey Medical School, Graduate School of Biomedical Sciences, School of Public Health, and School of Nursing (former UMDNJ School of Nursing).

## 2. Related Documents (refer to policies.rutgers.edu for additional information)

A. Funding: Grants and Contract Proposals

B. Indirect Cost Sharing

## 3. The Policy

I. DEFINITION

Because the term "fellow" is used to describe a large variety of positions, the designation of Postdoctoral Appointee is used here to identify individuals who have recently earned a Ph.D., M.D. or equivalent doctoral degree, and who join the above stated units of RBHS full-time for a limited period of time to continue advanced research studies and receive additional professional training under the supervision of a member of the faculty. The position is meant to broaden the individual's scientific background and provide additional research and scholarly training and experience.

Postdoctoral Appointees are classified as students. They may retain the title of Postdoctoral Appointee for a maximum of five years at RBHS or six years of total postdoctoral appointment at any institution, contingent upon satisfactory performance. Beyond that period they may be hired under another appropriate title, such as Research Associate. Certain circumstances may warrant extension of this period; requests for extensions must be made, in writing to the Dean of GSBS and will be granted at his/her discretion. The Postdoctoral Appointee title should not be used for individuals simultaneously classified as Clinical Fellows or Residents.

II. POLICY

A. This policy shall apply to all industry-sponsored clinical trials.

B. It is the policy of the University to charge industry sponsors for all direct and indirect costs incurred in the conduct of industry-supported clinical trials. All potential sponsors of clinical trial programs must be informed of this policy before initiating the negotiation budgets for clinical research projects that will be included in the clinical research contract.

C. The Vice President for Research and Economic Development, in consultation with the Sr. Vice President Finance and Administration, the Office of the Chancellor of RBHS and the Deans or their designees shall determine the minimum indirect cost rate for industry-sponsored clinical trials at the University and post it on the appropriate Rutgers research web page and other pages (e.g the Office of Research and Economic Development and the University Finance office website).

D. Any special contract, agreement or compelling request for an exception to the above policy will require a prior approval from the Dean of the involved School in consultation with the Vice President for Research and Economic Development.

DEFINITIONS

A. Facilities and Administrative (F&A) costs as defined in OMB Circular A-21 mean costs that are incurred for common or joint objectives and, therefore, cannot be identified readily and specifically with a particular sponsored project, an instructional activity, or any other institutional activity. F&A costs are synonymous with "indirect" costs and “overhead” costs.

B. Clinical trials are defined as the controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted under an industry-developed protocol or an investigator-developed protocol.