LOYOLA UNIVERSITY HEALTH SYSTEM

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ADMINISTRATIVE POLICY NUMBER: CR-001

Subject: Pricing Structure for Sponsored Clinical Research Studies

Date Implemented: June 2016

Date Revised:

Medical Center Administration Approval:

David Hecht, MD
Executive Vice President for Clinical Affairs

Wendy Leutgens, RN, MSN
President LUMC

Policy Owner: LUMC Research Operations Office Director

I. PURPOSE

A. Clinical research study budgets will meet or exceed LUMC costs and remain within fair market value to include: labor expenses, supplies, equipment, items, services, facilities, and patient care procedural costs.
B. All costs required to conduct a research study at LUMC must be covered by the sponsor study budget or an accompanying internal itemized budget breakdown which highlights the alternative source of funding.
C. All research budgets in which the sponsor provides lump sum funding require an accompanying internal, itemized budget highlighting the source and destination of research funds.
D. No budget deficits in any research agreement will proceed beyond negotiations without written justification and approval of the EVP, Clinical Affairs or designee.
E. This policy does not address pricing/billing to third party private payers, related parties or patients. Standard of care items and services follow standard clinical billing processes.

II. DEFINITIONS/APPLICATIONS

A. Industry Sponsored Research – for-profit commercial entities
B. Federally Funded Research – any federal or government agency, including not-for-profit organizations
C. Internally Funded Research – Unfunded (no external sponsor)

III. PROCEDURES

A. **Industry Sponsored Research** – For commercially sponsored research, the research fee schedule will incorporate a rate equal to the Medicare rate plus 35%. Please note: this is the internal charge to the University study account.

B. **Federally Funded Research** – For National Institutes of Health (NIH) studies and studies funded by not-for-profit organizations (e.g., American Heart Association, Foundations, etc.), the research fee schedule will incorporate a rate equal to the

Medicare rate for clinical services. Rates will be based on current year Medicare rates and will not be fixed over multiple years.

1. This recognizes the federal government will not pay more for clinical research than for standard clinical care.
2. This recognizes studies funded by non-for-profit organizations generally have limited financial resources and are difficult to fund research projects at the industry rate.

C. **Internally Funded Research** (Unfunded) – For studies without external funding, the research fee schedule will incorporate a rate equal to the Medicare rate.

D. **Inflation** – Clinical trial budgets that span multiple years should account for an inflation factor by one of the following approaches:
   1. The rate is increased at a certain percentage each year for the service; or
   2. A fixed fee is built into the budget from the start that will accommodate potential future increases to fees.
   3. For existing industry studies with significant shortfalls, the budget should be renegotiated.

E. **Notifications** – The Research Operations Office (ROO) will work with the department to ensure appropriate notifications to LUMC Patient Financial Services (PFS) billing and LUC Sponsored Programs Accounting (SPA) when non-standard budget requirements or special circumstances exist.

IV. RESPONSIBILITY

A. **Patient Financial Services (PFS)** will ensure the Research Fee Schedules in the Research Portal are updated annually.

B. **LUMC Research Operations Office (ROO)** will provide the rate structure to apply to the Research Fee Schedule based on sponsor type as defined above.

C. **Departments** will use the Research Fee Schedule when developing clinical research budgets involving patient care costs as defined by NIH Policy.