I.   SCOPE

These guidelines are applicable to industry or for-profit funded clinical trials performed by SSOM faculty or staff with funding mechanisms that do not have limitations on salary recovery. "Clinical Trials", a "Study", or "Studies" for the purpose of this document are defined as any investigation involving human subjects or human tissue samples.

II.   PROCEDURES

A.   Budget

1. Guidelines

   a. Investigator, research nurse, research coordinator, and other study personnel effort should be built into the budget as separate line items.
   b. The budget is part of the final executed clinical trial agreement and is to include all projected costs associated with the conduct of the study.

2. Process

   a. The department (administrator or study team) is responsible for developing a cost based analysis for all industry and for-profit funded clinical trials.
   b. The budget administrator submits the budget for administrative review to department or a research central office (Cancer Clinical Trials Office and the Loyola University Chicago Clinical Research Office).
   c. Once approved by the department or central office, the budget administrator requests approval from the SSOM Business Director to charge full salary (ie may exceed the NIH cap). He/she provides documentation to support there are no salary caps for the specific industry funding mechanism.
   d. The budget administrator provides department/central office approval and SSOM Business Director approval to the LUC Office of Contract Administration.
   e. The LUC Office of Contract Administration is responsible for facilitating review of the payment terms to ensure consistency with the budget and associated fees.
   f. Receipt of the final contract (including the budget) and final approval will be facilitated and tracked by the LUC Office of Contract Administration.
   g. The LUC Office of Contract Administration will process and upload the executed research agreement and budget in the Research Portal.
   h. The budget administrator includes documentation of the SSOM Business Director's approval of charging full salary in the award documentation that is sent to HSC Finance when it is time to open the post-award budget within the Research Portal.

B.   Payroll Forms:

1. Budget administrator or designee submits PAF for faculty or an EIF for Staff to accurately charge payroll to the study accounting unit (AU). Refer to PAF General Instructions on Portal under Fiscal Affairs.

2. Include in comment section of EIF or PAF that approval has been obtained to charge full salary on AU and include initial of staff member submitting.

3. Utilizing the comments regarding the approval, HSC Finance is able to accurately calculate effort percentages that will be used for the manual effort adjustments within the portal.

C.   Tracking

1. SSOM Business Director will track and maintain record of all staff and faculty whose salary is managed through this SOP.

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III.   **REFERENCES**

    A. <u>NIH Grants Policy Statement</u>
       LUMC / LUC Operational Assessment and Study Startup Checklist

IV.   **ASSOCIATED DOCUMENTS AND FORMS**

    A. Budget Checklist
    B. Industry Budget Template

V.   **APPROVALS**

_____   12/20/19
Vice President of Clinical Affairs, LUMC (or designee)   Date

_____   12/16/19
Vice Dean of Administration, SSOM (or designee)   Date