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Author: Research Compliance Committee Research Integrity Office	Effective Date: 7/00	Revised Date: 11/02 09/08

Purpose: To provide guidelines for the preparation of study budgets.

Policy Statement: All study budgets shall be approved by the University of Louisville Office of Industry Contract and Research Integrity Office.

Departments Affected: University of Louisville Office of Industry Contract and Research Integrity Office, Principal Investigator/ Study Coordinator/Business Manager, Impacted departments.

Guidelines:

- Sponsor sends proposed Clinical Agreement to Principal Investigator/Business Manager/Study Coordinator for review.
- Business Manager/ Study Coordinator reviews outline of costs per patient, flow of test and appointments, etc and determines standard of care vs additional care costs that are research related.
- Research Integrity Office (RIO) is available to assist the study team during their initial budget preparation
- Study team can obtain research prices by contacting RIO.
- Billing Compliance Table (BCT) is generated to identify and to facilitate our researchers to mark correct payers box for charges incurred during the conduct of clinical trial. Also, to identify the test or procedure is standard of care or research related.
- Research Integrity Office (RIO) reviews BCT prior to approving the study to conduct
- A T account number will be issued for researcher to be used for all study related charges.
- Office of Industry Contract (OIC) completes negotiations and determines appropriate contract language in collaboration with the study site(s) and then forwards agreement to the sponsor for signature. Signed agreement will be returned OIC.
- Research Integrity Office (RIO) maintains a copy of final agreement signed by all parties involved.

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- Institution is responsible for receiving funds directly from the sponsor. Also, it is Institution's responsibility to reimburse the hospital for the services utilized during the study conduct.
- Note it is Investigator's and study team responsibility to identify all the related charges direct or indirect accurately in order to reimburse the sites for the tests and procedures being done.