

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Investigational Pharmacy Charging Information	
Relates to Policy/Procedure: SOP 900-11	
SOP#: 902-13	Version 2.0
Prepared by: Judi Kulko	Original date: 8/20/2013
Approved by: Judi Kulko	Date approved: 8/19/16

Purpose and Applicability: To ensure that all investigators who are conducting clinical research/trials that utilize pharmacy services (e.g., storing, mixing supplying drugs) contact the research pharmacists and obtain a complete Pharmacy budget sheet which is sent to OCTR with complete pre-packet workbook.

Background and Significance: The Budget Workbook was developed to standardize the research budget process at the UConn Health. Investigational drug and approved drugs are used in many clinical trials and must be The Pharmacy is involved in many clinical trials which use investigational and/or approved drugs. The pharmacy has standard charges for opening, managing and dispensing drugs used I clinical trials. All of this information is delineated on the Pharmacy budget sheet which is completed by the Research Pharmacist. It includes the charges and appropriate discounts applied by the pharmacy per their policy. This Pharmacy budget sheet must be provided to the OCTR in order to complete an accurate Budget Workbook.

Scope: This policy applies to all clinical trials that require drugs to be managed by the research pharmacy (e.g., storage, managing records, mixing and dispensing drugs). If drugs are to be stored in the PI office and dispensed through the PI's staff this policy does not apply

Responsibilities:

PI and/or study coordinator provide an overview of the study and a list of the drugs that will be used in the clinical trial and managed by the research pharmacy
Research pharmacist completes the pharmacy budget sheet and lists all relevant pharmacy charges for the life of the study including the appropriate research discount and provides a copy to the PI and study coordinator.
The PI and study coordinator reviews the pharmacy budget sheet and provides a copy to the Clinical & Administrative Research Coordinator in the OCTR

Procedural Steps:

- The PI and/or study coordinator contact the research pharmacist and provide her/him with the drugs that will be used in the clinical trial and which will be managed by the pharmacy department.
- The research pharmacist completes the pharmacy budget sheet including appropriate discounts.
- The study coordinator sends a copy of the pharmacy budget sheet with the pre-packet workbook to the Clinical & Administrative Research Coordinator in the OCTR

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- All drug charges are included in the final Budget Workbook. (This will include price with and without the Pharmacy discount).

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Reason for revision: 2.0 Name change	
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