



## Pharmacy Investigational Drug Service Clinical Policy

### Charges for Investigational Drug Services

**A. EFFECTIVE DATE :**

October 19, 2021

**B. PURPOSE :**

To assure that pharmacy services dedicated for support of clinical trials conducted are appropriately allocated and reimbursed.

**C. POLICY :**

1. Investigational Drug Services (IDS) will provide investigators with an estimate of pharmaceutical charges to support studies funded by industrial sponsors or those without sponsors.
2. Investigators will be charged for resources utilized or consumed by Investigation Drug Services.
3. IDS will prepare charges monthly, or as study needs dictate, for service rendered.
4. Fees for IDS services may be adjusted yearly or as deemed necessary.

**D. SCOPE :**

This policy applies to all UConn Health areas in which investigational drugs are used.

**E. DEFINITIONS :**

1. **Investigational Drug** – any drug, chemical, or biologic product as an active ingredient or placebo that is being used in the context of a clinical investigation. It has been granted Investigational New Drug (IND) status by the Food and Drug Administration
2. **Investigational Drug Service (IDS)** – a division of the UConn John Dempsey Hospital Department of Pharmacy that provides support for clinical drug studies including IRB consultation and dispensing services
3. **Investigational Pharmacist (IDS Rph)** – the pharmacist responsible for upholding the policies and procedures as well as the supervision of any support staff

**F. MATERIAL(S) NEEDED :**

None

**G. PROCEDURE :**

1. Prior to an initiation of a study, an authorized physician or study personnel will provide a protocol and an estimated charge worksheet with the top portion filled in to the investigational pharmacist (see applicable appendices).
2. The IDS pharmacist will review the protocol for drugs, supplies, and labor estimates to complete protocol requirements. The detailed listing of charges include study initiation and close out fees, compounding and dispensing fees, drugs and supplies, and study maintenance fees for studies that will last longer than 1 year. Purchase of investigational drug as needed for the study will be charged as the wholesaler price to the pharmacy.

3. A detailed list of charges will be prepared by the investigational pharmacist on an Estimated Charge Worksheet and this information will be provided to the investigator for acceptance.
4. Any Pharmaceutical sponsored studies will have the final IDS fees determined by the negotiated site budget with minimum costs as detailed in the Estimated Charge Worksheet (Appendix A).
5. Upon agreement of pharmacy service fees, the study will be billed monthly, or as study needs dictate. Billing will start once drug shipment has arrived to the pharmacy for the specific study and/or IRB approval has been granted.
6. The IDS pharmacist (or IDS technician) will prepare charges monthly and provide an invoice with all services and fees detailed for each month. Patient specific information will not be listed on the forms when applicable so blinks are not broken.
7. The fees will be placed on a transfer voucher and sent electronically to the appropriate department that oversees the investigational study.

**H. ATTACHMENTS :**

[Appendix A: Billing for Pharmaceutical Sponsored Studies](#)

[Appendix B: Billing for Cooperative Groups, Federal, Foundation or Investigator Initiated Sponsored Studies](#)

**I. REFERENCES :**

None

**J. SEARCH WORDS :**

Investigational

**K. ENFORCEMENT :**

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

**L. STAKEHOLDER APPROVALS :**

On File

**M. COMMITTEE APPROVALS :**

None

**N. FINAL APPROVAL :**

- |  |  |
|--|--|
| <p>1. <u>Andrew Agwunobi, MD (Signed)</u><br/>         Andrew Agwunobi, MD, MBA<br/> <b>UConn Health Chief Executive Officer</b></p>     | <p><u>10/21/2021</u><br/>         Date</p> |
| <p>2. <u>Anne D. Horbatuck, (Signed)</u><br/>         Anne D. Horbatuck, RN, BSN, MBA<br/> <b>Clinical Policy Committee Co-Chair</b></p> | <p><u>10/21/2021</u><br/>         Date</p> |

3. Scott Allen, MD (Signed) 10/21/2021  
Scott Allen, MD  
Clinical Policy Committee Co-Chair  
Date
4. Caryl Ryan (Signed) 10/20/2021  
Caryl Ryan, MS, BSN, RN  
Interim Chief Operating Officer, JDH  
VP Quality and Patient Services & Chief Nursing Officer  
Date

**O. REVISION HISTORY :**

Date Issued: 12/28/2012

Date Revised: 10/26/2015, 9/1/2017, 9/1/2020, 8/17/2021

Date Reviewed: