University Hospitals
Case Medical Center

STANDARD OPERATING PROCEDURE (SOP) FOR CLINICAL RESEARCH Title: Transporting Investigational Product to Other Sites	Last Revised: 1/2016 Prior Version: None
SOP NUMBER: SC-404	Page 1 of 3

1. PURPOSE:

UHCMC requires the use of Investigational Drug Services (IDS) to provide investigational product management for trials conducted by a UHCMC investigator. These services include the preparation, dispensing and management of the investigational product (IP).

Under certain circumstances, it may be necessary for the preparation, dispensing and/or management of the IP to be performed outside of IDS. In those circumstances, the PI for the study should complete an Investigational Drug Services Pharmacy Exception Request Form and forward it to the IDS Pharmacy.

When IDS will transfer or transport the IP to other sites or if IDS approves an exception form for the study and the transport or transfer of IP is required, this SOP applies.

FDA regulations require investigators to establish a record of the receipt, use, and disposition of all investigational agents. The purpose of this SOP is to:

1. ensure the agent disposition (receipt, dispensing, transfer, return or authorized local destruction of un-dispensed agent) is documented properly when transported to other sites

2. clarify the responsibilities of Investigational Drug Services, the Principal Investigator (PI) and study staff involved in the transport of test article to other sites which may or may not have a pharmacy on site

2. SCOPE:

This policy applies to the transfer or transport of investigational agents to sites which may or may not have a pharmacy on site.

3. RESPONSIBLE INDIVIDUALS

Investigational Drug Services staff, PI and those to whom the PI has delegated the task of transporting test article.

4. DEFINITIONS:

See Glossary

5. POLICY STATEMENT:

The PI and study sponsor will confer with IDS to establish necessary logistic processes to ensure proper handling, transfer and record keeping of investigational product during transport or when an Investigational Drug Services Pharmacy Exception Request is approved. A formal written process must be documented and agreed upon by PI, study sponsor and IDS.

The staff delegated the task of transfer and transport of investigational product must do so in compliance with the protocol, UH policies & procedures, ICH/GCP Guidelines and FDA 21 CFR 312.

6. PROCEDURES:

Following are several options for managing the transfer and transport of study articles to satellite locations.

6.1. When IDS transports study articles to satellite pharmacies: See IDS SOP: Transport and Transfer of Study Articles.

6.2. When IDS transports study article to satellites without pharmacies: See IDS Memo: UHCMC Satellite Participation in IRB Approved Clinical Trials.

6.2.1 A sample tool for documenting the transfer of study articles is provided for clinical research staff or designees who have Investigational Drug Services approval to transport or transfer study articles. Appendix A: Study Drug Transportation Record.

6.3 When designated study personnel transport investigational product, they must first confer with the study Sponsor and IDS to establish necessary logistic processes to ensure proper handling, transfer and record keeping of investigational product during transport.

7. REFERENCES

None

8. FORMS

Appendix A: Study Drug Transportation Record
Investigational Drug Services Exception Form
Investigational Drug Services Request Form

APPROVALS

Approved by Philip Cola –VP, Research and Technology – February 11, 2016
Approved by Carl Lufter, Director, Pharmacy– February 12, 2014

Study Drug Transportation Record

Note: Modify this tool as needed to reflect the process approved by the PI, study sponsor, and IDS

Protocol Name/Number: _____	Principal Investigator: _____
Subject ID:_____	Visit Date: ____/____/____

TRANSPORT FROM: _____
(Name of site)

Investigational Drug description (ID or lot number), quantity, and description:

_____

Name of site study drug is transported from: _____

Name of site study drug is transported to: _____

Date study drug leaves site: ____/_____/____ (dd/MMM/yyyy) Time study drug leaves site: _____:_____ (24-hour)

Prepared By (print and sign)**:**_____**Date:** ____/____/____

TRANSPORT TO:_____
(Name of site)

Investigational Drug description (ID or lot number), quantity, and description:

_____

Date study drug arrives: ____/_____/____ (dd/MMM/yyyy) Time study drug arrives: _____:_____ (24-hour)

Study drug received as described above? YES NO
(proper location, undamaged and in the same quantity above)

If no, please describe:
_____

Received By (print and sign)**:**_____**Date:** ____/____/____

UHCMC INVESTIGATIONAL DRUG SERVICES: EXCEPTION REQUEST FORM

University Hospitals Case Medical Center (UHCMC) recommends the use of Investigational Drug Services to provide drug management services for trials conducted by a UHCMC investigator. Under certain circumstances, it may be necessary for the preparation, dispensing and/or management of the investigational drug/biologic to be performed outside of Investigational Drug Services. In those circumstances, the principal investigator for the study should complete an exception form and forward it to Investigational Drug Service Pharmacy at InvestigationDrugService@UHhospitals.org

1. Investigator Name:
2. Investigator Contact Information (e-mail/phone):
3. Division/Department:
4. Study Title:
5. Drug(s) to be used in the study:
6. Reason for the request (please provide a complete explanation of circumstances, timing, location and drug criteria that support the request):
7. Please provide the following information*:

   Who will be responsible for the shipping/receiving of the study drug?

   Where and how will the study drug be stored?

   Who will have access to the study drug?

   Who will be responsible for the dispensation and tracking of the study drug? (*Must be IRB- approved Physician Investigator*)

   Who will be responsible for providing the study drug to the participant? (i.e. handing the study drug to the participant)

Principal Investigator/Physician are ultimately responsible for care and disposition of study articles.
Please provide a copy of the study protocol and all investigator brochures for each study drug with the signed request form.

Signed: _____
Principal Investigator

**Study drug must be stored in a secured and locked location, accessible to authorized personnel only. These areas must have sufficient security systems in place, such as locks, alarms, window bars, and or security personnel, to prevent unauthorized entry and access to study products.*

IDS INTERNAL USE ONLY

Request decision (date): Signed:_____ Pharmacist	□ **accepted** □ **not accepted (*note reason why*):**

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Investigational Drug/Biologics Services (IDS) Request Form

University Hospitals Case Medical Center (UHCMC) requires the use of the Investigational Drug/Biologics Services to provide drug management for trials conducted by a UHCMC investigator. These services include the preparation, dispensing and/or management of the investigational drug. Please complete section 1 of this form for all new protocols requiring this service and send to InvstigationalDrugService@uhhospitals.org.

Section 1: To be completed by department administrator or Principal Investigator.

A. Investigator Name:
B. Investigator Contact Information (email/phone):
C. Division/Department:
D. Study Title:
E. Drug(s) to be used in the study:
F. Enrollment Accrual Period:
G. Expected Subject Enrollment:
H. Number of study visits per patient requiring drug dispensing
I. Drug storage requirement Yes
J. Will IDS be responsible for drug destruction Yes

PI Signature: _____ Date: _____

Section 2: To be completed by IDS and returned to Center for Clinical Research & Technology (researchbiller@UHhospitals.org)

PTAEO ACCOUNT Number: _____