UVMMC Investigational Drug Services and IRB Review

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UVMMC Investigational Drug Services (IDS)

Any protocol that includes administration of drugs not yet approved by the FDA for use or drugs being tested for an unapproved use, regardless of how the medications are dispensed, will be assigned an IDS ancillary review.

This review will be to assess feasibility and plans for adherence to VT Board of Pharmacy rules as applicable.

UVMMC Pharm3 policy

IDS will need to review and approve a research study prior to IRB review.

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Investigational Drugs: Medication Use Policy

- Use of all investigational drugs at UVM Medical Center will be approved by either the UVM IRB or an external IRB under a reliance agreement and must comply with all UVM Medical Center policies and safe medication practices.
- The Pharmacy Department is responsible for the oversight of the storage, dispensing, labeling, and distribution of investigational medications and will be notified of the intent for use by the IRB.
- SOP's are set up to meet the Vermont Board of Pharmacy Administrative Rules and Joint Commission Standards regarding investigational drugs, which include, but are not limited to, ***investigational drugs or approved drugs used in an investigational manner***.

Coordination with the IRB

- A feasibility review of all protocols that utilize UVMMC Investigational Drug Service (IDS) to receive, store, control, or dispense an investigational agent require ancillary pharmacy approval.
- •Ancillary reviews will be assigned to IDS when the RPO has identified a protocol using an investigational drug or approved drug in an investigational manner.
- •IDS will need to review and approve a research study using IDS prior to beginning research or adding to a Committee agenda.

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Ancillary Review in Click

Ancillary Reviews

Review Type	Organization	Person	Reqd	Accepted	Comments	Docs
Billing Compliance	IRB Ancillary–Billing Compliance	Trenda Jones Karen Brautcheck Lynn Combs	yes			
Clinical Research Center	IRB Ancillary-CRC	Kathleen Dwinell Kimberly Luebbers Joan Bertolet	yes			
IMF Invoice Review	IRB Ancillary–IMF Invoice Report	Adam Sbardellati	yes			
Investigational Drug Service	IRB Ancillary-Investigational Drug Services	Callie Fortin Aimee Merkert	yes	yes		
OCTR Contract Review	IRB Ancillary-OCTR-Contract	Mark Tomase Kimberly Luebbers	yes			

There are no Committee Member Review Comments to show at this time.

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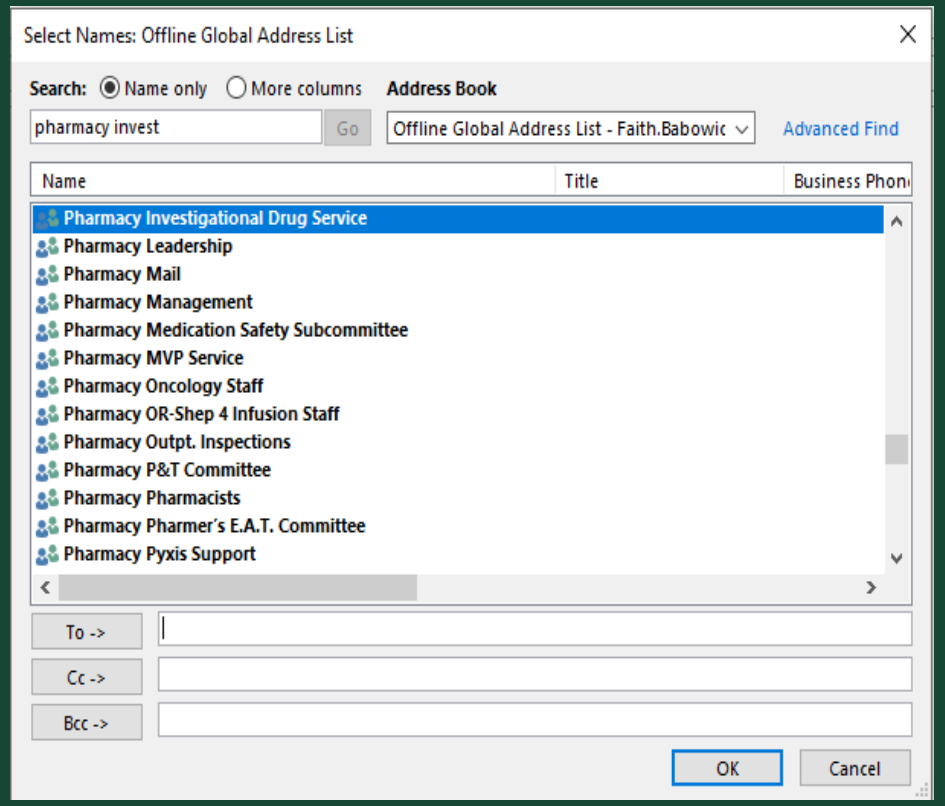
Contacting IDS

- Emailing IDS Group
- Pharmacyinvestigationaldrugservice@uvmhealth.org
- Phone: 802-847-4863 during business hours
- May leave a voicemail if off hours
- Fax: 802-847-1614



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Investigational Drug Services

Specialized skill-set

- Clinical research study process
- National and local regulations governing drug research
- Dissemination of information to other healthcare providers and pharmacy staff

Training in

- ICH GCP
- HIPAA
- IRB/Protection of human subjects
- Competencies and policies required by hospital and board of pharmacy

Investigational Drug Services

Balance requirements of study with:

- State and federal pharmacy laws
- Pharmacy practice standards
- Institution policies and procedures
- Joint commission or other accreditation standards
- GCP guidance

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IDS Model Within UVM Health Network

Part of the inpatient UVMMC pharmacy department

Hours: M-F 8:00am-4:30pm

UVMMC central inpatient pharmacy available for off hours support with advanced notice and approval from IDS group for studies with legitimate requirements

IDS Pharmacist Clinician

IDS Pharmacy Technician

Callie Fortin is the Lead Pharmacist for all studies. Two trained Pharmacist for study support and coverage if needed

Jill Rockwood is fulltime with two IDS trained technicians for coverage if needed

Oncology IDS Pharmacist Clinician

Megan Hinton is the Lead Pharmacist for all Oncology studies

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IDS: Roles and Responsibilities

Study Set-up

Budget

Dispensing procedures

Compounding procedures

Compounding oral dosage forms

Health care provider sheet

EPIC build (+/- order sets)

Dispensing labels

Training to additional staff as needed

Feasibility reviews for the IRB

Study Maintenance

Product accountability

Temperature monitoring

Sponsor communication

Product receipt

IRT data entry

Inventory management

Maintaining study blind

Monitor visits

Study closeout

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Site Selection

Please provide:

Notification of potential study

- ***If study will not include an investigational product, but does involve medication-IDS must still be notified***

Protocol

Pharmacy manual

Safety Data Sheet and Investigator Brochure as available

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Feasibility Reviews

- Appropriateness of research visit location
- Number of potential subjects
- Number of dispensing visits
- Duration of study
- Randomization
- Appropriateness of method
- Blinding
- Federal, local and institutional policy and regulation

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Feasibility Reviews

Investigational drug product handling	
IRT systems	Description of drug & packaging
Drug sourcing	Ancillary supplies
Concomitant meds	Storage conditions
Special handling precautions	Hazardous drug designation
Product preparation	Product dispensing
Subject returns	Product administration

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Ongoing communication

- IRB status
- Regulatory and sponsor communications
- Timeline of study opening/Site Initiation Visit (SIV) or decision not to pursue study
- Updates on status of screening
- Weekly dispense visit schedule
- Monitor visits
- Study closure/close-out visit

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Budget Request

Must be accompanied by:

- Protocol
- Pharmacy Manual
- Safety data sheet (as available)
- Investigator Brochure (as available)

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Budget Request Form for Pharmacy Investigational Drug Services

Phone (802) 847-4863

Instructions: Send this completed form with a copy of the Protocol and Pharmacy Manual to the "Pharmacy Investigational Drug Service Smith 102" email distribution list. Once all materials are received, the IDS team will review and send back a budget estimate.

Protocol Title: Click here to enter text.

Principal Investigator: Click here to enter text. Sponsor: Click here to enter text.

Study Coordinator: Name Click here to enter text. Phone Click here to enter text.

Funding Type: ☐ Industry Sponsored ☐ Cooperative Group ☐ Grant ☐Other Click here

Anticipated month of IRB submission Click here to enter text.

List all investigational products based on source including standard of care medications

Sponsor provided Click here to enter text.

Site Inventory (obtained by IDS) Click here to enter text.

Other-need to specify Click here to enter text.

Are any of the investigational products hazardous? Click here to enter text.

Study Drug **Administration** Location (check all that apply)

☐ MCHV Campus inpatient ☐ MCHV Campus EP2 Oncology ☐ University Health Center

☐ Clinical Research Center ☐ Children's Specialty Center ☐ Shepardson 4 Infusion Center

☐ Vermont Lung Center ☐ Will be administered at home ☐ Other-specify Click here

Anticipated Study Duration: Click here to enter text.

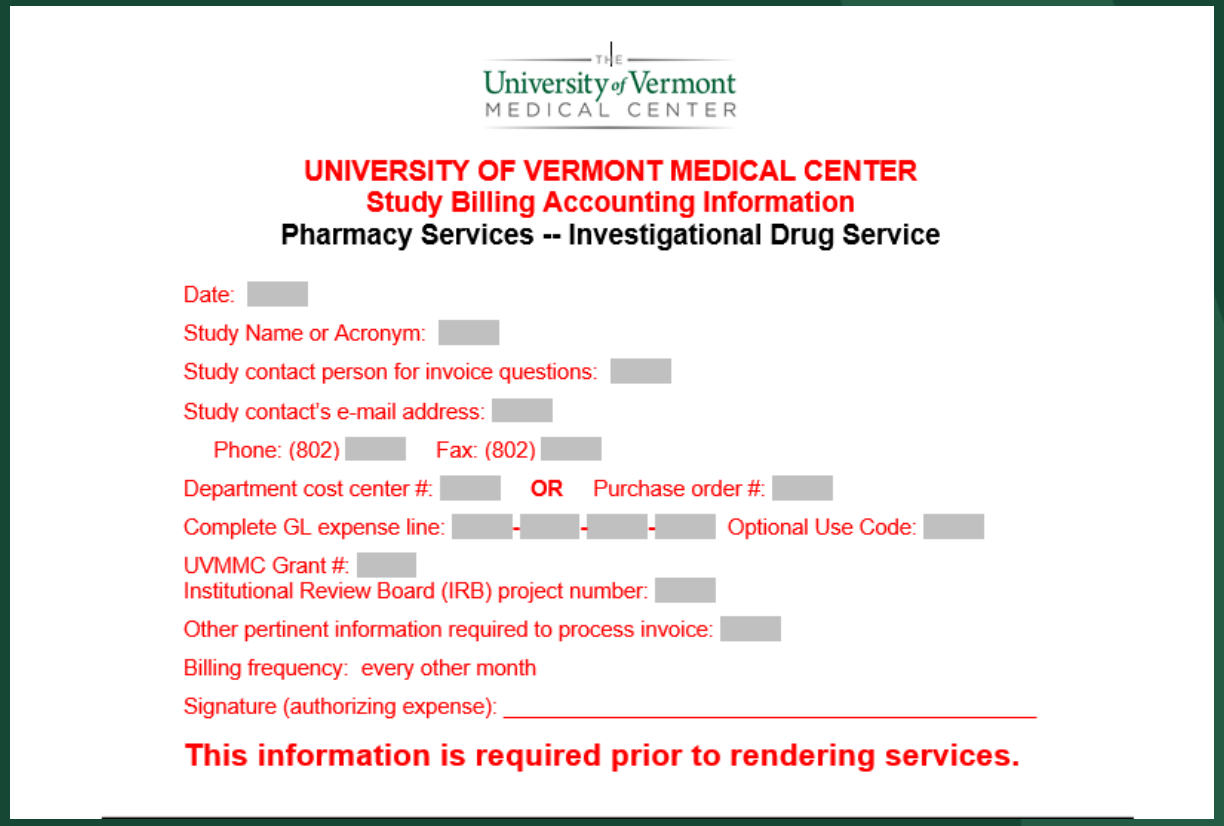
Dispensing days per Subject: Click here to enter text.

Enrollment/IDS Support only required Mon-Fri 0800-1600: ☐ Yes ☐No (please explain off-hours requirement of study) Click here to enter text.

Estimated number of Subjects for site: Click here to enter text.

Submitted by: Click here to enter text. Title Click here to enter text. Date Submitted Click here to enter

Billing Account Information



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Study Billing Accounting Information
Pharmacy Services -- Investigational Drug Service

Date:

Study Name or Acronym:

Study contact person for invoice questions:

Study contact's e-mail address:

Phone: (802) Fax: (802)

Department cost center #: **OR** Purchase order #:

Complete GL expense line: - - - Optional Use Code:

UVMMC Grant #:

Institutional Review Board (IRB) project number:

Other pertinent information required to process invoice:

Billing frequency: every other month

Signature (authorizing expense): _____

This information is required prior to rendering services.

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Weekly Orders Form

Weekly Study Orders					WEEK OF:			
Protocol #	IRB #	Subject ID #	Subject Name	DOB	Visit #	Date of Visit	Time of Visit	Date of dose IVRS randomization

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IDS008 / Pharm111

IDS should not need to be listed on the study as Key Personnel

Curriculum vitae (CV) available only during audits

Pharmacist and pharmacy technician licensing/certification information available through the Vermont Board of Pharmacy

GCP expiration available through Click and certificates available upon request

Only the lead pharmacist must sign the delegation log

All policies available upon request

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