

Pharmacy & The IRB

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SCOPE OF SERVICE

The Department of Pharmacy maintains an Investigational Drug Service (IDS) to support research activities at Thomas Jefferson University (TJU). The IDS maintains the control and accountability of medications in human clinical trials (FDA approved and non-approved) in compliance with Good Clinical Practices (GCPs), Good Manufacturing Practices (GMPs) and regulations and laws as appropriate. Clinical trial support is provided for patients across all age groups.



Investigational Drug Service

- **Staffing- 2 full time Pharmacists**
- **Continuous coverage 24 hr/ day; 7 days / week**
 - Coverage provided by Night Call and Pharmacy Residents
- **Current Metrics:**
 - 110 Active Accruing
 - 102 Pending
 - 37 Closed for Accrual

In-Patient /Out-Patient

- IN-PATIENT:

Hospital Policy 114.06: “Drugs procured for use in an investigational study will be stored in the Investigational Drug Service located in the central Pharmacy.”

-IDS must receive, track and dispense drugs for all inpatient clinical trials

- OUT-PATIENT:

Investigators are not required to use service.

-If a patient is admitted on an investigational medication, medication will need to be identified along with a copy of protocol and informed consent in patient chart

OBJECTIVE for IRB Review

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To provide insight on how to approach an IRB submission for review with a pharmacy focus



IRB Review

OHR-2 Review:

- Review OHR-2 for drugs involved in trial
 - Classification of Medication
 - FDA Approved Medication vs. Investigational
 - What Phase (1, 2, 3, 4)?
- Background Information?
 - If FDA Approved
 - Is dosing consistent with current guidelines?

IRB Review

- Background Information continued
 - If Investigational Medication
 - Clinical trial design appropriate
 - Dosing appropriate
 - Does OHR2 clearly state treatment regimen?

IRB Review

*Background Information continued

- If Investigational – Previous clinical trial information?
 - Phase 1- Animal studies

- Design of trial

- Does design meet needs of study objectives?
- Placebo –controlled? How will placebo be provided?
- Blinded Study?- How will blind be maintained?
- Randomization?- What system will be utilized for randomization?

IRB Review

- Risk vs. Benefit
 - FDA Approved Drug: Adverse events consistent with drug profile?
 - Investigational Drug: Adverse events consistent with pre-clinical/clinical data/ investigator brochure?



IRB Review

- * Drug Supply
 - Is drug provided?
 - Are patients responsible for any cost?
- Management of Drug
 - Inpatient vs Outpatient?
 - Inpatient-Hospital P&P requires IDS to manage
 - Outpatient- IDS vs. study research team
 - Are systems in place for study research team to manage?

IRB Review

- Informed consent
 - Consistent with OHR-2?
 - Focus on language regarding drug provided?