

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
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Approved By: ORI Director	Signature	Date	Date First Effective: 07-24-06
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	
Approved By: IDS Director	Signature	Date	Revision Date: 05-09-19

OBJECTIVE

To describe the procedures for coordination between the University of Kentucky (UK) Investigational Drug Service (IDS), the Institutional Review Board (IRB), and the Office of Research Integrity (ORI) to ensure the safe and efficient conduct of clinical drug trials

GENERAL DESCRIPTION

UK is committed to ensuring the rights and welfare of human subjects involved in research using investigational drugs, agents, and/or biologics, including gene therapy medications and recombinant DNA (r-DNA). UK has established procedures to ensure that the use of any investigational drug is in compliance with institutional policies for the protection of human subjects as well as UK Pharmacy Department policies governing routine drug distribution, federal regulations, The Joint Commission (TJC) and sponsor policies. The IDS, a unit within the UK Department of Pharmacy, supports clinical drug studies by ensuring consistent handling of these products with regard to procurement, storage, dispensing, inventory control, and disposal. The UK IRB and the IDS have established procedures to coordinate the review and approval of clinical investigations involving investigational drugs in accordance with applicable law, governing regulations, and institutional policy.

Definitions

The term *investigational drug or agent* refers to any pharmaceutical forms of a new drug/agent or biologic used in a clinical investigation. The terms include products that are not generally recognized as safe and effective for any use under the conditions prescribed, recommended, or suggested by the Food and Drug Administration (FDA) *or* products already approved by the FDA as safe and effective that are being studied for new indications.

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RESPONSIBILITY

Execution of SOP: IRB, IDS Director, IDS Staff, ORI Staff, ORI Research Compliance Officer (RCO), Principal Investigator (PI)/Study Personnel, UK Pharmacy and Therapeutics Committee, Institutional Biosafety Committee (IBC)

PROCEDURES

1. UK policy requires that the IRB review and approve all investigational drug use involving human subjects prior to initiation of the study regardless of whether investigators conduct investigational drug studies on an inpatient or an outpatient basis.
2. The IDS Director or designee serves as an ex-officio member of the UK Medical IRBs and provides review and oversight of research involving investigational drugs—inpatient and outpatient.
3. The IDS Director supplies the IBC, principal investigator (PI), and the study coordinator(s) with information on investigational drug protocols, particularly gene therapy protocols, as needed to ensure the safety and welfare of human subjects.
4. The IDS complies with existing Department of Pharmacy procedures and additional requirements established for dispensing investigational drugs. These procedures include verification of IRB protocol approval and informed consent, record keeping, preparation or packaging of final product, labeling of dispensed product, and disposal of unused or partially used medication.
5. IDS audits of compliance with investigational drug procedures are consistent with the requirements of TJC, the UK Pharmacy and Therapeutics Committee, and other regulatory agencies as they relate to dispensing investigational drugs.

Inpatient Investigational Drug Research

1. UK policy requires that all inpatient investigational drug investigations use the services of the IDS for storage, control, and dispensing of the drug in question unless the PI requests an exception during the protocol review process and the IDS agrees to the exception.
2. The PI prepares and submits an application and detailed sponsor protocol to the IRB for review. The ORI forwards electronic copies of medical IRB agendas to the IDS Director or designee for review.
3. IDS staff review the protocol and drug information forms to ascertain compliance with investigational drug regulations, UK policy, and the proposed mechanisms for storing, manufacturing, dispensing, and administering the drug in question. This review also takes

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into consideration the ability of the IDS to meet protocol requirements based on resources, personnel time, and drug/drug delivery system availability.

4. The IDS offers the PI necessary assistance to establish and maintain compliance with UK policies for drug storage, manufacturing, dispensing, and administration to hospitalized patients.
5. In the event of any concerns with the protocol, IDS staff submit concerns along with recommendations of possible alternatives to the PI for clarification or reassessment and to the IRB/ORI.
6. In the event that any concerns remain unresolved between the IDS and the PI, IDS staff forward the complete documentation to the Pharmacy and Therapeutics Committee for review and adjudication before making a final determination.
7. Once the IRB review is complete, the PI must provide a copy of the approval letter to the IDS before the IDS pharmacist will dispense an investigational drug.
8. The IDS does not dispense investigational drugs for a clinical drug trial without documentation of IRB approval.
9. The IDS maintains a copy of the research protocol in a secure area and keeps the IRB letter of approval on file.
10. The PI is responsible for providing the IDS a copy of any amendments to the protocol made during the course of the study when applicable to storage, control, and dispensing of the study drug.
11. The PI or designee provides training to personnel administering investigational drugs on the objectives of the research protocol and specific information about the drug.
12. The IDS assists the PI in staff orientation. All study personnel must administer investigational drugs under the general direction of the PI who is a medical professional (physician or dentist).
13. With the cooperation of the PI, the IDS prepares necessary drug information monographs for appropriate personnel and makes these documents available to all nurses, physicians, and pharmacists throughout the UK Hospital/Chandler Medical Center.
14. Prior to the initiation of the study, the IDS arranges with the PI to receive, store, label, dispense, maintain inventory, and audit all investigational drugs used in the conduct of the protocol in accordance with UK policy, FDA regulations, and National Institutes of Health (NIH) guidelines.

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15. The IDS only dispenses investigational drugs upon pharmacist's receipt of an authorized physician's order (prescription) containing all information required by Department of Pharmacy policy.
16. The IDS does not dispense investigational drugs without required information unless the PI negotiates an exception and modification process in cases of critical care studies.
17. The PI or designee is responsible for obtaining and documenting informed consent from the subject or legally authorized representative prior to administering investigational drugs. The PI or designee provides to the IDS verbal or written confirmation of the completed informed consent process including documentation as required.
18. The IDS pharmacist prepares and dispenses the investigational drug in accordance with the protocol, established Department of Pharmacy manufacturing guidelines, and the Pharmacists' Drug Information Form. The label must contain the statement "For Investigational Use Only."
19. The IDS completes final reconciliation of investigational drug accountability logs upon notification of a study closure by the protocol sponsor or PI and arranges a close-out audit by the protocol study monitor.

Outpatient Investigational Drug Research

1. The IDS offers its services to investigators conducting clinical outpatient investigational drug studies. However, such investigators have the option to not use the IDS for storage, control, and dispensing of the drug in question.
2. The IDS handles outpatient investigational drug studies which do choose to rely on the services of the IDS according to the *Inpatient Investigational Drug Research* procedures outlined above.
3. Investigators who choose not to use the services of the IDS for outpatient investigational drug studies must complete and submit a *Use of Investigational New Drug Form* with the IRB application.
4. The IRB reviews and approves the plan for control of the investigational drug or biologic under study as described in the IRB application during a convened meeting unless the study is eligible for expedited review.
5. The IDS pharmacist conducts an annual audit of the policy and procedures for storage and dispensing of investigational drugs by researchers not using the IDS to assure that storage and dispensing comply with federal, state, and institutional regulations and standards.

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6. The IDS notifies the PI in advance of the audit.
7. The IDS pharmacist uses a standard IDS audit form to aid in verifying adherence to applicable laws and regulations for use and accountability of investigational drugs.
8. Upon completion of the audit, the IDS prepares and sends a memorandum to the PI describing the audit results and suggestions for improvement, if any.
9. If a subsequent audit finds that the PI did not comply with the original suggestions for improvement, the IDS notifies the PI and reports the audit findings to the IRB.

Emergency Use and Single Patient Clearance

1. Physicians who wish to use an investigational drug under an emergency use protocol and single patient clearance must apply to the IRB Chair for clearance to proceed with the emergency use. (See [ORI/IRB Emergency Use SOP](#).)
2. The physician must have documented clearance from the IRB Chair to use investigational drugs under this system.
3. The IRB Chair reviews the protocol for emergency use, determines whether the emergency use request fits within the criteria of [21 CFR 50.23](#) and, if it does, provides a copy of a single patient clearance letter to the investigator.
4. The PI forwards a copy of the IRB clearance letter to the IDS for single patient use. The IDS will not dispense an investigational drug without this clearance.
5. If there is insufficient time to obtain clearance from the IRB chair or designee and the immediate use of the investigational drug is, in the healthcare provider's opinion, required to preserve the life of the patient, the IDS may dispense the investigational drug. The investigator must submit the emergency use report to the IRB for review within five (5) working days from the date of emergency use. (See [ORI/IRB Emergency Use SOP](#).)

Complaints and Alleged Noncompliance

1. If the IDS receives a complaint from a subject, subject's family member, staff, or researcher concerning alleged noncompliance or issues with subject's rights and welfare of human subjects, the IDS immediately (within two days) notifies the ORI RCO. The IDS may confer with the ORI RCO to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, IDS, or both.

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2. If the ORI RCO receives a complaint or alleged noncompliance pertinent to IDS and the complaint or alleged noncompliance is applicable to IDS policies and procedures, the ORI RCO immediately (within two days) notifies the IDS. The ORI RCO may confer with the IDS to assess whether the complaint/alleged noncompliance falls under the purview of the IRB, IDS, or both.
3. If the complaint/alleged noncompliance falls under IRB purview, the ORI initiates an inquiry following ORI/IRB standard operating procedures. The IRB is also responsible for determining whether the incident meets requirements for reporting to any federal regulatory agencies. In making the determination, the IRB follows standard operating procedures for reporting. (See [Mandated Reporting to External Agencies SOP](#).)
4. After review of the complaint/alleged noncompliance is complete, the ORI RCO is responsible for providing the IDS with a copy of the final determination, if applicable to the IDS. If the IRB determines that the incident falls under the requirements for reporting to a federal regulatory agency and is applicable to the IDS, the ORI RCO is responsible for sending a copy of the federal report to the IDS.

REFERENCES

Not applicable