



HEALTH RESEARCH ASSOCIATION

1640 Marengo Street – 7th Floor
Los Angeles, CA 90033

**POLICY &
RESPONSIBILITIES**

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Subject:		Issued By:	
JOB RESPONSIBILITIES BY IDS JOB TITLE		IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA’s President & CEO	
Policy #:	Issue Date:	Revised Date:	Effective Date:
2029	March 1, 2008	March 12, 2008	April 1, 2008

Reference: Original Job Responsibilities by IDS Job Title Policy dated 5-1-2007 and updated as of 9-30-2007 and 3-1-2008. See also, California Board of Pharmacy Lawbook located here: http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf.

PURPOSE

HRA and the IDS Pharmacy require that study drugs, biologics and medical devices used in human subjects’ research be stored, handled, and dispensed in full compliance with regulations and/or requirements of the FDA, JCAHO, the California Board of Pharmacy; and in accordance with applicable Institutional policies, procedures and guidelines.

POLICY

IDS Staff must handle all study drugs, biologics and medical devices according to these policies:

1. **PRINCIPAL INVESTIGATOR RESPONSIBLE FOR COMPLIANCE:** It is the responsibility of the Principal Investigator (PI) to comply with all Institutional, state and federal regulations in regards to the distribution of study drugs and biologics, as well as medical devices; and;
2. **ADVANCE IRB APPROVAL IS REQUIRED:** An Administrative Panel on Human Subjects – also known as an Institutional Review Board (IRB) – must approve the use of a study drug, biologic and/or medical device prior to its distribution, except in the case of an Emergency Use. More information on the emergency use of an investigational drug, device or biologic can be found in Chapter 18, Subsection 4 of a USC-OPRS document located here: http://www.usc.edu/admin/provost/oprs/private/docs/oprs/pnp/Policies_and_Procedures_Final.pdf

RESPONSIBILITIES

Below are detailed job responsibilities for the following positions (*Note: Press “Control” + “Left-Click” simultaneously on the following job titles in blue to go to the specific text for that job description*): [PRINCIPAL INVESTIGATOR](#), [PHARMACIST-IN-CHARGE](#), [PHARMACY TECH](#), and [NON-LICENSED PERSON](#):



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1. **PRINCIPAL INVESTIGATOR:** Job responsibilities for the Principal Investigator (PI) at the IDS Pharmacy are:
- The PI will provide the IDS Pharmacy with proof of a signed Informed Consent (IC) Form before the IDS Pharmacy can dispense any study drug, biologic or medical device. A copy of the first IC page containing the name of the study-specific protocol, as well as a copy of the signed signature page of the IC are also acceptable;
 - The PI will provide the IDS Pharmacy with a copy of the fully-executed FDA Form 1572 located here: <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-1572.pdf> or the Study-Specific Protocol Face Sheet as submitted to the IRB listing Co-investigators and all other Study Team personnel;
 - The PI is responsible for placing a copy of the signed IRB-approved IC form in the patient's chart prior to administration of the first dose of any study drug or biologic, or before the patient's first encounter with an investigational device;
 - The PI is responsible for the education of Co- investigators, Study Team personnel, and USC + LAC Medical Center personnel who prescribe, distribute, and/or administer the investigational drug, biologic or medical device;
 - The PI is responsible for working directly with HRA's Office of Contract Administration (OCA) Department relative to budgeting and HRA's Accounts Receivable (A-R) Department relative to invoicing for a particular study's pharmacy costs including the following types of costs: storage, handling (compounding) and dispensing of study drugs, biologics and devices. OCA, A-R and the IDS Pharmacy will work together to ensure that adequate funding for these types of pharmacy costs are incorporated into the grant or proposal – or else provided from other internal sources – and to also ensure that all such costs are properly invoiced to the appropriate payer at the appropriate time;
 - The PI will provide the IDS Pharmacy with a current copy of the study-specific protocol, including all revisions or amendments, and the PI's brochure, if applicable. The PI will also keep the IDS Pharmacy informed of any study-specific protocol modifications that affect therapy or distribution of the investigational drug, biologic or device;
 - The PI will notify the IDS Pharmacy when the treatment phase of the study has been completed and when the study is completely terminated (i.e., follow-up phase completed); and
 - The PI is responsible for reporting all Adverse Events (AEs) related to the administration of study drugs, biologics and/or devices in accordance with IRB and FDA policy.



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PHARMACIST-IN-CHARGE: Job responsibilities for the Pharmacist-in-Charge at IDS are:

- The Pharmacist-in-Charge is an IDS Pharmacy employee and works at HRA's IDS Pharmacy. The Pharmacist-in-Charge has responsibility for the daily operation of the IDS Pharmacy and is responsible for the IDS Pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy;
- The IDS Pharmacy must designate a Pharmacist-in-Charge and within 30 days must inform the California Board of Pharmacy (contact information is available here: <http://www.pharmacy.ca.gov/>) in writing of the identity and license number of that pharmacist and the date that they were designated as the Pharmacist-in-Charge. The IDS Pharmacy also must notify the California Board of Pharmacy within 30 days of the date whenever a previously-registered pharmacist ceases to be the IDS Pharmacist-in-Charge;
- Any person with a pharmacy license must notify the California Board of Pharmacy within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as the manager of, the IDS Pharmacy. Any pharmacist who takes charge of, or acts as a manager of a pharmacy must notify the California Board of Pharmacy within 30 days of their termination of employment. Failure to notify the California Board of Pharmacy within the 30-day period in either of these situations shall constitute grounds for disciplinary action;
- Any person with a pharmacy license who willingly fails to notify the California Board of Pharmacy of the termination of employment of any pharmacist who takes charge of, or acts as manager of, a pharmacy and who continues to permit the compounding or dispensing of prescriptions or furnishes drugs or cytotoxic agents in that pharmacy, except by a pharmacist, is subject to summary suspension or revocation of their license to conduct a pharmacy;
- Within 30 days after changing their address of record with the California Board of Pharmacy, or after changing their name, the Pharmacist-in-Charge must notify the executive officer of the Board of Pharmacy of the change in their address or name;



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- The Pharmacist-in-Charge will ensure that an On-Call Pharmacist takes their place if the Pharmacist-in-Charge is absent due to illness, vacation or for other reasons, including after-hours and holiday coverage. The IDS Pharmacy’s “On-Call Service” Policy & Procedure, including the On-Call Pharmacist Agreement, is located here: http://www.health-research.org/files/pharmacy/On_Call.pdf;
- Dangerous drugs or biologics and/or dangerous medical devices, which require a prescription and are not safe for human use without a prescription, must be ordered by the IDS Pharmacy, delivered to the IDS Pharmacy and received by, and signed for, by the Pharmacist-in-Charge or their designated agent;
- Dangerous drugs or biologics and dangerous medical devices transferred, sold or delivered to a person within California are to be transferred, sold or delivered only to a licensed pharmacy such as HRA’s IDS Pharmacy;
- A pharmacist can be a Pharmacist-in-Charge at two pharmacies only if the locations are less than 50 miles apart. A pharmacist may refuse to act as the Pharmacist-in-Charge at a second pharmacy if they determine that doing so would interfere with their effective performance at the first pharmacy. In such a situation, the Pharmacist-in-Charge must notify the pharmacy owner, in writing, specifying their reasons for declining to be the Pharmacist-in-Charge at the second pharmacy. The pharmacist can not be discharged, disciplined or discriminated against for taking this action;
- For a period not to exceed 120 days, a pharmacist who is an employee, officer or administrator of the pharmacy, or the pharmacy owner, may be designated as the Interim Pharmacist-in-Charge if the pharmacist is already involved in the management of the pharmacy. Documentation of both this action and efforts being made to obtain and designate a permanent Pharmacist-in-Charge must be available to the California Board of Pharmacy;



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- The Pharmacist-in-Charge must complete a periodic self-assessment of the IDS Pharmacy’s compliance with federal and state pharmacy laws. This self-assessment must take place every two years, before July 1 of every odd-numbered year. An additional self-assessment must be completed within 30 days of employment by any new Pharmacist-in-Charge or whenever a new pharmacy permit is issued. The self-assessment consists of the Pharmacist-in-Charge completing form 17M-13, which can be found on pages 18 through 45 of the document located here: http://www.pharmacy.ca.gov/laws_regs/1706_2_exact.pdf. Completed self-assessments must be kept on file by the IDS Pharmacy for three years after they are prepared and submitted to the Board of Pharmacy;
- The Pharmacist-in-Charge is responsible for ensuring that continuous quality improvement measures are developed, followed and maintained relative to the compounding of sterile injectable drugs. For additional information on Quality Assurance Audits, see the IDS Pharmacy’s “Internal Quality Assurance (Audits)” Policy & Procedure located here: <http://www.health-research.org/files/pharmacy/InternalAudits.pdf>;
- The Pharmacist-in-Charge is responsible for maintaining their license with the California Board of Pharmacy. For more information on licensure requirements, please see the IDS Pharmacy’s “Licensure & Professional Standards” Policy & Procedure located here: <http://www.health-research.org/files/pharmacy/Licensure.pdf>;
- Information on the training of IDS Staff-Members relative to compounding and sterile admixture techniques can be found in IDS Pharmacy’s “Sterile Admixture & Injectable Drug Compounding” Policy & Procedure located here: <http://www.health-research.org/files/pharmacy/Sterile.pdf>;
- All prescription records for controlled substances must be maintained by the IDS Pharmacy for three years from the date of dispensing. More information about the IDS’s policy regarding controlled substances is located here: <http://www.health-research.org/files/pharmacy/Controlled.pdf>. All prescription records for non-controlled substances must be maintained at the IDS Pharmacy for one year from the date of dispensing, and for two years thereafter at an offsite storage location. More about the IDS Pharmacy’s Record Keeping Requirements can be found here: <http://www.health-research.org/files/pharmacy/CTM.pdf>;



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- Records of the manufacturing, sale, acquisition or disposition of dangerous drugs or devices are subject to inspection by officers of the law and shall be made available at the IDS Pharmacy during normal business hours subject to the two business day advance notice retrieval allowance requirement detailed in the IDS Pharmacy's waiver of requirement for onsite storage. These records are kept by the IDS Pharmacy for at least three years from the date they are created. The IDS Pharmacy also keeps an active inventory of dangerous drugs, biologics and dangerous medical devices currently in use. The Pharmacist-in-Charge is jointly responsible with the IDS Pharmacy's owner, officer and partner for the proper maintenance of all records and inventory. The Pharmacist-in-Charge is not criminally responsible for any acts committed by the IDS Pharmacy's owner, officer, partner or employee that violate the keeping of these records and inventory if the Pharmacist-in-Charge had no knowledge of these violations and/or did not knowingly participate in any deception;
- The IDS Pharmacy's licensee may remove the original records of acquisition and disposition of dangerous drugs, biologics and dangerous medical devices from the IDS Pharmacy for license-related purposes if a duplicate set of these records is retained at the IDS Pharmacy at all times;
- Electronic records of the acquisition and disposition of dangerous drugs and dangerous devices must be maintained so that the Pharmacist-in-Charge can produce both a hard copy and an electronic copy during normal business hours, and upon the two business-day advance notice retrieval allowance requirement per the IDS Pharmacy's waiver to store such records offsite;
- The IDS Pharmacy maintains a storage area where its records are secure from unauthorized access and will produce the records to the California Board of Pharmacy or an officer of the law within two business days per waiver requirements. Failure to do so may result in the Board of Pharmacy canceling the waiver without a hearing;



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- If the California Board of Pharmacy disciplines the Pharmacist-in-Charge for the violation of a state or federal law or regulation committed by another person – and the Pharmacist-in-Charge reported the violation or suspected violation to the California Board of Pharmacy as soon as was reasonably possible following the discovery of the violation and took steps to stop and remedy the violation or suspected violation – that report shall be used as a mitigating factor by the California Board of Pharmacy. In addition, the Pharmacist-in-Charge must not have engaged, directly or indirectly, in any conduct that violated any state or federal law or regulation pertaining to the practice of pharmacy and not permitted, encouraged, approved of, either tacitly or implicitly or through willful ignorance, any conduct committed by any other person who may have violated state or federal laws or regulations pertaining to the practice of pharmacy;
- Only a licensed pharmacist may compound and/or dispense dangerous drugs, biologics and/or receive or distribute dangerous medical devices;
- Interfering with the Pharmacist-in-Charge's efforts to comply with the laws governing a pharmacy is a misdemeanor legal offense;
- The IDS Pharmacy maintains its facilities, space, fixtures and equipment so that drugs, biologics and devices are safely and properly prepared, maintained, secured and distributed. In addition, IDS Pharmacy and its fixtures and equipment are clean and orderly, dry, well-ventilated, free from rodents and pests and properly lighted;
- A sink with hot and cold running water for pharmaceutical purposes is located within IDS Pharmacy. A readily accessible restroom with a toilet and washbasin with running water is also available within IDS Pharmacy;
- The Pharmacist-in-Charge, or an On-Call Pharmacist on duty at IDS Pharmacy, is responsible for IDS security including control against theft or diversion of dangerous drugs, biologics and/or dangerous medical devices as well as any related records. Only the Pharmacist-in-Charge, or an On-Call Pharmacist at IDS Pharmacy, may have a key to the pharmacy;

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- In addition to the Pharmacist-in-Charge, only one of the following may have a key to IDS Pharmacy: the IDS Pharmacy's owner, the building owner or manager, or a family member of the IDS Pharmacy's owner. The key is to be kept in a tamper-evident container and delivered to the Pharmacist-in-Charge, or On-Call Pharmacist on duty at IDS Pharmacy, or to provide access to emergency personnel in the case of an emergency such as a fire, flood or earthquake, whenever requested. The signature of the Pharmacist-in-Charge is to be present and tamper-evident so that the Pharmacist-in-Charge, or On-Call Pharmacist on duty at the IDS Pharmacy, can easily determine whether or not the key has been removed from the container;
- The IDS Pharmacy's "IDS Security" Policy & Procedure is located here: <http://www.health-research.org/files/pharmacy/Security.pdf>; and
- The IDS Pharmacy security, safety, cleanliness and properly working sink and restroom facilities must be certified by the IDS Pharmacy's Pharmacist-in-Charge prior to every license renewal.

2. **PHARMACY TECH:** The job responsibilities for a Pharmacy Tech at IDS Pharmacy are:

- The Pharmacy Tech at the IDS Pharmacy is licensed by the California Board of Pharmacy, wears identification clearly identifying themselves as a Pharmacy Tech, and assists the Pharmacist-in-Charge, or On-Call Pharmacist, whenever the pharmacist and Pharmacy Tech are both on duty;
- The Pharmacy Tech is under the direct supervision and control of the Pharmacist-in-Charge, or the On-Call Pharmacist, so that the pharmacist is fully aware of all Pharmacy Tech activities revolving around the preparation and dispensing of medications including the maintenance of appropriate records of such activities;
- The Pharmacy Tech may be involved in packaging, manipulative, repetitive, and/or other nondiscretionary tasks related to the processing of a prescription; but not the duties restricted to the Pharmacist-in-Charge or the On-Call Pharmacist. Nondiscretionary tasks for the Pharmacy Tech include removing drugs from stock; counting, pouring or mixing pharmaceuticals; placing the measured product into a container; affixing labels to containers; and packaging and repackaging of drugs, biologics and medical devices. The Pharmacy Tech may assist the Pharmacist-in-Charge, or On-Call Pharmacist, with the dispensing of a prescription for a controlled or a non-controlled substance, but may not perform such functions without direct supervision;



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- Any function performed by a Pharmacy Tech in connection with dispensing prescriptions, including the repackaging of bulk drug and the storage of pharmaceuticals, must be verified and documented in writing by the Pharmacist-in-Charge or the On-Call Pharmacist. Verification is indicated by the Pharmacist-in-Charge, or the On-Call Pharmacist, clearly initialing the prescription label before the medication is provided to the patient’s caregiver;
- Since the IDS Pharmacy employs only one, full-time pharmacist, who is the Pharmacist-in-Charge, there will only be one Pharmacy Tech permitted at the IDS Pharmacy by the California Board of Pharmacy. Additional Pharmacy Techs are permitted only if there is more than one full-time pharmacist working at the IDS Pharmacy;
- The Pharmacy Tech, with the approval of a licensed pharmacist working for the IDS Pharmacy, may perform nondiscretionary tasks when the Pharmacist-in-Charge, or On-Call Pharmacist, is at lunch or on break. No prescription medication may be provided to a patient’s caregiver unless the prescription is a refill that Pharmacist-in-Charge, or On-Call Pharmacist, has checked and initialed. The Pharmacist-in-Charge or, On-Call Pharmacist, is responsible for the Pharmacy Tech and will review any tasks performed by the Pharmacy Tech when the Pharmacist-in-Charge, or On-Call Pharmacist, returns to the IDS Pharmacy after any temporary absence;
- The Pharmacy Tech is responsible for maintaining their license with the California Board of Pharmacy. For more information, see the IDS Pharmacy’s “Licensure & Professional Standards” Policy & Procedure located here: <http://www.health-research.org/files/pharmacy/Licensure.pdf>;
- Within 30 days after changing their address of record with the California Board of Pharmacy, or after changing their name, the Pharmacy Tech must notify the executive officer of the Board of Pharmacy of the change to their address and/or name;
- If licensed as a pharmacist in the future, the Pharmacy Tech registration no longer will be valid and the Pharmacy Tech license must be returned to the California Board of Pharmacy within 15 days; and
- The IDS Pharmacy’s job description for its Pharmacy Tech is on the next page of this policy. Records to verify compliance with the Pharmacy Tech responsibilities in this document, including the job description that follows, must be kept for three years from the date of their creation.



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Job Duties for HRA's IDS Pharmacy Tech include, but are not limited to, the following:

Work Hours: 0830 to 1700

1 x 30-minute lunch break & 2 x 10 minute rest breaks

Daily Duties:

1. Record temperature logs;
2. Clean IV hood with alcohol and/or bleach solution. Initial appropriate logs after cleaning;
3. Check e-mail;
4. Fill prescriptions;
5. Log out medications used after filling prescriptions. Check expiration dates, lot numbers, med-kit numbers and inventory of each and every prescription filled;
6. Verify each patient has signed most recent Informed Consent form;
7. Deliver prescriptions in a timely manner;
8. Unpack drug shipments and confirm shipment arrival according to study-specific protocol (IVRS, fax, mail);
9. Record drug shipments in appropriate study specific protocol binders and computer system (enter lot numbers, expiration dates, and med-kit numbers when appropriate). Reconcile computer, study-specific protocol binder, and physical inventories;
10. Call for empty boxes and "sharps" containers to be picked up;
11. Handle/file incoming correspondence (faxes, e-mails);
12. Forward and unforward calls; and
13. Comply with federal and state pharmacy laws, regulations, policies and procedures.

Weekly Duties:

1. Order needed supplies;
2. Print out temperature logs;
3. Organize pharmacy (storage room, IV clean room, and office); and
4. Restock clean room supplies.

Monthly Duties:

1. Attend Staff meetings.

As Needed Duties:

1. Make study-specific protocol binders as new study-specific protocols are received;
2. Attend/participate in new study-specific protocol training; and
3. Schedule Auditor/Monitor visits and assist with visits.

I have read and understood my responsibilities.

Pharmacy Tech

Date

Pharmacist-in-Charge

Date

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3. **NON-LICENSED PERSON**: The job responsibilities for a non-licensed person at IDS Pharmacy include:

- In the event that the IDS Pharmacy employs a non-licensed person, such as a Pharmacy Tech trainee, the Pharmacist-in-Charge, or On-Call Pharmacist, supervises and instructs the non-licensed person according to laws and regulations in the California Board of Pharmacy Lawbook located here: http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf; and;
- The IDS Pharmacy will only employ a non-licensed person in the pharmacy to perform simple administrative tasks, which do not involve the dispensing of dangerous drugs, biologics or medical devices. At the direction of the Pharmacist-in-Charge, or On-Call Pharmacist, the non-licensed person may also request and receive prescription refill authorizations.

RESPONSIBILITY

Pharmacist-in-Charge
Principal Investigator
Pharmacy Tech
Non-Licensed Persons Working at IDS
All IDS Staff
HRA's President & CEO