



Stanford Hospital and Clinics
Pharmacy
Investigational Drug Services
(IDS)

Marty Hamilton, Pharm D

7-28-09



Drugs for Research or Lab Use

- Responsibility: Pharmacy Buyer
- 723-2538
- sreyes@stanfordmed.org (currently)
- Order using an SU13 or Interdepartmental Requisition form
 - Drug Name, Strength, Package Size, Quantity needed
 - Contact Name and Phone #
 - PTA Account # for billing and approval signature
 - 4 letter Organization Code required as of 8/2008
- Hand deliver to Pharmacy Room H0302 or via ID Mail MC5616 or fax to 5-6262
- 48 hour turnaround unless stat. Stats have an expedite charge of \$20 (currently).
- Pricing to any University purchase is Hospital Pharmacy cost of drug + 20% (all University purchases including NIH studies)



Stanford IDS Information

- Lead Pharmacist:
 - Martha (Marty) Hamilton, Pharm D
- Lead Technician
 - Ted Cummings, CPhT 650-723-5273
- Shipping Address:
 - Investigational Drug Services
 - Room H0302 (Important! NOT H302)
 - 300 Pasteur Drive
 - Stanford, CA 94305
- Phone: 650-725-5295
- Fax: 650-725-6262
- Email: mahamilton@stanfordmed.org



IDS Services

- Randomizations (as part of investigator initiated study)
- Repackaging of Bulk Drug for Physician Dispensing
- Preparation of Drug and Matching Placebo Capsules
- Dispensing of Investigational Drugs and Management of Drug Supplies in Compliance with Federal/State and Protocol Guidelines



Randomizations

- Method:
 - Randomization.com or Randomization.org or other internet sources
- Information Needed
 - Copy of Protocol to determine
 - # of treatment arms of study
 - Stratification Strategies
 - Planned # subjects to enroll
 - Cost is approximately \$100 - \$200



Repackaging of Bulk Drug

- IRB Study Approval Letter
- Drug supply to be repackaged
- Completed Interdepartmental Request form
- Packaging Instructions:
 - # tabs/bottle and # bottles, dose instructions
 - MD name, phone #
- Cost: Variable. Approximately \$2.50 to \$5.00/bottle plus variable setup fee



Sample Label

- Pt ID: _____ Date: _____
- Drug XYZ 40mg #45 (mfg)
- Take 1 tablet twice daily as directed.
- Expires: 8/1/2010
- Dr. Like Research
- Phone: 650-222-3333



Preparation of Drug and Matching Placebo Capsules

- Small studies ONLY. (approximately 100 capsules). LONG lead time.
- Cost: Approximately \$1.50/capsule plus setup fee
- Referreral to compounding pharmacies outside of Stanford



Management of Drug Studies Preliminaries

- Site Qualification Visit for sponsored studies
- Budget Estimates for all studies
 - Supply entire protocol
 - Supply pharmacy manual if there is one
 - Current 2009 pharmacy budgeting tool



Management of Drug Studies Startup

- Information for Pharmacy
 - Complete Protocol (unless already supplied)
 - IRB Approval Letter
 - Investigator Brochure if non FDA approved
 - PTA and ORG code for billing
- Site Initiation Visits
 - Email to schedule meeting at pharmacy to review pharmacy procedures



Management of Drug Studies

Active Phase

- Pharmacy requirements to dispense drug
 - Proof of informed consent
 - Copy of the signature page of consent (the one signed by patient or parent)
 - Prescription/Order to be signed by
 - P.I or Sub P.I. listed on 1572
 - Licensed Person with rx writing privileges (NP) acting under direct supervision of PI or Sub PI



Management of Drug Studies

Active Phase / Termination

- Monitoring/Closeout Visits
 - Appointments are Mandatory. Schedule at least 48 hours in advance.
 - Monitors or Study Coordinators should email to set up appointments.
 - No appointments between 11am – 1pm
- Record Retention
 - Sponsored Studies—originals to PI and copies retained in pharmacy for 3 years
- Investigator Initiated Studies
 - Notify pharmacy of closure



IDS Billing Process in Pharmacy

- Collate charges, prepare bills and submit them to study coordinator for approval signatures.
- Turn signed bills over to Pharmacy billing personnel who then enter the charges into the Pharmacy interdepartmental charge system.
- Printout is then sent to Pharmacy Accounts Receivable, where the charges are entered into another computer system to transfer the funds from the University account to Hospital account.



Pharmacy Billing—Problems

- Pharmacy cannot bill 0800 #
- Pharmacy billing takes months to process
- Contact Denise Ramirez at 725-5802 to expedite journal transfers if account closure is an issue or for questions about pharmacy charges that appear on your bill.