Compounded Drug Products for Research Protocols
Modified: January 2017

Background:

In certain circumstances, both FDA approved and non-FDA approved drugs must be compounded to provide the final product to be used in the research study. This often includes the compounding of a placebo product to be used in blinded drug studies. To ensure the products being used are safe for human use, the IRB must be notified and approve the compounding pharmacy.

Q: If the UF Health Shands’ Investigational Drug Pharmacy (IDS) is used, does the IRB require any documentation for approval?

No. If the IDS is compounding the product, the notification to the IRB regarding this information is all that is required.

Q: If the product is to be administered in a Shands Teaching Hospital & Clinics, Inc. facility, who is required to approve the compounding pharmacy?

Under these circumstances, the Shands Pharmacy must also approve the compounding pharmacy.

Q: What are the IRB requirements in order to approve a compounded product from an outside compounding pharmacy?

1. Compounded products will only be obtained from an outside vendor (compounding pharmacy) on an individual patient-specific basis.

2. An IRB approved written informed consent form must be obtained from a subject or IRB approved legally authorized representative prior to administration of the test medication.

3. An outside vendor (compounding pharmacy) will be allowed based on the following criteria:
   a. Only compounding pharmacies whose internal policies are consistent with the FDA’s Compliance Policy Guide (http://www.fda.gov/ora/complianceref/cpg/cpgdrg/cpg460-200.html) will be approved.
   b. An outside vendor (compounding pharmacy) must have a contract with the University of Florida and/or Shands Teaching Hospital & Clinics, Inc.

4. The outside vendor must supply the following documentation to be considered:
   a. Current copy:
      i. Of the state pharmacy license where the pharmacy resides and proof of registration with the Florida Board Of Pharmacy as a nonresident pharmacy, or
      ii. Current copy of the State of Florida pharmacy license
   b. Current DEA registration if preparing controlled substances
   c. An IND (when appropriate) for that investigational drug
   d. Current Pharmacist licenses and Pharmacy Technician registrations
   e. Staff competency assessments for sterile product compounding
   f. Media fill test results for staff compounding sterile products
   g. Evidence that supports extended expiration dating if applicable
   h. Evidence that verifies staff members are complying with USP 797 standards for gowning, gloving, and glove-tip processes
   i. Evidence of routine surface microbiological environmental monitoring
j. Evidence of performance of nonviable and viable particle testing in primary engineering controls (e.g. LAFH) and room air

5. Drugs that have been withdrawn or removed from the market for safety reasons will not be acquired under any circumstances.

6. Chemicals used in the preparation of compounded pharmaceutical products must be USP/NF grade.

7. For sterile products prepared from non-sterile ingredients, the final product must be checked by a reference laboratory for actual drug content, sterility, and pyrogenicity and meet ASHP standards for compounded products.