



**HEALTH RESEARCH ASSOCIATION**

1640 Marengo Street – 7<sup>th</sup> Floor  
Los Angeles, CA 90033

**POLICY & PROCEDURE**

Subject: <b>ENROLLMENT, RANDOMIZATION &amp; BLINDING</b>		Issued By: IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA’s President & CEO	
Policy #: 2014	Issue Date: November 1, 2006	Revised Date: August 20, 2007	Effective Date: September 30, 2007

Reference: Original Patient Enrollment and Randomization & Blinding Policies dated 4-12-2006 and updated as of 11-1-2006.

**PURPOSE**

To ensure that the IDS Pharmacy Staff follow consistent procedures when it comes to patient enrollment, randomization and blinding.

**POLICY**

1. **IDS PHARMACY STAFF WILL FOLLOW STUDY-SPECIFIC PROTOCOL PROCEDURES:** IDS Staff must comply with each study-specific protocol when it comes to patient accrual, randomization and blinding. It is the responsibility of the Pharmacist-in-Charge to ensure that study-specific protocol procedures are strictly followed.

**GUIDELINES & PROCEDURES**

1. **RANDOMIZATION:**

- a. **MUST FOLLOW STUDY-SPECIFIC PROTOCOL PRECISELY:** IDS Staff will closely follow the randomization instructions for each study-specific protocol;
- b. **RANDOMIZE AFTER VERIFYING PHYSICIAN ORDERS:** Once physician orders are verified, the study-specific protocol must be checked for randomization procedures;
- c. **SPONSOR-PROVIDED RANDOMIZATION LISTS:** For Sponsor-issued randomization lists, the subject’s name and date must be recorded next to the randomization number (unless other instructions are specified by the Sponsor in the study-specific protocol);
- d. **FOLLOW STUDY-SPECIFIC PROTOCOL INSTRUCTIONS FOR IVRS:** For telephone randomization using Interactive Voice Response System (IVRS) procedures, follow the study-specific protocol instructions;
- e. **IVRS ACCOUNTS MUST NOT BE SHARED:** IVRS accounts serve as “electronic signatures.” Therefore, IVRS accounts must not be shared among IDS Pharmacy Staff, unless instructed to do so by the Sponsor;
- f. **DOCUMENTATION & CONFIRMATION:** Randomization will then be documented in the study-specific protocol Drug Accountability Log Sheet and the confirmation will be filed in the study-specific protocol binder;

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- g. **DO NOT RE-ISSUE RANDOMIZATION NUMBERS:** Randomization numbers must not be reissued, unless requested by the Sponsor in writing.

2. **BLINDING:**

- a. **BLINDING RECORDS AND INFORMATION MUST BE KEPT IN THE IDS PHARMACY STUDY-SPECIFIC PROTOCOL BINDERS:** The IDS Pharmacy will maintain the blinding information in study-specific protocol binders;
- b. **CODES KEPT IN SEALED ENVELOPES:** All randomization codes will be kept inside a sealed envelope within the study-specific protocol binder;
- c. **IDENTICAL LABELING:** The labeling of study drug and placebo medication must be identical for every single blinded study;
- d. **NON-EMERGENCY BLIND BREAKING:** Written authorization to “break the blind” must be obtained from the Sponsor in non-life threatening situations. The Pharmacist-in-Charge will document the name of the person requesting to break the blind as well as the reason for breaking the blind. This documentation should be signed and dated by the Pharmacist-in-Charge as well as by the person requesting the break. If necessary, the Principal Investigator (PI) of the study should be informed. One copy of the written blind-breaking documentation should be sent to HRA's President & CEO and a second copy of the documentation should be filed in the study-specific protocol binder;
- e. **EMERGENCY BLIND BREAKING:** When knowledge of the study product is essential for clinical management and the welfare of the subject as determined by the treating physician and/or the Sponsor, the Pharmacist-in-Charge may break the blind of a particular subject's treatment assignment. HRA's President & CEO, as well as the study's PI, must be made aware of this situation as soon as it is practical to do so;
- f. **“BLIND-BROKEN” PATIENTS MUST BE DISCONTINUED:** Any patient for whom the blind has been broken will immediately be discontinued from the study and no further efficacy evaluations may be performed.

**RESPONSIBILITY**

Pharmacist-in-Charge / PIs and PI Study Teams / All IDS Staff