



HEALTH RESEARCH ASSOCIATION

1640 Marengo Street – 7th Floor
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POLICY & PROCEDURE

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Subject: PROTOCOL INITIATION		Issued By: IDS PHARMACY	
		Approved By: Kathleen R. Hurtado R.Ph. HRA's President & CEO	
Policy #: 2022	Issue Date: February 28, 2007	Revised Date:	Effective Date: March 15, 2007

Reference: Vanderbilt University P&P located here: <http://vumcpolicies.mc.vanderbilt.edu/E-Manual/Hpolicy.nsf/AllDocs/C982299FF763CE2B86256FBD00684E5E>.

PURPOSE

To ensure that standardized protocol initiation policies and procedures are used whenever a new clinical trial is begun using IDS Pharmacy Staff and services.

POLICY & PROCEDURE

Prior to subject enrollment, the IDS must be in receipt of the following:

1. Copy of research protocol;
2. Any amendments to the protocol;
3. Copy of IRB approval letter;
4. FDA Form 1572, if applicable, located at:
<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-1572.pdf> ;
5. Copy of Informed Consent Form(s);
6. Investigators' brochure; and
7. Drug label pages and accountability forms (if provided by Sponsor).

RESPONSIBILITY

Pharmacist-in-Charge
All IDS Staff
PIs
Study Coordinators