

Appendix B:

DEPARTMENT OF PHARMACY - INVESTIGATIONAL DRUG SERVICES
VCU HEALTH SYSTEM - RICHMOND, VIRGINIA

**AGREEMENT GOVERNING USE OF COMPUTER
INVESTIGATIONAL DRUG ACCOUNTABILITY SYSTEM AND USE OF MY ELECTRONIC
SIGNATURE**

Security and confidentiality is a matter of concern for all persons who have access to the Investigational Drug Accountability Computer System (known as Vestigo). Each person accessing the Investigational Drug Accountability System data and resources holds a position of trust relative to this information and must recognize the responsibilities entrusted in preserving the security and confidentiality of the systems and information.

Depending on the study design and documentation/record keeping requirements, Vestigo may include subject Protected Health Information (PHI) and unblinded study treatment information. Authorized monitors must only request access to Vestigo if appropriate for their role and scope of work. Authorized monitors must only view and download files as directly required for conduct of clinical trial oversight and recordkeeping; all files must be stored securely and used in accordance with ICH guidance and FDA requirements. IDS is responsible for maintaining Pharmacy Study File (PSF); see *P&P IDS Documentation, Recordkeeping, and Storage* for further details.

As an authorized user of this system, I understand and agree that I am responsible for safeguarding my electronic signature password and computer-generated medical and study documents to prevent unauthorized use. I understand that the electronic signature (user ID and password combination) will be the legally binding equivalent of a traditional handwritten signature with all the ethical and legal implications thereof.

I affirm with my signature that I have read, understand, and agree to fulfill the provisions of this Agreement.

Completion of all fields is required for Vestigo access.

SIGNED BY: _____

PRINT NAME: _____ **DATE:** _____

STUDY NAME(S) (PRIMARY IDENTIFIER): _____

(if monitoring for more than one trial, you may list all and IDS will save a copy of this form in Vestigo for each trial; any additional studies will require a form completed per trial to grant access)

COMPANY OF EMPLOYMENT and SPONSOR: _____

TITLE and ROLE: _____

EMAIL: _____

PHONE: _____