Clinical Trial Inventory Sheet

*Primary Sponsor Name: _____

*Research Group Association: HSR IACUC IBC SBS Other

*Research Group Number (HIC#/HSR#): _____

Sponsor Protocol #: _____

Industry Sponsored Research - Company Contact Information

Division/Dept: _____

Address: _____

City/State/Zip: _____

Contact Name: _____

Email: _____

Phone: _____

PTAO Project# _____ *OSP Award # _____

Drug/Device Name: _____

Drug IND/Device IDE # _____

Retention Language per Contract/Protocol:

_____

_____

Study/Trial Name:

_____

_____

_____

Study/Trial End Date:_____ *PI Name/Computing ID _____

Description of Records (may include Drug/Device Name):

_____

_____

*Date Range - Beginning: _____ *Date Range - Ending: _____

Number of boxes: _____

(Use back for individual box listings and contents)

Current Location: _____

*Primary Contact Computing ID: _____

Clinical Trial Inventory Sheet

Box Listing:

Box Legacy #	Description	Date Range

Clinical Trial Inventory Sheet Instructions

This sheet will assist in collecting the information required to enter Clinical Trial Data and Administrative records into the URMA System for centralized management of the approval to destroy from the Sponsor and track the storage (with a storage vendor or within your own compliant storage). More information on storage and the URMA system can found on the Records Management website: www.virginia.edu/recordsmanagement

Each sheet will represent one study – and include all boxes of study material or all electronic storage locations.

You will need access to the Administrative Records of the study, including the study protocol and IRB approval information. Below are definitions of the fields on Page 1:

*Primary Sponsor Name - - the name of the company or organization who is the sponsor of the project - if a subcontract, indicate the name of the organization contracting with UVA. (Examples: NIH, Komen Foundation, Kaiser-Permanente, etc).

*Research Group Association - Please indicate the UVA Internal review board required for the study (if known) - Select from drop down list. If there is more than one IRB associated with the same study, select based upon the following priority list: (1)HSR; (2)SBS; (3)IACUC; (4)IBC; (5)Other.

*Research Group Number (IRB Number) – Enter the IRB or other review board number here. (If you do not know this number, enter 00s to match the format required).

Sponsor Protocol # – sponsor's protocol number from the Protocol.

Industry Sponsored Research - Company Contact Information
Sponsor Division/Department, Address, Sponsor City, State and Zip (or related international information) from the contact sheet in the Protocol.
Contact Name – first and last name of the main contact for the study – a sponsor trial coordinator or lead investigator.
Email and Phone – for the person listed in the Contact information above.

PTAO Project Number and OSP Award – both come from the PTAO – if unknown please place 00000 in the OSP award number.

Drug/Device Name & Drug IND/Device IDE# - listed in the protocol or other administrative/instructions received from the sponsor.

Retention Language Per Contract – This language is usually listed in the protocol, check the table of contents of the Protocol or the agreement for retention language. It may be called Data Retention or Data Management.

Study/Trial Name – name of the study as listed on the official protocol or IRB approval.

Study/Trial End Date – The date listed in Oracle as the "End Date" for the contract/agreement.

*PI Name/Computing ID – the principle investigator for the study at UVa.

Description of Records – a general description of the records held in all boxes (note: you will provide details on individual boxes or files/folders on the backside of the form.

*Trial Start Date & *Trial Close Date – date when the study was approved by IRB, and date when the officially ended activity.

Number of boxes – number of boxes for the study (use the 10 x 12 x 15 size only!)

Current Location – Building and room number.
*Primary Contact Computing ID – yourself or the person in the department responsible for the records.