Research Records Inventory Form - Data and Participant Records

Research Group Association: ☐ HSR ☐ IACUC ☐ IBC ☐ SBS ☐ Other

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

Primary Sponsor Protocol/Study #: _____

Primary Sponsor Name: _____

Sponsor Department/Division: _____

Sponsor Address: _____

Contact Name: _____

Contact Phone #: _____

Contact Email: _____

Secondary Sponsor? If yes, add name/contact information: _____

_____

Study/Trial Name: _____

_____

Study/IRB Status: ☐ Active ☐ Closed ☐ Unknown

Drug IND/Device IDE #: _____

Drug/Device Name: _____

Retention Language per Contract: _____

_____

Study Subjects: ☐ Adults ☐ Minor & Adults ☐ Minors ☐ Unknown

If study includes minors, indicate birth year of youngest minor subject: _____

IRB Close Date: _____

PI Name/Computing ID: _____

Date Range - Start: _____ **Date Range - End:** _____

Current Location: _____ **Primary Contact Name:** _____

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Number of boxes: _____

Use next page for individual box listings and contents.

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Box Legacy #	Description	Date Range

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This sheet will assist in collecting the information required to enter Research Data and Participant Records into the URMA System. More information on storage and URMA can found on the Records & Information Management website: www.recordsmanagement.virginia.edu

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.

* Indicates a required field in URMA

***Research Group Association:** indicate the UVA Internal review board required for the study. 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 unknown, enter 0s.

Primary Sponsor Protocol/Study #: sponsor's protocol or study number

***Primary Sponsor:** the name of the company or organization sponsor of the project – if a subcontract, indicate the name of the organization contracting with UVA.

Primary Sponsor Department/Division: indicate if available.

Primary Sponsor Address: indicate if available.

Primary Sponsor Contact Name: first and last name of the main contact for the study – a sponsor trial coordinator or lead investigator.

Primary Sponsor Contact Email: for the person listed in the Contact Name field above.

Primary Sponsor Contact Phone: for the person listed in the Contact Name field above

***Add Secondary Sponsor:** if yes, add information.

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

Study/IRB Status: indicate whether active, closed, or unknown.

Drug/Device IND/Device IDE#: listed in the protocol received from the sponsor.

Drug/Device Name: name of drug or device used in study.

Retention Language Per Contract: include any information about record retention. Check the table of contents - it may be called Data Retention or Data Management.

Study Subjects: indicate the type of subjects studied. If minors were studied, add the birth year of the

youngest subject, if known, to make calculating retention easier.

IRB Close Date: date the study was closed by the IRB.

PI Computing ID: computing ID for the principal investigator for the study at UVA.

PI Name: first and last name of the UVA principal investigator.

***Date Range-Start & Date Range-End:** general dates of the study start and finish (for use in creating box records in URMA).

Current Location: building and room number (for use in creating box records in URMA).

***Primary Contact Name:** yourself or the person in the department responsible for the records (for use in creating box records in URMA).

Number of boxes: number of boxes for the study. Use the 10 x 12 x 15 size box only. One URMA record should be created for each box.