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**Appendix G: Transfer of Data, Records and Samples**

Data Responsible Person: Matt DeVries and Carolyn Apperson-Hansen
Records Responsible Person: Matt DeVries
Samples Responsible Person: Matt DeVries and Tech Transfer

Background:
Reference: CWRU Policy on Custody of Research Data LINKED HERE

**Data** are defined as the material, originally recorded by or for the investigator, commonly accepted in the scientific community as necessary to validate research findings. Research data include but are not limited to laboratory notebooks, as well as any other records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of the form or the media on which they are recorded.

The term **"Active"** as it pertains to this document refers to any sample or data that due to federal, state, local, or institutional rule are required to be retained for records purposes, such as NIH-related paperwork being required to be retained for 7 years following the close of the final year of a grant -or- FDA-related records being required to be kept and stored per written terms and conditions of the funded research program.

In general, all active data, samples, and records generated during your tenure are the property of CWRU. CWRU and the School of Medicine (typically the department where the departing personnel resided) will retain the original versions of all Datasets, Samples, and Records, with the departing personnel able to take copies of data and records, and splits/aliquots/subcultures of any samples. Any deviation from the above needs to be detailed in the Departing Personnel Data Custody and Retention Plan. The Departing Personnel Data Custody and Retention Plan must be approved by the SOM Office of Research Administration and CWRU Vice President for Research and Technology Transfer, as well as acknowledged by all named custodians.

Requirements of Departing Personnel Data Custody and Retention Plan:

- Inventory of Datasets
- Inventory of Samples
- Inventory of Paper Records
- Narrative of Plan (Developed by departing personnel, departing department senior administrator, authorized representative for the SOM Office of research administration)
    - Must Address:
        - Deviations of the in general practices noted above
        - Identification of any datasets, samples, and records that led generation of invention disclosures and/or licenseable intellectual property
        - Identification of any MTA's associated with any data, samples, or records (pay special attention to cell cultures acquired from a vendor such as ATCC)
        - The current location of data, samples, and records
        - Departing PI's Intention for ALL data, samples, and records
        - The physical and technological logistics of any data or record copying/transfer
        - Description of all responsibilities vis a vis PHI, HIPAA, and FISMA surrounding the data, samples, and records

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    - Source of payment for all copying/record replication
- **FOLLOWING COMPLETION AND REVIEW OF INVENTORY:** A Material Transfer Agreement and a Data Use Agreement needs to be negotiated between CWRU and your new institution for any samples and/or data respectively
    - Obtain the name and contact information of a contact in your new institution's intellectual property or technology transfer office.
    - Contact the School of Medicine Office of Research Administration to initiate this process.
        - SOM:ORA will initiate and facilitate creation of appropriate MTAs and DUAs, utilizing templates where applicable, however active participation on the part of the departing PI and department will be required. Department is encouraged to frequently inquire on the status.

1. Construct an Inventory of ALL active* **BASIC SCIENCE** datasets generated during your time at CWRU, provide a copy to the Office of Research Administration and to your current Department Administrator, **Do not include any FDA-regulated datasets.** Please add rows as needed.

| Dataset Name (e.g. Lung ELISAs 2002-2013) | Data Type (bioassay, questionnaire) | PHI/HIPAA/FISMA Yes/No | Data Format (Paper, electronic, etc.) | Sponsor of Data Generation (e.g. NIH) | Intention for dataset (e.g. Take a copy with me, leave with CWRU) | Primary Contact for the data upon your departure (typically a close collaborator or department admin) |
|---|---|---|---|---|---|---|
| | | | | | | |

2. Construct an Inventory of ALL active* **CLINICAL SCIENCE** datasets generated during your time at CWRU, provide a copy to the Office of Research Administration and to your current Department Administrator. **Do not include any FDA-regulated datasets.** Please add rows as needed.

| Dataset Name (e.g. Lung ELISAs 2002-2013) | Data Type (bioassay, questionnaire) | PHI/HIPAA/FISMA Yes/No | Data Format (Paper, electronic, etc.) | Sponsor of Data Generation (e.g. NIH) | Intention for dataset (e.g. Take a copy with me, leave with CWRU) | Primary Contact for the data upon your departure (typically a close collaborator or department admin) |
|---|---|---|---|---|---|---|
| | | | | | | |

3. Construct an Inventory of ALL **BASIC SCIENCE** samples from any active* studies currently stored at CWRU generated during your tenure, provide a copy to the Office of Research Administration and to your current Department Administrator. **Do not include any FDA-regulated samples.** Please add rows as needed.

| Sample Name (e.g. Mouse Tumor Biopsies 2002-2013) | Tissue Type (eg. blood, organ) | PHI/HIPAA/FISMA Yes/No | Storage Conditions (e.g. -80 Freezer) | Sponsor of Sample Collection(e.g. NIH) | Source (e.g. Primary Culture, ATCC) | Intention for samples (e.g. Take a split/aliquot with me, destroy) | Primary Contact for the samples upon your departure (typically a close collaborator or department admin) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

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4. Construct an Inventory of ALL **CLINICAL SCIENCE** samples from any active* studies currently stored at CWRU generated during your tenure, provide a copy to the Office of Research Administration and to your current Department Administrator **Do not include any FDA-regulated samples.** (Please add rows as needed)

| Sample Name (e.g. Mouse Tumor Biopsies 2002-2013) | Tissue Type (eg. blood, organ) | PHI/HIPAA/ FISMA Yes/No | Storage Conditions (e.g. -80 Freezer) | Sponsor of Sample Collection(e.g. NIH) | Source (e.g. Primary Culture, ATCC) | Intention for samples (e.g. Take a split/aliquot with me, destroy) | Primary Contact for the samples upon your departure (typically a close collaborator or department admin) |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

5. Construct an Inventory of ALL laboratory notebooks (paper or digital) created at CWRU during your tenure using the following format. Provide a copy to the Office of Research Administration and to your current Department Administrator. **Do not include any FDA-Regulated paper records.** (Please add rows as necessary.)

| Record Name (e.g. Lab Notebook 2001-2002) | Name/Roll of Author (e.g. Jenny Smith - Post Doc) | PHI/HIPAA/FISMA Yes/No | Sponsor of Authoriship(e.g. NIH) | Intention for Record (e.g. Take a copy with me, destroy) | Primary Contact for the notebooks upon your departure (typically a close collaborator or department admin) |
|---|---|---|---|---|---|
| | | | | | |

6. **Only applicable to research (active or inactive) which comply with FDA requirements or has IDE or IND provisions:**
    a. For each study with the above conditions provide:
        i. Inventory of administrative datasets (eg. patient follow up schedule, etc)
        ii. Inventory of samples
        iii. Inventory of equipment
        iv. Inventory or research datasets distributed outside of the study team (eg. steering committee, medical monitor, DSMB committee, Interim analysis, final analysis, annual progress report)
            1. Needs to include:
                a. Code
                b. Reports
                c. Process documents
                d. etc.
    b. For each study provide the name and role of the CWRU data transfer project team and the receiving institution's data transfer project team.
        i. Members of each team (may include)
            1. Primary Contact
            2. Regulatory professional
            3. Data management professional
            4. Data security/systems/IT professional
            5. Statistician
            6. Study coordinator (Receiving team only)

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c. For each study provide a copy of applicable CWRU and Receiving Institutional policies
d. For each study complete the data copy, transfer, and archival plan template LINKED HERE
e. For each study:
    i. Provide a list of all ongoing data auditing and monitoring activities be sure to include the date of each activity
    ii. Specify if the study is ongoing at CWRU

NOTE: Biological, Chemical or Radiolgical Samples must be moved utilizing use a DOT-certified vendor.

By signing this form you acknowledge that the PI has completed the form per the guidelines described above.

Data Custody and Retention Plan completed with SOM:ORA and attached:

PI Initials _____

SOM:ORA Initials:_____

Faculty Member Signature: Date:

Department Administrator Name: Date:
Department Administrator Signature:

Department Chair Name: Date:
Department Chair Signature:

**Appendix G is to be returned as part of the completed Faculty Member Departure packet.**