**IRB Research Registry/Repository Regulatory Binder Contents**

**Introduction**

Registries/Repositories are “living lending libraries” or “banks” of data and/or specimens. They are forward-looking and created to provide subject data or specimens for research in the future. To that purpose, the documents, Standard Operating Procedures (SOPs), etc., should be updated frequently to stay on the cutting edge of Best Practices and plan for the future. In the long run, it is much easier to be ahead of the regulatory “curve” than to play catch up.

The Informed Consent document (ICF) governs what the registry/repository can do with the data or specimens. It is imperative that the permissions in the ICF are matched with the data or specimen usage so tracking permissions/sharing is crucial. It is recommended that the ICF describe data/specimen usage with the widest allowable scope to provide the registry/repository with the greatest freedom to contribute to future research.

**This Registry/Repository Regulatory Binder template** asks questions pertinent to each tab or tab section. These questions should be addressed in the documents for that tab or tab section.

Each tab or tab section lists the documents to be included under that tab or tab section. This had built in redundancy.

**Definitions:**

A **'human subjects/research registry'** is an organized collection of retrievable, identifiable information (pertaining to living humans) that is intentionally maintained for use as a prospective instrument for the conduct of research. A research registry may also be called a repository or a data or specimen bank. This document utilizes the term ‘registry’ to refer to all collections for research purposes.

Note that collection of data or specimens for a specific protocol DO NOT constitute a registry IF the data or specimens will not be saved for future unspecified research purposes.

**Registry owner is the PI responsible for the registry/repository.**

“ICF” is the Informed Consent Document

“IF” is the abbreviation for “Incidental Findings”. This term refers to findings that are not necessarily the focus of the study but may have clinical significance to the subject.

Research data such as the specimens/data stored in the registry need the highest security during collection, storage and transfer as required by VCU standards.

**Note: please keep in mind that a registry/repository is not a research study. It is more akin to a library or a bank or a business unless it is collecting samples/data directly to the registry/repository and not just accepting or sharing submissions from studies.**

**Current state of registries and repositories**

Some registries and repositories will be submitting data/specimens from studies with ICFs that mention contributions to a registry/repository. The registry/repository needs a method/process for verifying that the contributing study’s ICF matches the purpose, scope, etc., of the registry/repository.

It is recommended that new registries/repositories have their own ICF (separate from a study ICF) that can be discussed with the potential participant at the time of the initial study consent conversation or when appropriate. In that case, the participant would sign and date both ICFs (study and repository/registry) and receive signed copies of each. The study ICF should mention that if the participant agrees (and signs the registry/repository ICF), samples/data will be collected for depositing into the registry/repository.

It is best for these ICFs to eliminate checkboxes for participants to request being notified before samples are sent out. Few studies have the staff and monies to be able to comply with this request and the ICF should be clear enough to make a second permission unwarranted.

Some registries/repositories may be set up to collect samples directly from a population without a study being involved. In this case, the registry/repository would be set up to resemble a normal study. It would have an ICF that describes the risks of collecting the samples/data (not necessary if samples are being submitted to a registry/repository from a study), plus all the usual aspects of recruiting, etc.

Personnel, Laboratory, IRB tabs are all standard in study regulatory binders but included here for the registry/repository convenience.

**Cover Sheet**

Principal Investigator/Guardian

HM#

Registry Title

IRB Review Data

IRB Primary Reviewer’s name

IRB Analyst’s name

**“Registry/Repository Guardian/PI Responsible” Tab**

Are the responsibilities of the “Guardian” clearly noted? Such as:

1. Ensuring data/specimens are obtained and released according to the IRB approved Registry/repository protocol

2. Executing a Data/Sample sharing agreement each time data/samples are released for research purposes

3. Ensuring security and confidentiality of stored data/specimens

4. Ensuring security and confidentiality of samples and specimens during transfer

5. Tracking submissions and releases of data and specimens

6. Maintaining methods for identifying data/samples for which consent has been withdrawn and ensuring there will be no future use.

7. Identifying data/samples that have limitations on future uses and ensuring that future uses are not contrary to those limits

8. Certifying genetic opt out status, if applicable

**“Personnel” Tab**

For personnel who will handle specimens or identifiable data:

Copies of CVs- must be less than two years old (and kept up to date), signed and dated by each person.

Copies of CITI training completion – including basic, refreshers, and Good Clinical Practice (GCP) certificates

Copies of any other training certificates related to qualifications for performing duties

**Licensure**

Valid, current licenses/certification for all professional study staff (e.g., medical, nursing license and laboratory managers)

**“Laboratory Documents” Tab (if applicable)**

Lab Certification (e.g. CLIA, CAP) and updates

Normal lab/reference values and updates

Keep updated documents to exhibit the competency of all lab facilities being utilized and to support the reliability of test results.

If lab documentation is filed separately, write a signed and dated note-to-file indicating the location and file here.

**“IRB” Tab**

Most IRB documents will now be maintained in RAMS. However, it is best practice to review the RAMS documents periodically to ensure all these items are present. If something is missing, please notify the IRB office.

All RAMS submission documents, including approved/validated recruitment materials and additional study information distributed to participants should include version numbers and/or dates.

Required Content

1. Copies of signed and dated submissions:
   1. Initial RAMS submission
   2. Continuing Reviews
   3. Amendments
   4. Unanticipated Problem Reports
   5. Sponsor and monitor reports/communications
   6. DSMB Reports
   7. Unanticipated Problem reports
   8. SAE reports & log
   9. WIRB, CIRB, etc., documents
   10. Closure documents including final reports.
2. Original Approval letters and or notification of IRB decisions
3. Copy of Investigator responses to IRB communications
4. Approved recruitment materials
5. Approved study related information distributed to participants or LARs.
6. All foreign language related materials (if applicable)
7. A print out VCU FWA information
8. Any additional correspondence related to the study

**“Standard Operating Procedure (SOP)/Policy” Tab**

**General Policies**

**Description:**

purpose of the registry/repository explanation

Specify whether this registry will include samples or is only data.

Location of registry/repository

Description of type of data/specimens

Description of the population from which data/specimens were obtained

Describe contact with subjects, if any.

Note if the registry/repository has a Certificate of Confidentiality

**Funding Information**

Note funding source (It should be noted in the RAMS submission and in the ICF)

Funding source title

PT#

Contract number and sponsor

Subcontract, if any

Primary awardee institution\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Fellows involved

Department

Other information

Note if there any industry funds supporting this project.

Place a copy of the Office of Research and Innovation negotiated data sharing/usage agreement between VCU and the funder (DUA).

**“Documents” Tab**

Template for a “PI responsibility” agreement (to be signed before accepting or releasing samples/specimens).

Describe the document Retention Policy.

Describe the registry requirement regarding inclusion of the IRB approval documentation when submitting a request to share or request specimens/data.

Describe whether the registry accepts specimens/data when the subjects have requested notification of information learned from their specimens/data. If so, describe the registry resources and a plan to fulfill that request.

Include a policy that describes how registry documentation will be maintained and for how long.

Describe the process for tracking withdrawal requests and noting when they are completed.

Describe the process for tracking subject’s specimens/data who do not give permission for any genetic testing to be done.

Describe how specimens/data will be tracked and who is responsible for this.

Describe the plan for requiring and maintaining committee approvals (vetting, IRB, biosafety, etc.)? Include the approval documentation.

Ensure that the policy discusses data access/sharing agreements.

Does the registry/repository require copies of versions of ICFs under which the samples/data were collected? If so, are these ICFs stored and maintained in case a review is necessary?

Do the SOPs adequately address security and oversight for the registry?

**Vetting**

Include:

A description of the process for vetting each request (incoming or outgoing specimens/data) for scientific value.

Describe the “vetting committee’s” responsibilities, personnel, meeting frequency (and method). Personnel on the vetting committee should be updated as changes occur (similar to a research study).

Describe the policy regarding the types of genetic analysis that might take place (scope) with genetic material.

**Conflict of Interest policy**

Describe the plan for managing/disclosing Conflict of Interest.

**Personnel**

Describe the policy governing personnel management such as hiring, training, supervising, and terminating registry personnel.

**Legacy Planning**

Describe the plan to address what will occur if the registry owner changes or the registry is terminated.

**“Request Evaluation Criteria” SOP Tab**

The “vetting” committee should discuss these topics in their meeting related to releasing specimens (Answer these questions in the regulatory binder in order to be proactive and speed up approvals):

Biomarker and Assay Rationale

Stability of the biomarker in current storage conditions

Reproducibility of the assay

Volume of sample required

Range of biomarker

Test-retest reliability of the assay

Previous use of assay in human samples

Experimental Plan and Feasibility

Has sufficient technical groundwork been performed to justify the use of this valuable material?

Are sample sizes justified based on power analysis?

A data analysis plan incorporating analysis of the relevant aspects of the dataset should be discussed.

Collaborative Team and Environment

Do the investigator and collaborators possess the appropriate expertise to carry out the proposed work?

Are key areas of expertise adequately supported as needed?

Describe the organization/institutional environment in which the work will be done contribute to the probability of success?

Are materials, technologies and additional support personnel available to ensure progress?

Do the proposed experiments take advantage of the unique features of the environment or employ useful collaborative arrangements?

Is there evidence of institutional support?

The vetting committee should discuss the number of samples in the entire repository related to the number of specimens being requested by a particular investigator. A decision on whether to release the samples should be based on scientific merit of the requester’s study.

**Inventions & Products**

For a research repository: Does the ICF contain a statement noting that the specimens may be used in research that could result in new discoveries and that donor subjects do not retain any property rights to their materials and will not receive any financial benefits?

**Costs**

Does the registry/repository ICF explain that it may charge investigators for requested data/specimens? This charge should not be for profit, but for maintenance costs of the registry/repository.

See an example of a repository fee structure for more information:

<https://www.niddkrepository.org/pages/costs/> .

**Incidental Findings (optional at this point in time)** This pertains to Incidental Findings or findings related to the original study but found in later research.

Does the registry plan to return “actionable” clinical findings to the researcher who submitted the specimens/data? If so, describe this plan.

Do the sharing ICFs (incoming and outgoing) address whether the PI proposes to return incidental findings (IF)?

Do the sharing (incoming and outgoing) ICFs describe the method for sharing findings with subjects?

Do the ICFs offer subjects the choice to “opt out” of receiving actionable clinical findings?

When the registry releases specimens/data to an investigator, does the registry request that the applicable finding be shared back to the registry?

Does the submitting study’s ICF include an opt out checkbox for receiving genetic results?

**Publishing**

The publication SOP should address issues of:

Citing the registry/repository in publications

Authorship in compliance with ICMJE criteria ( [www.ICMJE.org)](http://www.ICMJE.org))

Responsible Conduct of Research ethics

Submitting to Open Access journals in order to disseminate findings as widely as possible.

Will manuscripts be submitted to peer reviewed journals?

Agreement to send a copy of each published manuscript to the registry/repository (the registry/repository Does have the option to require reviewing of the manuscript before submission to a publisher)

**“Incoming Data/specimens” Tab**

Do the SOPs describe the process by which an investigator can request to submit specimens/data?

Are the forms for submitting specimens/data created and available? Including a requirement for a signed Submittal Agreement?

If data/specimens are being shared with the repository from a research study:

Is there a process for determining whether the consent process is consistent with the information provided to participants regarding obtaining/sharing of their data? Such as:

Does the registry request a copy of every subject’s ICF or require the PI to attest to having the appropriate consent to share the specimens/data?

Is there a process for assuring that the original (collecting) study ICF allows for sharing samples/data for future research in accordance with the registry scope? If not, is there a management method for identifying consent/permission/assent for particular areas of research and a process for ensuring that specimens/data are only shared in consented research areas. Is there a process to double check this information?

Does the ICF describe limitations to data/specimen withdrawal? For example, data/specimens can be withdrawn “until they are in use by a researcher. However, if the subject wants to withdraw from the registry, no further specimens or data will be shared and data/samples will be destroyed”.

Does the ICF describe the process for withdrawal in a step by step manner? How is the withdrawal request communicated to the registry owner/manager?

**“Outgoing (sharing of) Data/Specimens” Tab**

Will data/specimens be shared with identifiers?

Will data/specimens be blinded to the requesting investigator?

Do the SOPs describe the process by which an investigator can request specimens/data

Are the forms for requesting specimens/data created and available?

Does the vetting committee review the request and determine the adequacy of the request for releasing specimens/data?

Does the registry owner initiate and ensure completion of a data sharing agreement before releasing any specimens/data to the requesting researcher (if outside of VCU)?

Is there a process to check that only appropriately consented/approved specimens/data is released (verification of the ICF for the scope of research)?

Is the release/transmission of specimens/data adequately secure?

Is released/transmitted specimens/data tracked?

Will requesting investigators be encouraged or required to deposit any findings/analyses into the registry/repository database?

**“Data/Specimen Maintenance and Storage” Tab**

Will the specimens be processed before storage in the registry or will they be prepped before they arrive? If processing will be needed, do the SOPs describe where this will be performed and who is responsible for this.

Is there a description of the location where each type of specimen will be stored and how it will be labeled?

Describe the SOP describe how specimens/data will be destroyed if the registry is terminated.

**Specimen – non-renewable**

Where will samples be stored?

If samples are stored off site, will the PI monitor the storage with the same diligence as if samples were on site?

If samples are being stored in a freezer:

Does the registry PI have access to a freezer? If the PI does not own the freezer; describe and upload the PI's freezer agreement with the freezer owner.

Does the freezer utilize a temperature log, temperature alarm, personnel access log? Who answers the freezer alarm (during office hours and after office hours)?

Describe the freezer lock.

**Data**

How will research data be recorded? Examples: remote data entry (central database off site), local database (excel), on line secure database (REDCap), etc.

Do the SOPs describe where data will be stored and how it will be protected?

Will any data be stored on a portable drive?

Will all personnel with access to the data have a unique password?

Is there a plan to check for data breaches and how to manage them if they occur?

**HIPAA**

Is any HIPAA data being stored/shared with the registry?

Do the SOPs describe how the code key will be separated from specimens/data and stored in a secure location with limited personnel access?

**Labeling**

Do the SOPs describe how specimens/data will be labeled with identifiers/codes?

Will specimens/data be recoded (double coded) at the time of arrival to the registry? Will this be tracked in case there is a need to contact the researcher about a subject?

**Coding**

How will codes be generated?

Is there single, double or triple coding? Are all the codes tracked with a key?

Will the registry/repository require that receiving PIs recode the data/specimens and keep a key and/or send the key back to the registry in case the data/specimens need to be tracked for some reason?

Where will the key (linking documentation) be stored?

Are the personnel who have access to the key identified?

Do these personnel have up to date CITI certification (basic, refreshers & GCP)?

Certificates should be stored in the Registry Regulatory Binder.