



# IRB RESEARCH REPOSITORY COMPLIANCE PROGRAM

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# Why a Policy Now?

- The regulations have always included oversight for research repositories, with guidance dating back to 1997 and new guidance in 2004 & 2010
- Recent cases and the increased interest in maximizing the utility of limited resources have created a focus on how to do this correctly.
  - ▣ When done improperly, can lead to limitations on future uses, destruction of valuable resources, court cases, and distrust.
  - ▣ Consideration of what is legal vs. what is ethically acceptable

# Goals of Compliance Program

- Compliance with regulatory requirements
- Maximize utility of resources
  - ▣ Facilitating sharing of data/samples
  - ▣ Decreasing limits on use
- Standardize the process institution-wide
- Decrease ongoing compliance requirements for continuing reviews.

# Compliance Program: One Year Goal

- Launching June 1, 2010
- The IRB will develop many tools and host training sessions to help you develop the appropriate structure for your repository.
- Compliance initiative runs for one year
- After May 31, 2011 – any OHSU human subjects research repositories discovered to be operating without IRB approval will be reportable to the Office for Human Research Protections – constitutes conducting unapproved research.

# Applicability of the Policy

- This policy applies to human subject research repositories established by OHSU investigators for the purpose of storing data and/or specimens for future research purposes.
- This policy does not apply to data/specimens that are collected and stored as part of routine clinical care or hospital procedures, for example, blood banks, pathology, surveillance, or quality assurance. However it does apply to data/specimens from these sources that are then stored for future research.

# Repository - Defined

- Registries, data banks, and tissue banks are all considered “repositories” for regulatory purposes. Any reference in this policy to repositories applies equally to data banks, tissue banks, and registries.
- Generally, a repository collects, stores and distributes human tissue, specimens and/or data for use in future research projects. Any collection of human biological materials (including data) is considered to be a repository when there is no explicit plan to destroy the materials when the specific research project that generates the materials ends.

# More on Definition...

- The collection and storage of specimens/data becomes a research repository when there is a specific intention for the data/specimens to be used repeatedly for research purposes, or stored for future research and/or shared with other investigators.
- The prospective collection and storage of data/specimens only for a defined research purposes (including holding samples to “batch” them for assays), as part of a single IRB-approved protocol is not considered a repository.

# More on Definition...

- If there is no explicit plan to destroy the data/specimens when the specific original research project ends, the investigator may maintain the data/specimens under continued IRB approval for uses as approved in the original protocol.
- Once a use is desired beyond the primary research goals of the original protocol, the PI must establish an IRB-approved research repository protocol for any future research uses or submit data/specimens into an existing IRB-approved repository.

# Approval Requirements

- A human specimen/data repository may be categorized in one of three ways:
  - ▣ Non-human subjects repositories (NHS)
  - ▣ Exempt Repositories
  - ▣ Non-Exempt Repositories
- All research repositories, except those qualifying as non-human subjects research, require review and approval by the IRB.

# Non-Human Subjects Research Repository

- Non-Human Subjects Research – this is an activity that doesn't meet the definition of human subject or research.
  - ▣ Research projects that are originally deemed non-human subjects (NHS) research and converted to a repository are considered NHS repositories.
  - ▣ Data/specimens that are de-identified as part of the original research protocol will likely be deemed NHS repositories.
  - ▣ A request for determination should be sought to have the IRB confirm the NHS status.

# Exempt Repositories

- Exempt Repositories – these meet the regulatory definition of being exempt from the full requirement of IRB oversight.
- For repositories that are exempt, continuing oversight by the IRB is limited to annual renewals.
- Repositories will NOT be found to be exempt if the data/specimens retain any identifier or link that would permit anyone to identify, directly or indirectly, the person whose data/specimens are stored.

# Non-Exempt Repositories

- The operation of any non-exempt research repository requires standard continued oversight by the IRB.
- Creating a repository specific protocol will be required for the review.
- The IRB will review and approve the repository protocol specifying the conditions under which data and specimens may be accepted into the repositories, how they will be securely stored, and the procedures under which they will be shared in order to ensure that adequate measures are employed to protect the privacy of subjects, maintain the confidentiality of the data and the integrity of specimens.

# The Basics of a Repository

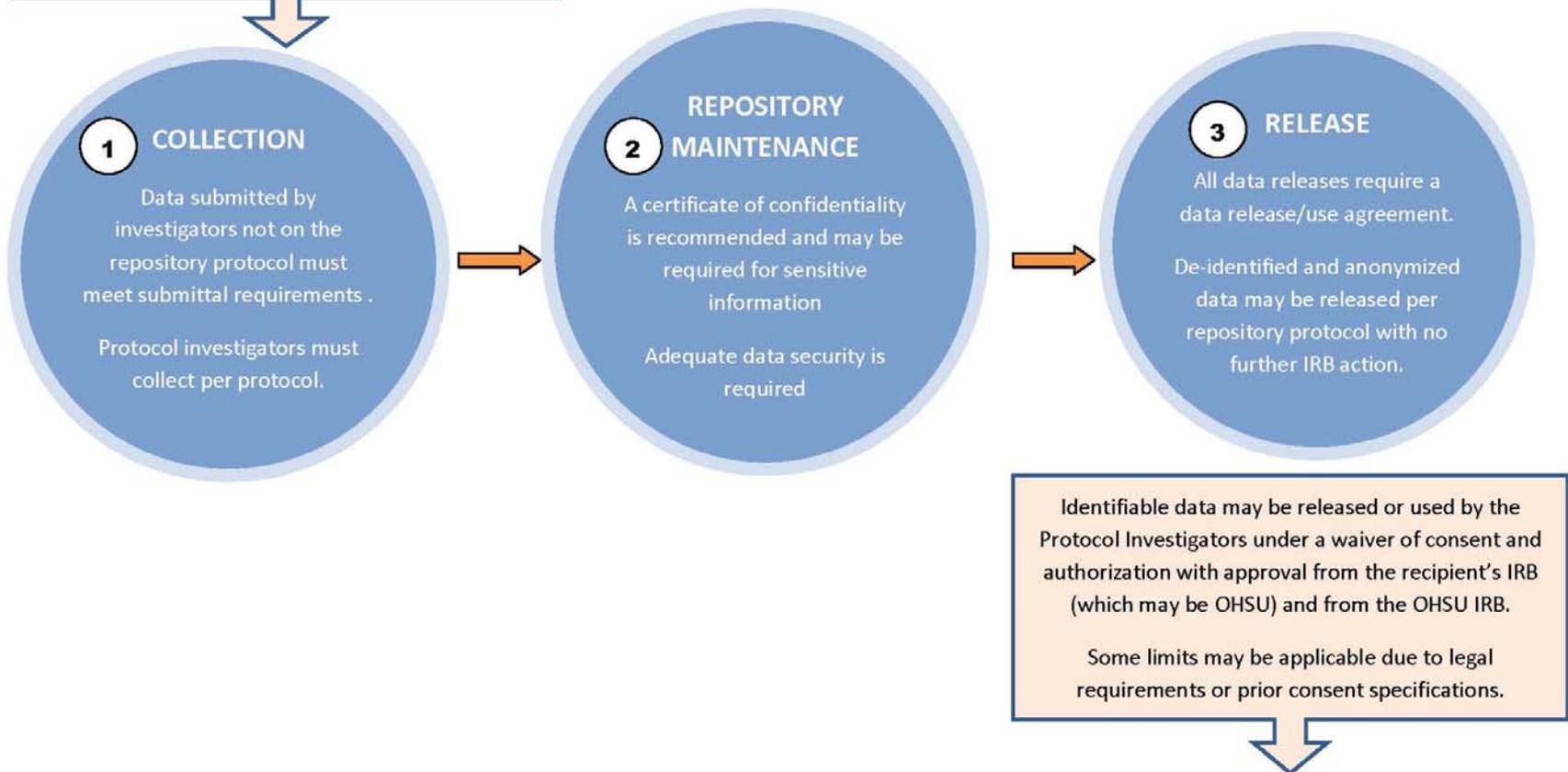
- Repository activities involve three components:
  - 1) the collection of materials,
  - 2) the repository storage and data management

and

  - 3) the use by recipient investigators.

# Research Repositories with Identifiers/links – No or non-specific Consent.

- A. Research data collected under a waiver of consent.
- B. Research data collected with consent, but no specific provision for future research.
- C. Research data collected with consent, but with limits on future uses.
- D. Medical records data.



# Research Repositories with Identifiers – Future Research Consent Obtained.

Data collected via research interactions or clinical care with specific consent obtained for storage for future research.

Research data collected with consent, but with limits on future uses.

## 1 COLLECTION

Data submitted by investigators not on the repository protocol must meet submittal requirements .

Protocol investigators must collect per protocol.

## 2 REPOSITORY MAINTENANCE

A certificate of confidentiality is recommended and may be required for sensitive information

Adequate data security is required

## 3 RELEASE

All data releases require a data release/use agreement.

De-identified and anonymized data may be released per repository protocol with no further IRB action.

Identifiable data may be released per repository protocol with a waiver of consent and authorization and approval from the recipient's IRB.

Some limits may be applicable due to legal requirements or prior consent specifications.

# Collection

- Data & Specimens to be Included
  - ▣ Description
  - ▣ Sources
  - ▣ Acquisition process
  - ▣ Consent & Authorization (or waiver)
  - ▣ Conditions for Acceptance – Submittal Agreement
  - ▣ Confirmation of local IRB approval

# Maintenance

## □ **Security and confidentiality.**

- Description how and where data/specimens will be stored, and
- Description of how the privacy of subjects and the confidentiality of data will be protected, including if a Certificate of Confidentiality will be obtained.

## □ **Access to the data/specimens.**

- Description of who will have access to the data/specimens,
- Description of what the requirements are for access.
- Indication of who is designated as the Guardian.

# Maintenance [2] - Guardian

- **DEFINITION - Guardian:** A person who has primary control of data and specimens and maintenance of the repository. This person may be delegated by the Principal Investigator; however the PI retains ultimate responsibility for the oversight of the repository.
- **Details of the Guardian's responsibilities, including:**
  - ▣ Ensuring that data/specimens are received and released according to OHSU policy and the IRB approved repository protocol.
  - ▣ Executing a usage agreement each time data or specimens are released for research purposes.
  - ▣ Ensuring the security and confidentiality of stored data and specimens,

# Maintenance [3] - Guardian

- More Details of the Guardian's responsibilities
  - ▣ Secure data and specimen distribution.
  - ▣ Tracking acquisitions and release of data and specimens.
  - ▣ Methods for identifying data/samples for which consent has been withdrawn and will ensure no future use.
  - ▣ Identifying data/samples which have limitations on future uses and ensuring that future uses are not contrary to those limits.
  - ▣ Certifying genetic opt out status with OHSU officials, if applicable.

# Security and Confidentiality

- Coding. A method to code the data/specimens, including a process to protect/maintain the key to the code and limit access to the key. The coding system must be adequate to reduce the possibility of re-identification.
- Control of access to the data/specimens - access to the un-coded data/specimens must be restricted to a limited number of repository staff. Accountability for controlling and monitoring access must be provided.

# Security and Confidentiality [2]

- Usage requirements - A complete description of the process for requesting and releasing data must be included.
- Methods for certification that the releases are not contrary to any previously imposed limits, via law, previous consent, genetic opt out, or other applicable limits.
- Ensuring that material transfer agreements are used when necessary for the transfer of biological materials

# Release

- Description of Mechanisms release of data/specimens.
- A statement that separate IRB approval/determination will be required for each specific human subject research activity that uses identifiable data/specimens from the repository.
- Methods for securing Usage Agreements from recipient investigators.

# Release [2]

- Usage requirements - A complete description of the process for requesting and releasing data must be included.
- Methods for certification that the release are not contrary to any previously imposed limits, via law, previous consent, genetic opt out, or other applicable limits.
- Ensuring that material transfer agreements are used when necessary for the transfer of biological materials

# Some definitions

- **Submittal Agreement:** An agreement that attests that specimens collected were obtained with written informed consent of the donor-subjects utilizing an informed consent document approved by the local IRB or under an IRB Approved waiver of informed consent.
- **Usage Agreement:** An agreement that details the conditions for receipt and future use of data and/or specimens from a repository.

# Submitting for IRB Approval

- The electronic IRB (eIRB) will contain a specific application for the creation of new research repositories.
- Any existing study that is completed but has collected data and/or specimens for future research purposes may choose to convert the study to a repository via a modification or continuing review application.
- It is recommended that a request for determination be sought from the OHSU IRB whenever there is a question of IRB oversight requirements.

# Submitting for IRB Approval [2]

- **Database/Repository is Maintained at OHSU** - When the database/repository is maintained partly or completely at OHSU, a repository protocol must be submitted for the database/repository itself.
- **Database/Repository is Maintained Outside of OHSU** - When an investigator is contributing data/specimens to a repository not held by OHSU, the OHSU IRB must approve at a minimum the collection protocol, the consent process and the submittal agreement. This can be done as a new application or an amendment to an existing study. However, not all submittals meet the requirements for engagement in human subjects research and a request for determination may be sought.

# Submitting for IRB Approval [3]

- **Requesting Data/Specimens from a Repository**
  - When an investigator is requesting coded or identifiable data from an established repository, a study submission is required either as a new study or as a modification to an existing study.
  - The OHSU IRB must approve at a minimum the protocol, data request/collection tools, the usage agreement, consent process (most likely a waiver), and IRB approval of repository from which the request is being made.
  - For anonymous and some coded data, a request for determination should be submitted.

# Study Specific Repositories

- When collecting data/specimens in the course of a study and depositing them into a database/repository that will be used ONLY for the research goals of that specific study:
  - ▣ A separate repository protocol/consent form is recommended, but not required.
  - ▣ Any proposed use beyond the original study will require creation of a repository protocol.
  - ▣ Some modifications to that study may be required to become compliant with this policy.

# Study Specific Repositories [2]

- If a separate repository protocol is not created, the study protocol/consent form must contain the following information about the database/repository:
  - ▣ Method of data/specimen storage and use;
  - ▣ Data points and specimens to be stored. Include all identifiers.
  - ▣ Designated repository guardian and list of who will have access to the repository; and
  - ▣ Methods to protect confidentiality
  - ▣ A statement that the samples/information may be used for future research. This statement may be specific or broad; however it will dictate the limits on future uses.

# Conversion of a Study Protocol to a Repository

- For currently approved IRB protocols, including those not only with a specific research study, but also a research database/repository to store data/specimens for future studies:
  - ▣ Once the research study and subsequent data analysis are complete, the repository protocol can be separated into a repository specific IRB submission and the original research study submission can then be terminated.
  - ▣ This can be done at continuing review or via a modification

# Conversion of a Clinical to a Research Database/Repository.

- Data/specimens that have been stored in a database/repository solely for clinical, QI purposes or other standard non-research purposes in the past can be moved into a research database/repository under an IRB waiver of C/A.

# Modifications & Continuing Reviews

- Modifications must be submitted only for changes to the protocol, not for every data/material exchange. If you are accepting data/material that is beyond what is described in the scope of the study or wishing to release beyond the scope, the modification must be submitted for review.
- Releases requiring a waiver of consent & authorization require review by an IRB.
- Continuing reviews must include a summary of data exchanges for the past year.

# Terminating a Repository

- When there is no intent to continue to operate a repository for future research or if the data/specimens are being transferred to another repository, the repository should be terminated via a modification in the eIRB.
- The termination request must include the disposition of the data and samples, including details on transfer, donation or destruction of specimens or data in a secure way.
- When applicable, a description of any communications with research participants regarding disposition of data and samples should be submitted for approval.

# Upcoming Educational Sessions

- May 04 - PI Town Hall
- May 11 - Targeted Training – Basic Scientists
- May 27 - Repositories & Consent
- June 3 - Targeted Training – SON/SBER
- June 08 - Writing a Repository Protocol
- June 22 - Submitting & Releasing Data from Repositories
- TBD eIRB Changes
- TBD Repositories FAQs

# Questions?

Effective Date  
6/1/2010

Year-long  
compliance  
initiative ends  
5/31/2011

- **Repository Information Page**  
<http://www.ohsu.edu/xd/research/about/integrity/irb/repository-policy.cfm>
- **More details & Updates are in development – Keep checking back.**