IRB RESEARCH REPOSITORY COMPLIANCE PROGRAM: eIRB REVISIONS

Mindy Roberts, MA, CIP
Assistant Director, ORIO

Agenda

- ❑ Review the definition of a repository
- ❑ Discuss the three main routes to achieving compliance with the Repository Policy
- ❑ Discuss tools to help determine next steps
- ❑ Review website resources
- ❑ Summarize key points

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- ☑ ***Review the definition of a repository***
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What is considered a repository?

- The collection and storage of data/specimens 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.

- Any collection of data/specimens 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.

What is not considered a repository?

- The prospective collection and storage of data/specimens only for defined research purposes (including holding samples to "batch" them for assays), as part of a single IRB-approved protocol is <u>not considered a repository.</u>

- Refer to materials located on our website for additional details on the Repository Policy

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Achieving Compliance

- There are three main routes to achieving compliance with the Repository Policy within eIRB:

  - Create a 'Repository Only' submission
  - Create a 'New Study' submission that includes a repository component
  - Complete additional policy requirements within an existing submission, either through Modification or Continuing Review

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'Repository Only' submissions

□ A new path has been created to specifically define repositories that are not combined with a research study.

Start a new eIRB Application by filling out this Initial Review Questionnaire (IRQ).

* **Short Study Title:** Oral antibiotic failure in Cystic Fibrosis
Enter a short study title for your study. Use the short study title to identify your study in the system. If the NIH requires a same short study title here.

* Please select one of the following:

○ New Study

○ Request Waiver of Oversight to Another IRB

○ Future Human Subjects

○ Request a Determination ❓

◉ Repository Only (data/biological specimen registries, repositories, data banks or libraries)

Clear

'Repository Only' submissions

The 'Repository Determination' page asks questions to determine if IRB oversight is necessary, or, to determine if there are additional Oregon Genetic Privacy Act or HIPAA requirements that apply.

Repository Determination

* 1. Does the repository involve data or specimens obtained or being obtained from living individuals?

○ No - All subjects are dead. This would not qualify as human subjects research; however, HIPAA and/or Oregon Genetic Privacy Law requirements may apply.

○ Yes

Clear

* 2. Are the data or specimens individually identifiable?

○ No - All data or specimens have been stripped of all 18 identifiers before entry into the repository or, the data or specimens are coded and the code is not accessible to you or your staff.

○ Yes - Data or specimens contain one or more of the 18 identifiers, or, the data or specimens are coded and the code is accessible to you or your staff.

Clear

* 3. Indicate the purpose of collecting and storing the data or specimens:

○ Only as part of routine clinical care or hospital procedure (e.g. blood banks, pathology, surveillance, or quality assurance)

○ To use/contribute to future research projects

Clear

Additional compliance requirements:

* 4. Do the data or specimens include results from genetic tests or planned genetic testing?

○ No

○ Yes - Genetic opt-out requirements may apply.

Clear

i. If yes, describe your plan for compliance with the genetic opt-out policy:

'Repository Only' submissions

☐ Based on answers to the 'Repository Determination' page, you may be prompted to complete the new 'Defining the Repository' page.

☐ This page will ask you to indicate:
- ☐ Data, specimens, or both
- ☐ Types of specimens
- ☐ Source(s)
- ☐ If existing, whether obtained under consent or waiver
- ☐ Plan for prospective collection (consent or waiver)
- ☐ Details on genetics, cancer, VA, or OCTRI involvement

Defining the Repository

Repository activities involve 3 components:

1. Defining the collection of data or specimens
2. Establishing the repository maintenance & stewardship
3. Managing the release of data or specimens for research

First Component - Defining the collection of data or specimens

* 1. Does this repository include data, specimens or both? (check all that apply)

☐ Data
☐ Specimens

'Repository Only' submissions

☐ The number and types of documents required will depend on your repository, however, you may be asked to include:

- Repository specific Protocol
- Either a Waiver of C/A or a C/A form
- Submittal/usage agreement templates

All three components of a repository (collection, stewardship & release) will need to be defined clearly in your repository specific protocol and uploaded with this submission. Using the appropriate Repository Protocol Template, ensure description of the following:

- Purpose of the repository
- Process for sharing data or specimens
- Description of the types of data or specimens included & how they will be collected
- Description of storage & measures to protect privacy & confidentiality
- Description of who will have access to data or specimens, including who will be Guardian for the repository
- Description of consent & authorization process or if collection will be under a Waiver of Consent

'Repository Only' submissions

☐ Note: If you are only prompted to complete the 'Repository Determination' page, it's not likely that you will need to upload any additional materials before submitting for review, such as usage agreements or a consent form.

☐ The analyst will contact you if further information is needed.

Achieving Compliance

□ There are three main routes to achieving compliance with the Repository Policy within eIRB:

◘ Create a 'Repository Only' submission

☑ *Create a 'New Study' submission that includes a repository component*

◘ Complete additional policy requirements within an existing submission, either through Modification or Continuing Review

As part of a 'New Study' submission

- There are three existing questions within a 'New Study' IRQ that will prompt the additional 'Defining the Repository' page.

  - Q. 2.2.11 (Study Type page) asks if the study
    - *"Includes a Research Repository"*

  - Q. 2.7.6 (Project Questionnaire page) asks if research data will be
    - *"Created with the intent to store in a data repository (e.g. research database) for future research or analysis"*

  - Q. 6.2.4 (Biological Specimen & Collection page) asks if biological samples will be
    - *"Collected for storage in a tissue bank or repository including created with the intent to store for future research or analysis"*

As part of a 'New Study' submission
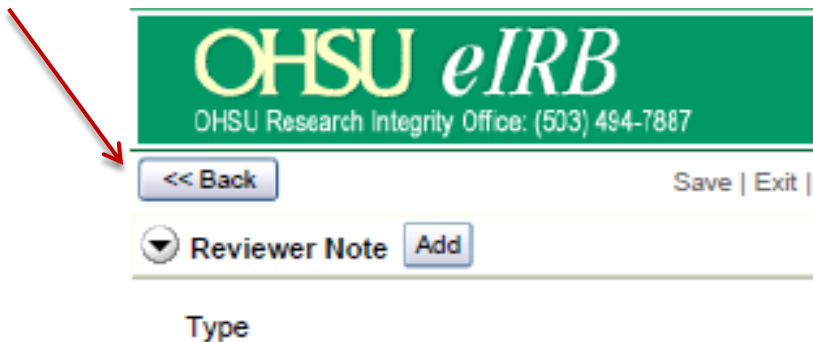
- If you feel the system gives you the 'Defining the Repository' page in error, you can evaluate your answers to those three questions by choosing to go back to previous pages.

As part of a 'New Study' submission

Defining the Repository

Repository activities involve 3 components:

1. Defining the collection of data or specimens
2. Establishing the repository maintenance & stewardship
3. Managing the release of data or specimens for research

First Component - Defining the collection of data or specimens

* 1. Does this repository include data, specimens or both? (check all that apply)

- [ ] Data
- [ ] Specimens

□ Otherwise, complete the new 'Defining the Repository' page to include a repository with your study.

As part of a 'New Study' submission

Tip: If you are creating a repository in conjunction with a study, consider creating a separate Repository Protocol to specifically define the details.

- This will make it easier when the study is over and you wish to continue the repository separately.
- Consult our repository website for a protocol template or a protocol checklist to guide you on what is required in your repository specific protocol.

Achieving Compliance

□ There are three main routes to achieving compliance with the Repository Policy within eIRB:

◘ Create a 'Repository Only' submission

◘ Create a 'New Study' submission that includes a repository component

☑ *Complete additional policy requirements within an existing submission, either through Modification or Continuing Review*

Within an existing submission

- Existing studies can be modified to include a new repository component. This can be accomplished via Modification or Continuing Review.

- If you already have an approved repository component with your existing study, you may need to complete additional requirements in order to be compliant with the Repository Policy. This also can be accomplished via Modification or Continuing Review.

Within an existing submission

☐ Modifications now have the capability to establish a repository for the first time, or come into compliance with the new policy by adding additional repository information.

Only answer this question if repository activities apply to your study. Otherwise, leave blank.

3.11. Repository Activities: ☐

○ Requesting to establish a Repository for the first time.

○ Already approved to store for future use and are submitting new information at this time. Indicate when approval of storage for future uses was first approved by the IRB:
Clear

○ Approved prior to the Repository Policy Launch (June 1, 2010)

○ After the Repository Policy Launch (June 1, 2010)
Clear

Within an existing submission

☐ Continuing Reviews now have the capability of adding or updating repository information.

18. OHSU has launched a Repository Policy defining future unspecified uses of data/specimens. Indicate future plans for data/specimens from this protocol:

○ No intent to store for future unspecified uses

○ I would like to store for future unspecified uses and request to establish a Repository for the first time

○ Data/specimens are already approved for future unspecified uses. If so, indicate status:

Clear

○ Approved prior to the Repository Policy Launch (June 1, 2010). Note: Revisions to your submission may be required in order to satisfy new policy requirements.

○ Approved after the Repository Policy Launch (June 1, 2010).

Clear

Dates will change to match eIRB go-live date

Within an existing submission

☐ Note: You will be asked to answer this question at your next Continuing Review.

18. OHSU has launched a Repository Policy defining future unspecified uses of data/specimens. Indicate future plans for data/specimens from this protocol:

◯ No intent to store for future unspecified uses

◯ I would like to store for future unspecified uses and request to establish a Repository for the first time

◯ Data/specimens are already approved for future unspecified uses. If so, indicate status:

Clear

◯ Approved prior to the Repository Policy Launch (June 1, 2010).
Note: Revisions to your submission may be required in order to satisfy new policy requirements.

◯ Approved after the Repository Policy Launch (June 1, 2010).

Clear

Your answer to this question can be revised at a later time via modification, or, you may answer differently on subsequent Continuing Reviews.

Within an existing submission

- Once the eIRB changes go live, a modification can be submitted at any time to bring your submission into compliance with the new policy.

- We may be contacting you if your current submission indicates that a repository is included with your submission.

- Otherwise, you will be asked to clarify and/or include any additional repository information at your next Continuing Review.

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Deciding what route to take...

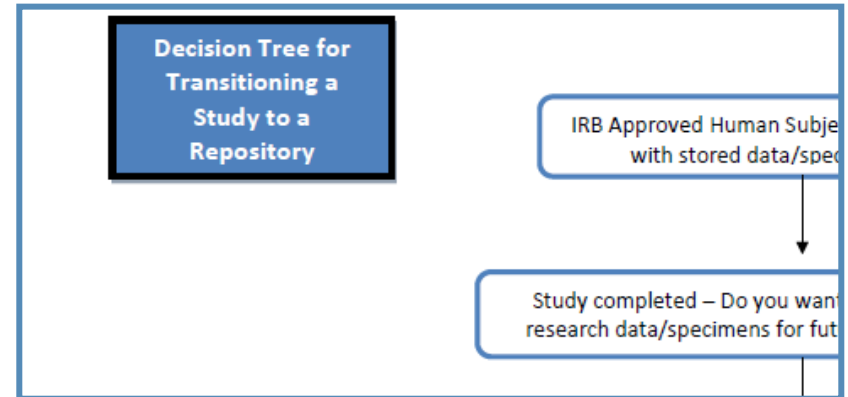□ When you are confident that you have or will have a repository, use:

□ **Repository Decision Table**

■ Follow the table to determine suggested steps for either existing repositories or submitting a repository for the first time

Repository Decision Table

Is the Repository existing or new?	Is this a repository only or is it part of a research study?	Do you have IRB approval?	Status
	Repository only	No	No intent to continue stor...
			Intend to continue storag...
		Yes	No intent to continue stor...
			Intend to continue storag...
Existing			

Deciding what route to take…

- For research studies that are completed but not yet terminated that either include a repository or you wish to establish a repository, use:

    - **Decision Tree for Transitioning a Study to a Repository**

- Note: Your decision centers on how immediate the future uses may be and your level of comfort with maintaining a study via the CRs or transitioning to a separate 'Repository Only' submission.

Deciding what route to take...

When you are <u>not</u> confident that you have a repository that requires oversight, we suggest using the:

- **'Repository Only' path**
  - This path has been designed to serve a 'request for determination' function.

While both the 'Request a Determination' & 'Repository Only' paths can be used, we suggest using the repository path as the questions are more clearly stated for future uses.

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Information & Templates

- Website contains additional information & templates
  - Protocol template & Protocol Checklist
  - Consent & Authorization template
  - Usage/Submittal Agreements
  - Decision Tree/Table for determining next steps
  - Policy
  - Background & Rationale
  - & more…

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☑ *Summarize key points*

Conclusion

- Key steps to comply with the Repository Policy:
  - Determine if your project qualifies as a repository
  - Evaluate routes to achieving compliance
  - Use tools to determine next steps
  - Refer to website for additional information and templates
  - Complete submission requirements to achieve approval
- Final thoughts
  - Our templates are suggested formats only, and are not required. You may draft your own versions of the required materials
  - Our analyst team will be available today after the session and will be available for 1:1 or department trainings as requested
  - We may be contacting you if your current submission indicates that a repository has already been described

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~~

- July 23 - eIRB Repository Submissions

- July 30 - eIRB Repository Submissions

- August 6 - eIRB Repository Submissions

- TBD Repositories FAQs

Questions?

Effective Date 6/1/2010

Year-long compliance initiative ends ~~5/31/2011~~

UPDATE: End date will be extended to coincide with one year after eIRB upgrades go live.

- Repository Information Page
  http://www.ohsu.edu/xd/research/about/integrity/irb/repository-policy.cfm

- IRB Main Webpage
  http://www.ohsu.edu/xd/research/about/integrity/irb/index.cfm

- More details & updates are in development – Keep checking back.