IRB RESEARCH REPOSITORY COMPLIANCE PROGRAM: **REMINDERS AND FAQs**

Compliance Deadline: August 31, 2011

Andrea Johnson, JD
Regulatory Specialist, ORIO

Agenda

- Review the definition of a repository
- Review the three main routes to achieving compliance with the Repository Policy and discuss FAQs
- Discuss management of repositories and FAQs
- Discuss FAQs regarding consent/authorization
- Summarize key points and review resources for more information

Agenda

- ✓ ***Review the definition of a repository***
- ❑ Review the three main routes to achieving compliance with the Repository Policy and discuss FAQs
- ❑ Discuss management of repositories and FAQs
- ❑ Discuss FAQs regarding consent/authorization
- ❑ Summarize key points and review resources for more information

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.
- See the Repository Policy online for more details.

FAQs - Is this a repository?

Scenario	Repository?
My study has been determined by the IRB to be "Not Human Subjects Research" (NHS) but I'm keeping the data or samples and might use them for future research.	No.
My study has been determined by the IRB to be "Exempt" and I want to keep the data or samples for future research.	Yes.
My study includes a plan to "batch" samples so that assays may be run more efficiently.	No.
Our department has a "shadow database" we've used for quality improvement/quality assurance (QI/QA) purposes.	Maybe. If it also might be used for research, then yes.
Our department keeps a list of contact information for people who want to be notified of future study participation opportunities.	Yes.

Agenda

- ✓ Review the definition of a repository
- ✓ ***Review the three main routes to achieving compliance with the Repository Policy and discuss FAQs***
- ❑ Discuss management of repositories and FAQs
- ❑ Discuss FAQs regarding consent/authorization
- ❑ Summarize key points and review resources for more information

Achieving Compliance

- **DEADLINE is August 31, 2011!**
- 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

Repository Only Submissions

- Separate pathway in IRQ
- Limited continuing review requirements
- **Required documents:**
  - Repository Protocol (no separate study protocol)
  - Submittal and Usage Agreements
  - Consent and Authorization Form (if prospectively collecting data/samples solely for the repository, not as part of a study)
  - Waiver of Authorization Form (if no authorization was given to store previously collected data/specimens)
  - Lay Summary
  - PPQ

FAQ – When to use Repository Only

Example Situations:
I have a collection of identifiable or coded data or samples stored in my lab that are not associated with an IRB-approved study.
I want to collect data or samples specifically for the purpose of storing them for future research.
I want to combine leftover data or samples from several of my studies into a single repository.
I want to terminate a study but keep the data or samples for possible future research.
I am not sure if my collection of data or samples is a repository and I want the IRB to make a determination.

Including a Repository in a New Study

- There are three existing questions within a 'New Study' IRQ that will prompt the additional repository questions.
  - 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"*

FAQs – Including a Repository in a New Study

- Do I need a separate repository protocol?
  - It is **highly recommended,** but not always required. If you want to keep the data/samples from the study, but you're not sure what you're going to do with them yet, you may put the collection and maintenance information in your study protocol. *See "Study Specific Repositories" in the policy for more info.*
  - You are **required** to have a separate repository protocol in place before the data/samples can be used for activities outside the scope of the study protocol.
  - You do not need a repository protocol for repositories located outside OHSU or for submitting the data/samples to a separate IRB-approved repository at OHSU.

FAQs – Including a Repository in a New Study

- What consent and authorization forms do I need for a study that includes a repository?
  - Key question is whether participating in the repository is **optional**. If not, just one consent/authorization.
  - Several possibilities for optional repositories. Recommended:
    - Tiered consent form (list options) with separate HIPAA forms
    - One combined consent/authorization for main study and one combined consent/authorization for repository

FAQs – Including a Repository in a New Study

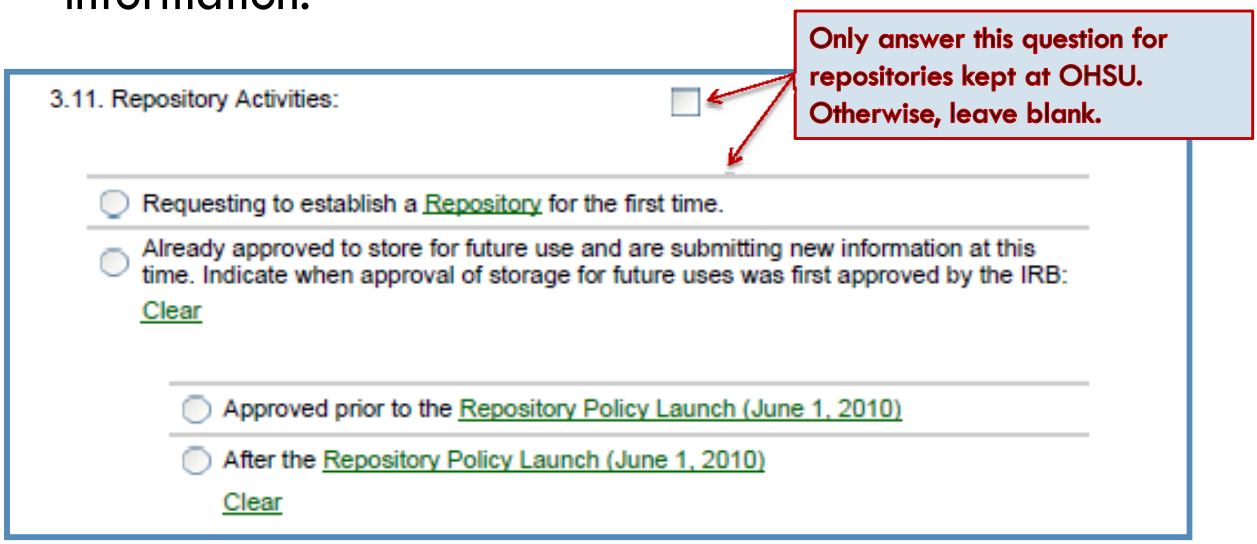
- Do I need to submit a Usage Agreement and Submittal Agreement for the repository at the time of my new study submission?
  - You do not need a submittal agreement if the repository will only collect data/samples from that study.
  - You do not need a usage agreement until you are ready to release the data/samples to other investigators.
  - You do not need a usage agreement to use data/samples from your own repository (*but you do need separate IRB approval to do a new study with these data/samples*).

Repository 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.

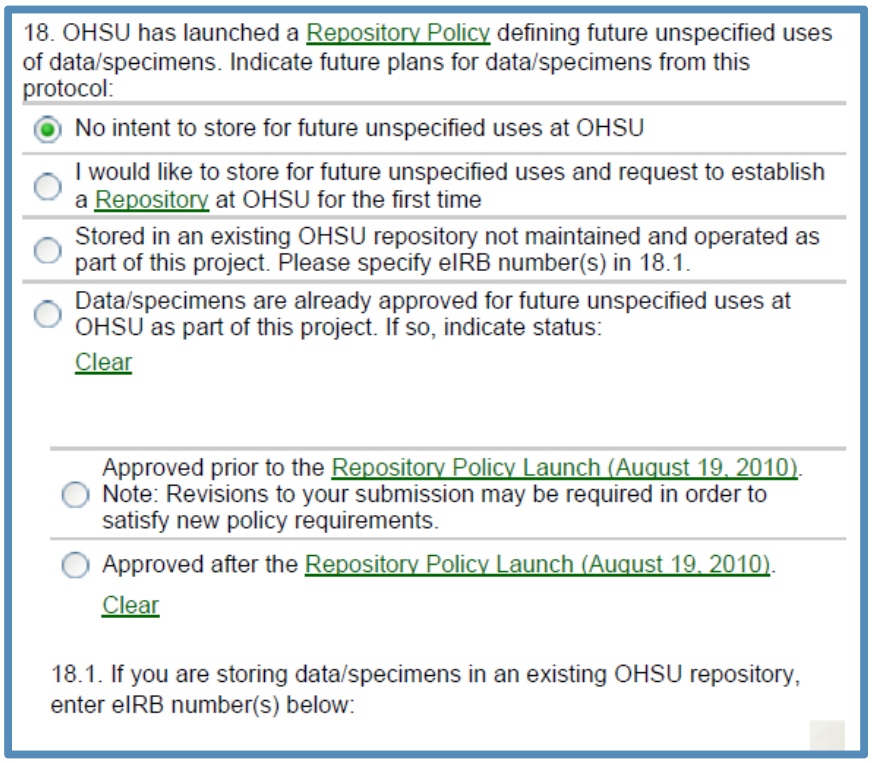
Repository Within an Existing Submission

- 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.



Repository Within an Existing Submission

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



Repository Within an Existing Submission

- The IRB Analyst Team is in the process of sending reminders about repository compliance. Expect to hear from us via the eIRB if you:
  - Have not had a continuing review since the policy launch in August 2010, or
  - Indicated in your last continuing review that you have "no intent to store at OHSU," but your IRQ indicates "yes" to one of the three repository trigger questions.

FAQs – within an existing submission

- When do I need a separate repository protocol?
  - By your next continuing review or August 31, 2011, whichever comes first.
  - Exception: Study Specific Repositories – only saving data/specimens from a single ongoing, approved study; no future uses identified yet. Storage and maintenance information must still be in study protocol. Separate repository protocol is highly recommended.
  - **Your study may lapse if a repository protocol is required and you do not submit one at your next continuing review.** Please allow yourself time to complete the repository requirements before your CRQ is due.

FAQs – within an existing submission

- What if my study is sending data/samples to a repository outside of OHSU?
  - Your only requirement is to complete a brief form ("Non-OHSU Repository Questions"), available on the repository website and forms website, and submit it with your CRQ.
- What if my study is submitting data/samples to an already approved repository at OHSU?
  - All you need to do is indicate this in the CRQ form, Q. 18. Enter the IRB number of the approved repository in the blank.
- **Note:** In both of these situations, the consent/authorization forms must indicate that data/specimens will be stored in a repository. Please check this when you submit your CRQ.

FAQs – Setting Up a Repository

- Is the PI of a repository always the "guardian?"
  - Not always. The PI may delegate someone else as the guardian, such as a co-investigator or study staff. However, the PI is ultimately responsible for keeping the repository in compliance with OHSU policy.
  - ***Don't forget to designate a guardian!!***
- Are there special requirements for repositories that hold samples that might be used for genetic research?
  - Yes. You must include in your repository protocol a plan for compliance with the Oregon Genetics Law and GINA.
  - You must comply with these requirements if there is any possibility that the samples will be used for genetic research in the future, even if no definite plan exists.

FAQs – Setting Up a Repository

- Do you have a repository protocol template?
  - We do not have one finalized yet, but we do have a checklist with all of the required elements available on the repository website.
- Do I have to use the templates for all of my repository documents?
  - The templates are a starting point, but you do not have to follow them exactly (other than using specifically required language, such as liability language or HIPAA authorization language). Your documents must, however, contain all required elements.
- Who should be listed on a repository as study staff?
  - Anyone who is involved in the management of the data and/or specimens. Researchers or staff from other research teams who submit materials to the repository or take information from the repository for separate research projects should **not** be listed as repository staff.

FAQs – Setting Up a Repository

- Are the fees different for submissions involving a repository?
  - No, they are the same, and only apply to industry-sponsored studies.
- Do I need to specify where the data or specimens in my repository are coming from?
  - Yes, you will be asked to list all sources on the Defining the OHSU Repository page in the eIRB.
- Our department compiles data and/or specimens from several studies for future research. How many different repositories do we need?
  - How you organize different repositories is up to you, but keep in mind that you must be able to manage each repository that you create.

Agenda

- ✓ Review the definition of a repository
- ✓ Review the three main routes to achieving compliance with the Repository Policy and discuss FAQs
- ✓ ***Discuss management of repositories and FAQs***
- ❑ Discuss FAQs regarding consent/authorization
- ❑ Summarize key points and review resources for more information

Managing a Repository

- Repository activities involve three components:
  - Collection of materials
  - Storage and data management
  - Use by recipient investigators
- The procedures and requirements involved in managing the repository must be described in the repository protocol.
- Submittals and releases carried out in accordance with the protocol must be tracked and submitted to the IRB at continuing review.
- The consent/authorization in place when the materials were collected will influence how the materials may be used in future research.

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.

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.

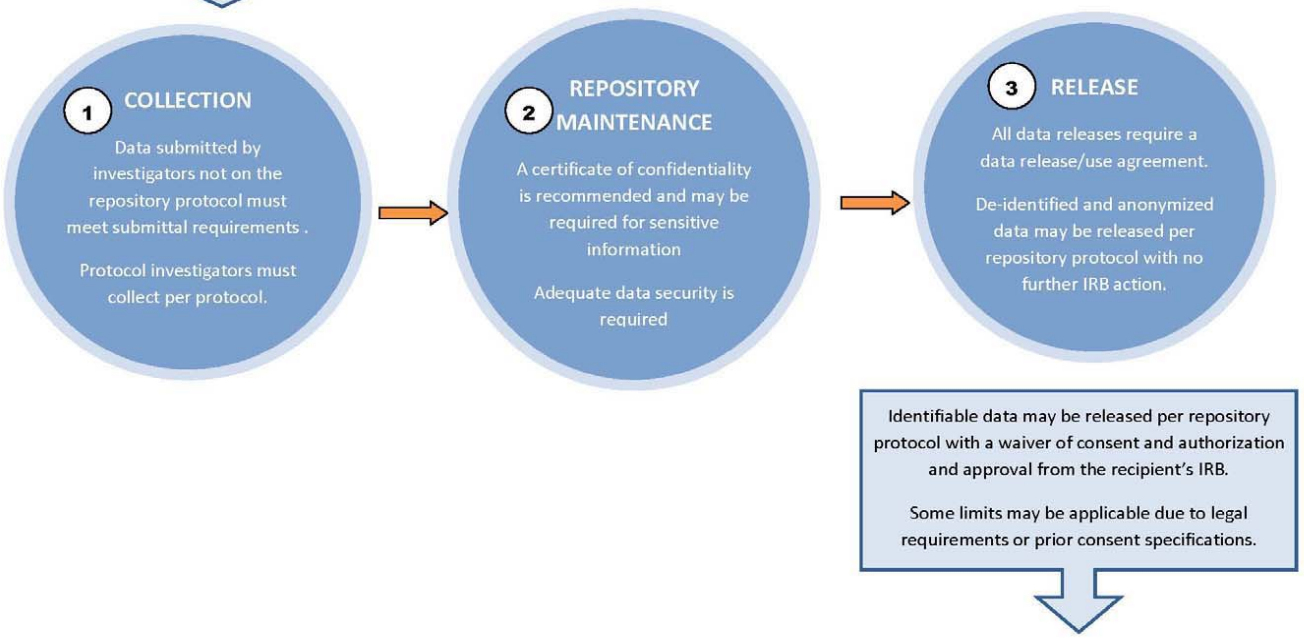
Identifiable data may be released or used by the Protocol Investigators under a waiver of consent and authorization with approval from the recipient's IRB (which may be OHSU) and from the OHSU IRB.

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

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.



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.

FAQs – Managing a Repository

- Someone wants to use my data and/or samples! Do I need to submit a modification?
  - So long as the release of data or specimens occurs within the scope of your repository protocol, a modification is not needed. Just keep track of these releases on a spreadsheet and submit them to the IRB at continuing review.
  - In general, there are **two situations when a modification is required:**
    - A release of data/specimens exceeds the scope of the repository protocol
    - A release of individually identifiable data/specimens that were not obtained with full informed consent to the proposed research use

FAQs – Managing a Repository

- Is it beneficial to de-identify the data/samples in my repository?
  - Not necessarily. While there are fewer IRB review requirements for repositories with de-identified information, maintaining identifiers (including coded identifiers) can expand the potential research uses of the information.
- Can data/samples be considered "de-identified" if they are stored with coded identifiers and subsequently used for a research project by one of the investigators listed on the repository?
  - **No.** So long as the investigator using the data/samples has access to the code, they will not be considered de-identified.

Agenda

- ✓ Review the definition of a repository
- ✓ Review the three main routes to achieving compliance with the Repository Policy and discuss FAQs
- ✓ Discuss management of repositories and FAQs
- ✓ ***Discuss FAQs regarding consent/authorization***
- ❑ Summarize key points and review resources for more information

FAQs – Consent and Authorization

- Does it matter whether you set up a repository using a waiver of consent and/or authorization as opposed to obtaining informed consent from all subjects up front?
  - Yes. The permissible future uses of data and specimens are limited by the scope of the subjects' consent at the time the data/specimens were collected.
  - Collecting data/specimens under fully informed consent, including consent to future research using the stored data/specimens, provides more flexibility in how the information may be used in the future.
  - Data and specimens collected under a waiver may not be used as broadly; for instance, you may be required to de-identify them for any future research, which could limit the value/extent of that research.

FAQs – Consent and Authorization

- Can I create a new repository that collects data/samples from finished studies where subjects did NOT consent to or authorize banking?
  - Generally, yes, but you will need to request waivers of consent and authorization when you submit the repository. There also may be restrictions on the future use of these data and specimens. For instance, you would probably be required to de-identify the data and specimens before releasing them to other investigators and/or using them in future research.
- Does the "indefinitely" in the boilerplate HIPAA language cover the requirement that people give HIPAA authorization for banking?
  - No. The "indefinitely" means that subjects authorize the use of their information only for the purposes indicated, however long it takes to carry out those purposes.

Agenda

- ✓ Review the definition of a repository
- ✓ Review the three main routes to achieving compliance with the Repository Policy and discuss FAQs
- ✓ Discuss management of repositories and FAQs
- ✓ Discuss FAQs regarding consent/authorization
- ✓ ***Summarize key points and review resources for more information***

Key steps to comply with the Repository Policy:

- Determine if your project qualifies as a repository
- Evaluate routes to achieving compliance
- Refer to website for additional information, templates, and tools to determine next steps
- Complete submission requirements to achieve approval by ***August 31, 2011***

Information & Templates

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

Questions?

Effective Date
6/1/2010

Year-long compliance initiative ends 8/31/2011

- 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.