IRB RESEARCH REPOSITORY COMPLIANCE PROGRAM:
Repository Protocols and FAQs

Compliance Deadline: August 31, 2011

Kathryn Schuff, MD, MCR   **Andrea Johnson, JD**

IRB Co-Chair   **Regulatory Specialist, ORIO**

Agenda

- ❑ What's a repository?
- ❑ How can I get IRB approval for my repository?
- ❑ Protocol requirements
- ❑ Your FAQs
- ❑ Tools and Resources

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What is considered a repository?

- The collection/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. (not one requiring IRB oversight…)
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 might also 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.

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How to get IRB approval for your repository

- Three routes to obtain IRB approval for your Repository:

  - New IRB project

    - Create a 'Repository Only' submission

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

  - Existing IRB project – add repository activities via:

    - Modification to existing study

    - Continuing Review of an existing study

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

Adding Repository Activities Within a Modification

- 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 for repositories kept at OHSU. Otherwise, leave blank.

3.11. Repository Activities: ☐

○ Requesting to establish a <u>Repository</u> 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:

<u>Clear</u>

○ Approved prior to the <u>Repository Policy Launch (June 1, 2010)</u>

○ After the <u>Repository Policy Launch (June 1, 2010)</u>

<u>Clear</u>

Adding Repository Activities at Continuing Review

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

Your analyst may be contacting you if you haven't done this already!

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 at OHSU
- ○ I would like to store for future unspecified uses and request to establish a Repository at OHSU for the first time
- ○ Stored in an existing OHSU repository not maintained and operated as part of this project. Please specify eIRB number(s) in 18.1.
- ○ Data/specimens are already approved for future unspecified uses at OHSU as part of this project. If so, indicate status:

Clear

- ○ Approved prior to the Repository Policy Launch (August 19, 2010). Note: Revisions to your submission may be required in order to satisfy new policy requirements.
- ○ Approved after the Repository Policy Launch (August 19, 2010).

Clear

18.1. If you are storing data/specimens in an existing OHSU repository, enter eIRB number(s) below:

Why is my analyst asking me about repository activities?

Three existing questions on the IRQ that will prompt your analyst to ask you about possible repository activities:

- 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*

Required Documents for Repository

□ New or modified:

  ◻ Repository Protocol

  ◻ Submittal and Usage Agreements

  ◻ Consent and Authorization Form

  ◻ Waiver of Authorization Form

  ◻ Lay Summary

  ◻ PPQ

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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 a 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.

- Regardless of whether you have a separate protocol, you will need to describe the repository activities.

Description of Repository Activities

1. Collection

- Describe data/ specimens
- Source
- Process for obtaining
- From other Investigators:
  - Submittal agreement
  - Check IRB approval
- Consent/Authorization or waiver
- Security during transfer

2. Repository Maintenance

- Security and confidentiality
  - Physical location, handling, storage conditions
  - Coding
  - Access to specimens/data
  - Security
  - Certificate of Confidentiality
- Repository Guardian
  - Who and What

3. Specimen/Data Release

- Process for release of specimens/data
  - Deidentified releases may occur without separate IRB approval
  - Identified releases require recipient and OHSU IRB approval
  - Repository Sharing Agreements
  - Security during release
- Tracking all releases
- Compliance with genetic privacy law (check opt out if not consented) any consent restrictions
- MTAs

Description of Repository Activities

Waived/Limited 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

2. Repository Maintenance
A certificate of confidentiality is recommended and may be required for sensitive information.
Adequate data security is required.

1. Collection
Data submitted by investigators not on the repository protocol must meet submittal requirements. Protocol investigators must collect per protocol.

3. Specimen/Data Release
All data releases require a data release/use agreement. **De-identified and anonymized** data may be release per repository protocol with no further IRB action.

Fully consented:
Data collected via research interactions of clinical care with specific consent obtained for storage for future research.
Research data collected with consent, but with limits on future uses.

Fully consented:
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.

Waived/Limited consent:
Identifiable data may be released or used by the Protocol Investigators under a **waiver of consent/authorization** from:
• **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.

FAQs – Repository Staff

- 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!!***

- 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 – Multi-study Repositories

- 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.

FAQs – IRB approval for Releases

- 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 – To Deidentify or not…

- 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.

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IRB RESEARCH REPOSITORY COMPLIANCE PROGRAM:
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Modifications – Submitting data/specimens to a separate repository

- ❑ **Q:** The MRQ doesn't give me the option to "store in an existing OHSU repository not maintained and operated as part of this project." How do I indicate this in a modification?

- ❑ **A:** You should indicate this in Q. 5 (a text box). However, only do this if you're making other changes with the modification. ***You don't need to submit a modification solely for this purpose.*** If you have not yet alerted us that you are storing data/samples from a study in a different repository, feel free to do so using the "Contact Researchers" function.

Waivers of Consent/Authorization

- **Q:** What kind of restrictions will be placed on studies that need to obtain waivers of consent/authorization in order to store data/specimens?

- **A:** Generally, data/specimens stored under a waiver of C/A may not be released for future research in identifiable form. They must be de-identified prior to release. This includes releasing to one of the contributing investigators.

  - **However,** the use/release of identifiable data/specimens may be considered on a case by case basis (submit a modification to the repository) if adequate justification is present.

  - Individually identifiable specimens may **NOT** be used for **genetic research** under a waiver of consent.

Waivers of Consent/Authorization

- **Q:** There is a Waiver of Authorization form, but no Waiver of Consent form. How do I request a Waiver of Informed Consent?

- **A:** Tell us somewhere in your submission (in a memo, in your repository protocol, in the project log when you submit, etc.) that you are requesting a waiver of informed consent. **Provide justification.** Specifically, we need to find that:
    - The research involves no more than minimal risk to subjects
    - The waiver will not adversely affect the rights and welfare of the subjects
    - The research could not practicably be carried out without the waiver
    - Where appropriate, subjects will be provided with pertinent follow-up information

Tips for combining data/specimens from several studies into a single repository

□ We need to know what kind of consent/ authorization was obtained in each source study.

□ If no consent/authorization to store for future research was obtained, there are *two options*:

    ■ Request a waiver of consent/authorization for that study

OR

    ■ Re-contact subjects and ask for consent/authorization to store for future research

Tips for combining data/specimens from several studies into a single repository

- If your repository includes data/specimens from several studies, it is very helpful to the IRB if you **submit a table or spreadsheet** that lists:
  - Each source study and its IRB # (if applicable)
  - The status of each source study (active, closed, terminated)
  - Whether the data/specimens are individually identifiable
  - The type of consent/authorization obtained in each source study (i.e. did subjects consent to and authorize storage for future research? Were there any limits, such as research only on a specific disease?)
  - For studies where C/A for storage were not obtained, whether you are requesting waivers of C/A or whether you will re-contact subjects

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*

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NEW Information & Templates

- Watch for the following updates on the Repository Website:
  - **Revised** Protocol Checklist
  - **Revised** Consent & Authorization template
  - Data Recipient Usage Agreement is now called **Repository Sharing Agreement**
  - Template **Tracking Spreadsheet** and Help Sheet for submissions and releases

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.