IRB RESEARCH REPOSITORY COMPLIANCE PROGRAM

FAQs: Designing and Managing Repositories

Compliance Deadline: August 31, 2011

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Agenda

❑ Review Repository Basics

    ❑ Do I have a repository that needs to comply?

    ❑ How do I comply with the policy?

❑ FAQs: Design and Management of Repositories

    ❑ Setting up manageable repositories

    ❑ Submissions and releases

    ❑ Consent and Authorization

❑ Resources for More Information

Agenda

- ✓ ***Review Repository Basics***
  - ✓ ***Do I have a repository that needs to comply?***
  - ✓ ***How do I comply with the policy?***
- ❑ FAQs: Design and Management of Repositories
  - ❑ Setting up manageable repositories
  - ❑ Submissions and releases
  - ❑ Consent and Authorization
- ❑ Resources for More Information

What is 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 or de-identify the materials when the specific research project that generates the materials ends.

- See the Repository Policy online for more details.

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.	Maybe. If the data/samples are identifiable, then yes.
My study includes a plan to "batch" samples so that assays may be run more efficiently.	No.

Is this a repository? (continued)

Scenario	Repository?
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.
My study is done and my paper has been published. I don't have any intention of doing future research with the original data, but I want to keep it in case someone questions my findings.	No.

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

Why is an analyst asking me about repository activities?

If you **selected any of the three options below in your IRQ,** you will receive a notice through the eIRB asking about 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"*

Repository Documents – What is required?

- **Repository Protocol** (or, for study-specific repositories only, a description of repository activities in study protocol)

- **Submittal Agreement** if your repository will receive data/specimens from multiple sources

- **Repository Sharing Agreement** if your repository will release data/specimens to other investigators

- **Consent and Authorization Form** if prospectively collecting data/samples for the repository

- **Waiver of Authorization Form** if no authorization was given to store previously collected data/specimens

- **Tracking Spreadsheet/Table** if pooling data/specimens from multiple sources (this should note original C/A status and any limits/restrictions on future uses)

- **PPQ**

- ~~Lay Summary~~ (No longer required for Repository Only submissions!)

Still have questions about the basics?

- Lots of resources on the repository website
  - NEW compilation of FAQs!
  - PowerPoint presentations from June and July Brown Bag Sessions
    - June: Procedures for compliance and FAQs
    - July: Writing repository protocols and more FAQs
- Attend a Repository Drop-In Session to work directly with an IRB Analyst
  - Fridays: August 12, 19, & 26 (11:30-1:30 – BRB 381)
  - Last Session: Tuesday, August 30 (9:30-Noon – BRB 381)

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  - ✓ How do I comply with the policy?
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  - ✓ ***Setting up manageable repositories***
  - ✓ ***Submissions and releases***
  - ✓ ***Consent and Authorization***
- ❑ Resources for More Information

Setting Up Manageable Repositories

Can I combine several studies into a single repository?

- Yes. Complete a Repository Only eIRB submission.
- Pros:
  - Reduces/simplifies continuing review requirements
  - Compiles and organizes data/specimens for better access by investigators and broader future research opportunities
- Cons:
  - Can be difficult to organize and manage if there are many different types of data/specimens
  - Requires careful tracking of any limits/restrictions imposed by prior consent and authorization mechanisms
- It may be easier to set up a few different repositories with similar types of data/specimens and consent/authorization.

Setting Up Manageable Repositories

Does the PI have to be the guardian?

- No, but the PI is ultimately responsible for compliance with policy and regulatory requirements (just like in a research study).

- The guardian must be someone who is willing and able to manage and track all submissions, maintenance activities, and releases. *Depending on the repository, this can be a lot of work!*

Who should be listed as a Co-I or Staff on the repository?

- Anyone with access to a code for identifiers

- Anyone involved in monitoring and/or tracking submittal/release

Setting Up Manageable Repositories

What special requirements do I need to consider if my repository has genetic information or might be used for **genetic research** in the future?

- ☐ Individually identifiable genetic research requires informed consent.
  - ☐ Original consent form must have granted permission for future genetic research.
  - ☐ IRB cannot grant a waiver for use of identifiable genetic information/specimens.
- ☐ Coded or anonymous genetic research is permitted with a waiver of informed consent if genetic opt-out status can be verified.
- ☐ See the IRB's Genetic Research Website for more information.

Setting Up Manageable Repositories

How much does the IRB need to know about the sources of data/specimens in my repository?

☐ The IRQ "Defining the Repository" page will ask for detailed information about your sources (eIRB numbers, etc.).

☐ The Repository Protocol should describe the sources more generally.

☐ If you have multiple sources, submit a spreadsheet or table at initial review that lists the consent/authorization status for each source.

Setting Up Manageable Repositories

If your repository includes data/specimens from several studies, it is very helpful to the IRB if you **submit a table or spreadsheet at initial review** 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

Setting Up Manageable Repositories

Do I need to submit a modification for each of the **source studies** going into my repository?

- Generally, no. The IRQ will be updated by an analyst. You may update your source study protocols if you choose, but it is not required.
- A modification to a source study is needed only if:
  - The consent/authorization forms do not discuss repository activities and need to be modified, and
  - You are not requesting a waiver to store – you plan to re-consent/authorize instead.

Do I need a modification to the **repository** when I add a new source?

- If the new source is consistent with the description of sources in your protocol, no modification is needed.
- Keep track of added sources (submittals) on your tracking spreadsheet. You will submit the spreadsheet at continuing review. You will also enter new sources in the CRQ, which will automatically update your IRQ.

Summary of Repository Activities

1. Collection

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

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 duties?

3. Specimen/Data Release

- Process for release of specimens/data
  - Check IRB approval of proposed research
  - Consent/Authorization or waiver
  - Repository Sharing Agreements
- Tracking all releases
- Compliance with genetic privacy law (check opt out if not consented) and any consent restrictions
- Security during release (MTA?)

Collection

What criteria and procedures are required for **submissions** to a repository from an investigator outside the repository?

- Verification that the source research is/was IRB approved (when applicable)

- Determination of whether consent/authorization for repository activities was obtained (or whether a waiver is needed)

- Verification and documentation of any limits or restrictions on future use

- The above items should be covered in a **signed Submittal Agreement.** If documentation of prior IRB approval and/or consent/authorization is available, it should be kept on file.

- A Material Transfer Agreement is needed if specimens are transferred from outside OHSU.

Collection

For a departmental repository, do all faculty in the department need to sign a submittal agreement every time they contribute to the repository?

- Not necessarily. You may modify the submittal agreement so that each person only signs one, and it covers all subsequent submissions.

- Alternatively, you may write a procedure into the repository protocol that includes verification of all elements that would otherwise be contained in the submittal agreement (IRB approval, consent/authorization, etc.)

- The same procedure may be used with or in place of Repository Sharing Agreements for releases to investigators within the department.

Collection

What information must be included in my tracking spreadsheet (for continuing review) with regard to submissions?

- List each source of data/specimens
  - IRB #s or study titles for research sources
  - Description of data/specimens if collecting directly from clinical records or pathology
  - Description of subject population for prospective collection
- Verify consent and authorization status for each source
  - Collected for research under IRB-approved C/A: Future research consent provided? Genetics? **Limitations on future use?** (waiver needed if no consent to repository activities)
  - Collected for research under a waiver of C/A (waiver needed for inclusion in repository)
  - Collected from non-research sources (waiver needed for inclusion in repository)
- Verify IRB approval for data/specimens from research sources

Maintenance

What do I do if someone wants to query my repository to see if a potential study is feasible (Prep to Research activities)?

- Anyone can use de-identified data for prep to research purposes without any IRB action.

- Investigators can query their own repositories for prep to research purposes with no IRB action. The procedures for doing this should be described in the repository protocol.

- Other investigators at OHSU can query a repository with identifiable data if they submit a prep to research form to the IRB via a request for determination.

- Non-OHSU investigators must have a waiver of authorization, via a modification to the repository, to access identifiable data.

- Prep to research activities should still be recorded on the tracking spreadsheet.

Release

Do I need to submit a modification every time data/specimens from my repository are used or released?

- Not necessarily. Your repository protocol must specify the criteria and procedures for use and/or release. If the use or release is consistent with your repository protocol, no modification is needed.

- You must keep track of all uses/releases on a spreadsheet and submit it at continuing review.

- *We have clarified the requirements for releasing identifiable information obtained without consent/authorization for repository activities. **A modification is not always required** for these releases if they are IRB approved and otherwise consistent with the approved repository protocol.*

Release

What criteria and procedures are required for **uses and releases** of data/specimens from my repository?

☐ Verification that the proposed research is IRB-approved (when applicable)

☐ IRB-approved waiver of authorization and waiver of consent, if needed, or plan to re-contact subjects for consent/authorization

☐ Verification that the proposed research is not contrary to any previously imposed limitations or restrictions (including genetic opt-out verification where applicable)

☐ The above items should be covered in a **signed Repository Sharing Agreement.** If documentation of IRB approval is available, it should be kept on file.

☐ A Material Transfer Agreement is needed if specimens are transferred outside OHSU.

Release

What types of releases and/or future research activities will NOT be permitted with the data/specimens from my repository?

- Your protocol cannot permit the release of identifiable data/specimens for a research project that does not have IRB approval. You must get separate approval from the OHSU IRB to do this, via a modification to your repository.

- Your protocol cannot permit the release or use of data/specimens for purposes contrary to any previously imposed limitations.

- You cannot release identifiable specimens for genetic research if informed consent for genetic research has not been obtained.

- If your repository contains sensitive information or information from vulnerable populations, the IRB may require other restrictions.

Release

What information must be included in my tracking spreadsheet (for continuing review) with regard to uses/releases?

- List each research project for which data/specimens were released
  - IRB #s or study titles
  - Description of data/specimens released (identifiable?)
- Verify mechanism for consent and authorization if identifiable
  - New signed authorization or waiver of authorization
  - New consent or waiver of consent
  - Verify that the use/release is not contrary to previous consent/authorization
- Verify IRB approval for proposed human subjects research

Consent and Authorization

- **Four types of permission** needed for repository activities:
  - Consent to store data/specimens in a repository
  - Authorization to store PHI in a repository
  - Consent for future unspecified research OR Consent for a specific research activity involving stored data/specimens
  - Authorization for use/disclosure of PHI for a specific research activity involving stored data/specimens
- **A waiver can be requested for any of the above.** Use this list as a guide to determine what waivers you need.
- *Authorization for use/disclosure of PHI for unspecified future research is not permitted.*
  - Each subsequent use of PHI for a new research study requires a new authorization or a waiver.
  - You will almost always need a waiver of authorization from the recipient's IRB before releasing data/specimens for research.

Consent and Authorization

What if I want to store data/samples from completed studies in which subjects did not consent to or authorize repository activities?

- If practicable, you can try to re-contact the subjects
- If not practicable, request waivers of consent and authorization:
  - Submit a waiver of authorization form with your repository. It should describe all data/specimens for which you need a waiver. It can also describe future collection of data/specimens.
  - There is no form for waiver of consent. Describe in your repository protocol or in a separate memo why the waiver is justified. Verify that inclusion in the repository is not contrary to previously imposed limits.

Consent and Authorization

Example description of data/specimens included in a waiver of authorization:

SECTION II: Description of <u>health information</u> to be collected (e.g., "blood pressure," "x-rays").	1) All data from retrospective chart review studies conducted by the OHSU Department of Neurology from 1990 forward; and 2) Specimens collected by investigators in the OHSU Department of Neurology during the course of IRB-approved research studies from 1990 forward, for which authorization to store specimens in a repository was not previously obtained.

Consent and Authorization

I am combining data/specimens from several studies into a single repository. Where do my consents, authorizations, and waivers go? In the repository submission or the source study submissions?

- You should only need one waiver of authorization form and one waiver of consent request. These should be part of your repository submission.

- If you are using the same repository consent/authorization for all source studies, it goes in your repository submission. No changes are needed to the source studies.

- If you are modifying the consent/authorization process for the source studies to get permission for repository activities, you will need modifications to each of those studies. These modified forms will not need to be part of the repository submission.

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Repository Website

- Repository Protocol Checklist

- Template Submittal and Sharing Agreements

- Template Repository Consent/Authorization

- Template Tracking Spreadsheet and Help Sheet

- Educational Materials, Policy, Guidance, and More!

IRB Analyst Drop-In Sessions

- Stop by **BRB 381** for individualized assistance from an Analyst. Bring your specific questions and/or materials to review. Laptops are available.
- Dates and Times:
  - Fridays in August – 12, 19, 26 – 11:30 to 1:30
  - Tuesday, August 30 – 9:30 to Noon

Links

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

- **Remember, submit all required materials by August 31, 2011!!**