Repository Refresher

I got my repository approved… now what??

Andrea Johnson, JD, CIP

Regulatory Specialist

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.

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What review category applies?

- Repository activities are subject to the same review categories as any other research activity (NHS, Exempt, Expedited, Full Board).
- Review category generally depends on:
  - Whether data/specimens are individually identifiable
  - Prospective collection procedures

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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 is NOT REQUIRED for Repository Only submissions!*

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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. Use/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?)

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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.

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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.

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Use/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.

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Use/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.

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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…..**YET!** **New regulations will change this. Watch for updates.**

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Repository Collaborations

Repository Activities	OHSU IRB Review Requirements
Repository is at OHSU • Other sites may contribute • Other sites may use	• Repository (incl. collection/release procedures) • Collection activities at OHSU • Subsequent uses at OHSU
Repository is elsewhere, OHSU is contributing to it	• Collection activities at OHSU • HIPAA requirements for release to repository
Repository is elsewhere, OHSU is using it	• Each new use at OHSU • Verify use is consistent with prior restrictions

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Continuing Review - Tracking

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

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Continuing Review - Tracking

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

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Continuing Review - Tracking

- Is a tracking sheet always required?
  - Yes, except when:
    - Repository is exempt
    - No collections/uses/releases have taken place yet.
- Do I have to use the template tracking sheets on the Forms page?
  - Nope. Many repositories will be able to use much simpler tracking sheets. Feel free to make your own.
- Do I have to track each individual specimen or person in my repository?
  - Not necessarily, unless that is helpful for you or otherwise required by your protocol.

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Do I need a mod for that??

- Using stored data/specimens for a new study
  - Only if not described in approved protocol.
- Adding data/specimens from a new source
  - Only if not described in approved protocol.
- Using stored data/specimens from a new repository for an approved research study
  - Only if not described in approved protocol.
- Adding repository staff or changing guardian
  - Yep.
- Modifying consent/authorization forms or process
  - Yes.

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Mark your calendars!

Guidance on Data Safety and Monitoring Plans

Thursday March 28th

11:30am – 12:30am

UHS 8B60

Visit our website for more information:
www.ohsu.edu/researchintegrity

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