IRB Process Guidance:
Repository and Secondary Research Review Routing

October 28, 2026

1. Definitions & Framework

Data and tissue repositories store information or biological specimens for unspecified future research. Repositories themselves do not answer a specific research question; rather, repository operations encompass three distinct components: collection, storage and management, and distribution of data/specimens.

Repositories can be:

- **Research Repositories:** Entities established with the primary intent of facilitating future research. Protocols must detail acquisition mechanisms, storage security, and distribution processes for secondary investigators.
- **Non-Research Entities:** Systems established primarily for clinical care, administrative operations, or diagnostic purposes (e.g., Electronic Medical Records [EMRs] and Clinical Diagnostic Archives). These entities are not governed by repository protocol requirements until materials are extracted for research purposes.

Although repositories are not research studies, federal regulations expect IRB oversight over repositories as each component of a research repository is governed by applicable federal human subject protection regulations, privacy laws (e.g., HIPAA), and institutional policies.

The approach below extrapolates the applicable regulatory frameworks to the review and oversight of repositories and secondary research using repository data/specimens, in the context where broad consent exemptions do not apply.

Institutional historic context and reasons for Full Board (FB) review (also called Convened review):

- Repositories and studies involving use of repository data and/or specimens were sent to FB review because they don't fit any regulatory expedited category.
- Secondary research was sent to FB to evaluate terms of the consent and data use limitations in relation to the original and newly proposed study.

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2. Projects that Establish a Research Repository -- Review Pathways

- **General Regulatory Rule:** If the establishment of a repository involves **greater-than-minimal risk** procedures, FB review is required.

- For minimal-risk repository creation, review paths depend on the specific collection mechanism. The following examples illustrate common determinations, but this is **not an exhaustive list**:

  Examples:
  - **Expedited Category 5 (Example):** Ongoing extraction of data from medical records to populate a data repository.
  - **Expedited Categories 2 & 5 (Example):** Phlebotomy performed specifically for repository storage (provided blood volumes and frequencies meet Category 2 criteria) combined with Electronic Medical Record (EMR) data extraction (Category 5).
  - **Full Board Review (Example):** Collection of specimens that require invasive or greater-than-minimal-risk clinical procedures performed solely for research repository creation (e.g., muscle biopsies or lumbar punctures for cerebrospinal fluid collection).

3. Secondary Research Studies

Secondary research is any research that reuses information or biospecimens that were originally collected for a different primary purpose, such as a prior research study (or repository), clinical care, or non-research activities.

The review level of secondary research studies is governed by a few factors.

- **Retrospective** materials qualify for assessment via **Expedited Category 5** regardless of whether their initial gathering served research or non-research

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functions, aligned with the 2007 Office for Human Research Protections (OHRP) regulatory guidance (Federal Register Notice).[1]

- Prospective application of Category 5 is strictly restricted to records or specimens acquired for **non-research purposes**. The use of Category 5 is **prohibited** when secondary protocols draw prospective items from active clinical trials or research studies. Under those circumstances, HRPO staff and IRB reviewers must evaluate if the prospective collection under the primary source protocol satisfies criteria for other Expedited Categories and specify this in the approval letter. If the source materials fail to meet these alternative expedited criteria, the secondary study must be routed to the **Full Board**.

4. Intake Assessment: New Study vs. Amendment

To maximize administrative efficiency, the IRB evaluates whether a secondary use should be processed as a **New Study** or an **Amendment**. The HRPO staff will apply a three-pronged assessment for this determination:

1. **Similarity of Research Aims:** Is there close alignment between the secondary research questions and the original study objectives?

2. **Consistency of the Research Team:** Is the secondary study conducted by the same primary research team?

3. **Identifiable Tissues and Waivers:** Does the study involve identifiable materials that rely on an existing waiver of consent and HIPAA authorization?

Routing Decision Logic: When the secondary research question is closely tied to the original aims, the research team is identical, and the project relies on existing waivers for the use of identifiable materials, the project functions as an extension of the primary study. In these cases, the submission should be processed as an **Amendment**. Routing the project as an amendment ensures that new research aims do not deviate so far from the

[1] OHRP clarified in 2007 the broad scope of expedited 5: *Expedited Category 5 includes research involving materials (data, documents, records, or specimens) that were previously collected for either nonresearch or research purposes, provided that any materials collected for research were not collected for the currently proposed research. For expedited category 5 to apply when the materials will be prospectively collected, they must be collected solely for nonresearch purposes.*

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original intent that the initial waiver of consent (or original consent provided) becomes ethically or legally invalid. If any of these conditions are not met, a **New Study** submission is required.

5. Quick-Reference Decision Matrix

The matrix below is being used as the primary tool for rapid, standardized decision-making during the intake phase for secondary research studies:

Scenario	Data/Specimen Timing	Source Type	Review Path / Action
Secondary Use	Retrospective (Exists at the time of initial IRB submission)	Research or Non-Research Repository	Expedited Category 5
Secondary Use	Prospective (Future collection)	Non-Research Only (e.g., EMR/Clinical Archives)	Expedited Category 5
Secondary Use	Prospective	Research Repository	Assess informed consent form and Expedited Categories Applicability
Secondary Use	Prospective (Future collection)	Ongoing Research Study	Assess other Expedited Categories; otherwise, Full Board
Study Extension	N/A	Similar Aims/ Same Team/ Identifiable Materials	Submit as **Amendment**

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