RESEARCH REPOSITORIES: OBTAINING CONSENT

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Repository - Defined

- Registries, data banks, and tissue banks are all considered “repositories” for regulatory purposes. Any reference in this policy to repositories applies equally to data banks, tissue banks, and registries.
Consent Requirements?

- Research repositories require either consent and authorization by participants for the storage and future research use of their data/specimens
  
  OR

- A waiver of consent and/or authorization by the IRB.
Consent Requirements

- The consent form should contain all the basic elements for consent form required by federal regulations.
- It must have a clear statement in the consent form that the subjects are giving permission for their data and/or specimens to be stored in the database/repository in order to be used in future research studies. This statement may be specific or broad; however, it will dictate the limits on future uses.
Consent Template

- Repository title – which may be different than parent study.
- PI & Guardian must be listed.
- Sponsor/support if applicable.
ABOUT RESEARCH REPOSITORIES

- Generally, a research repository collects, stores and distributes human tissue, specimens and/or data for use in future research projects. Research with blood, tissue or body fluids and health data can help researchers understand how the human body works and other health related questions. Storing and gathering lots of specimens and data together can help to conduct future research and avoid re-collecting specimens and data over and over again. With this stored information and samples, researchers may develop new tests to find diseases, new ways to treat diseases, or develop new products, such as drugs. Sometimes researchers collect and store many specimens and data together and use them for different kinds of research in the future, or share them with other scientists and this is called a research repository.
The purpose of this repository is to [describe purpose for the specimen collection and storage and what you hope to learn from the stored samples.]

- Inform subjects of the purpose of the repository.
- Provide a specific description of the research to be conducted with the specimens/data if known.
- Describe the types of genetic research that may be done in the future, e.g., “…looking for relationships between genes, the environment, and people’s habits or diet, and different diseases.” (May omit if there is certainty that genetic research will never occur, but this may be unlikely).
- Include genetic language for all specimen studies, regardless of plans to conduct genetic research.
WHAT SPECIMENS/DATA WILL BE COLLECTED?

- List what will be collected with lay terms as necessary.
Consent Template – How?

HOW WILL SPECIMENS/DATA BE COLLECTED?

- Describe succinctly and in chronological order those procedures that are part of the specimen-data collection process. Make it clear when samples and/or data are being collected for clinical care and then being stored or duplicated for research purposes.

- For samples, indicate the amount of specimens to be collected if appropriate. If blood is to be drawn, indicate the amount in lay terminology only (5cc = 1 teaspoon, 15cc = 1 tablespoon)

- If the subject’s medical records will be reviewed, describe the information to be collected.

- State approximately how much time the visits and procedures will require.
WHAT WILL HAPPEN TO THE SPECIMENS/DATA?

- Address specific areas about how the sample will be used and stored:
  - Provide a clear description of the operation of the specimen repository
    - Where will the specimen and data be stored?
    - Will they be identifiable?
    - Who will have access to the link?
    - How long will specimens and data be stored?
    - If applicable, when will the specimens be destroyed?
- Inform subjects of conditions under which data and specimens will be released to other investigators, indicating if identifiable data or specimens may be released.
Consent - Privacy & Confidentiality

- **Describe:** Methods for storing, coding, and securely transporting data and/or specimens.

- **Discuss** efforts to maintain privacy and risk of inadvertent release.

- **List** who can access data.

- **HIPAA AUTHORIZATION AT END.**
Consent – Risks & Discomforts.

- Describe reasonably foreseeable risks, side effects, discomforts, and inconveniences for collecting, storing, and releasing samples and/or data. List the risks in order of their importance.

- If a procedure is used to gather a specimen or samples or data it should be listed, unless that procedure was part of another study or clinical care.

- Confidentiality is first.
Consent

- Benefits – no direct benefits
- Statement that research results won’t be released to subject
- Liability
- Commercial development (for samples)
- Children must assent – cannot consent
- Need to include plans if will obtain consent at age of majority
The HIPAA research authorization is separate, however it is in the same template document.
The standard HRA has been modified to accommodate repositories.
Categories are deleted, since there is one purpose.
Consent Requirements – Submitting to a Non-OHSU Repository

- When an investigator is contributing data/specimens to a repository not held by OHSU, the OHSU IRB must approve at a minimum the collection protocol, the consent process and the submittal agreement.
Consent Requirements – Requesting from a Repository

- When an investigator is requesting coded or identifiable data or specimens from an established repository, a study submission is required either as a new study or as a modification to an existing study.

- The OHSU IRB must approve at a minimum the protocol, data collection tools, the usage agreement, consent process (most likely a waiver), and IRB approval of repository from which the request is being made.
Consent and Authorization (C/A)

- All repository protocols must include a description of how C/A has been or will be obtained from subjects, or why waiver of C/A is justified.
Future Uses

- Each secondary use will require either:
  - Consent or waiver of consent
  - HRA or waiver of authorization
- Original repository consent MAY cover secondary uses, but HIPAA will ALWAYS require an action.
Upcoming Educational Sessions

- May 27 - Repositories & Consent
- June 03 - Targeted Training – SON/SBER
- June 08 - Writing a Repository Protocol
- June 22 - Submitting & Releasing Data from Repositories
- TBD eIRB Changes
- TBD Repositories FAQs
Questions?

- **Repository Information Page**
  http://www.ohsu.edu/xd/research/about/integrity/irb/repository-policy.cfm

- **More details & Updates are in development – Keep checking back.**