Human Specimen Repositories: Requirements of 45 CFR part 46

PRIM&R
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Topics

- What's covered by 45 CFR part 46
- OHRP repository/database guidance
  - Repository model
  - Informed consent
- When research using coded information is NOT human subjects research
- Questions

2

Applicability of the HHS Regulations

- Research involving human subjects conducted or supported by HHS that is not otherwise exempt.
- Non-exempt human subjects research conducted under an applicable Assurance of Compliance – regardless of funding source.

3

Definition of Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)]

4

Human Subject

A living individual about whom an investigator conducting research obtains:

(1) Data through intervention or interaction with the individual; or

(2) Identifiable private information.

[45 CFR 46.102(f)]

5

Research Repositories & Databases: 3 Paths to Human Subjects Research

- Creating a research repository/database **through intervention or interaction with individual**
- Creating a research repository/database by **obtaining identifiable private information**
- Obtaining identifiable private information **from a research repository/database**.

6

OHRP Guidance: What is a Tissue Repository?

- Repositories collect, store, and distribute human tissue materials for research purposes.

7

OHRP Guidance: Components of Repositories

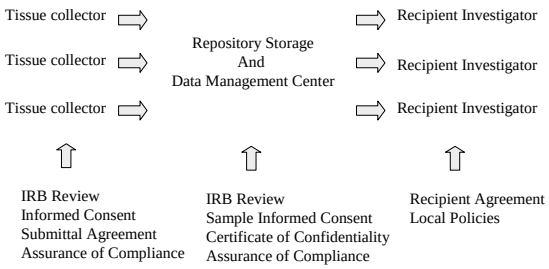
Repository activities involve three components:

- the collectors of tissue samples;
- the repository storage and data management center; and
- the recipient investigators.

Each component must satisfy certain requirements

8

OHRP Repository Guidance



9

Informed Consent

IF:

1. Samples collected for research purposes OR
2. Samples are associated with information that allows investigators to readily identify the donor,

THEN informed consent must be obtained from the donor unless appropriately waived by the IRB.

10

Informed Consent

A clear description of:

- Operation of the specimen repository.
- Specific types of research to be conducted, if known.
- Procedures for protecting the privacy of subjects and maintaining the confidentiality of data.

11

Informed Consent

- Possible consequences of genetic testing (e.g., insurance risks, misattributed paternity), when appropriate.
- Future withdrawal of the samples from the study (i.e., state whether subjects may, in the future, request that their samples be destroyed or that all personal identifiers be removed from samples).

12

Informed Consent

- Length of time that samples will be stored. If storage time is indefinite, so state.
- Subjects' access to information learned from the research, if they so choose.

13

Informed Consent

- Conditions under which data/specimens will be released to recipient-investigators; e.g.:
  - No secondary use.
  - Subjects have option to allow secondary use.
  - Only release samples stripped of all identifiers.
  - Only release of coded samples.
  - Subjects to be contacted for additional consent for secondary use.

14

When Research Using Coded Data is NOT Human Subjects Research

15

Human Subject

A living individual about whom an investigator conducting research obtains:

(1) Data through <u>intervention</u> or <u>interaction</u> with the individual; or

(2) <u>Identifiable private information</u>.

[45 CFR 46.102(f)]

16

<u>Identifiable</u> Private Information

Private information must be <u>individually identifiable</u> in order for obtaining the information to constitute research involving human subjects. [45 CFR 46.102(f)]

17

<u>Identifiable</u> Private Information

<u>Individually identifiable</u>: The identity of the subject is or may readily be ascertained by the investigator or associated with the information.

[45 CFR 46.102(f)]

18

Research Using Coded Data/Biologic Samples

- Private information or samples that retain a link to individually identifying information is ordinarily considered by OHRP to be individually identifiable to the investigator.
- But, there are exceptions…

19

Examples of When Coded Data/Biologic Samples Are Not Individually Identifiable to Investigators

1. The key to the code is destroyed;
2. The investigator and the holder of the individually identifying information sign an agreement prohibiting the release of individually identifying information to the investigator under any circumstances, until the individuals are deceased;

20

Examples of When Coded Data/Biologic Samples Are Not Individually Identifiable to Investigators

3. There are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of individual identifiers to the investigator under any circumstances, until the individuals are deceased; or
4. There are other legal requirements prohibiting the release of the link to the investigator, until the individuals are deceased.

21

In these examples, the research does not involve human subjects because investigators cannot readily ascertain the identity of the individuals.

22

Two Caveats About the Examples:

1. Person(s) doing coding of data/samples and person(s) holding codes are not part of research team.
2. Samples/data not being obtained for the specific research in question by an interaction or intervention with living individuals.

23

OHRP plans to issue further guidance on:

- **Coded private information/biological specimens**
- **Research repositories and databases**
- **Exemptions under 45 CFR 46.101(b)**

24

Guidance on the Web

- **OHRP's current repository guidance: http://ohrp.osophs.dhhs.gov/humansubjects/guidance/reposit.htm**

25