Tissue Banking Post HIPAA: Requirements of 45 CFR part 46

Julie Kaneshiro
Office for Human Research Protections
December 6, 2003
(PRIM&R B5)
Requirements of 45 CFR part 46 have not changed post HIPAA.
Topics

- What’s covered by 45 CFR part 46
- OHRP repository/database guidance
  - Repository model
  - Informed consent (how this differs from HIPAA Authorizations)
- When research using coded information is NOT human subjects research
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 at an institution holding an applicable Assurance of Compliance
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)]
Creation of a research repository or database is “research” under 45 CFR part 46
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)]
OHRP Guidance:
What is a Tissue Repository?

Repositories collect, store, and distribute human tissue materials for research purposes.
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.
OHRP Repository Guidance

Tissue collector → Repository Storage And Data Management Center

Tissue collector → IRB Review
Informed Consent Submittal Agreement
Assurance of Compliance

Tissue collector → Recipient Investigator

Recipient Investigator → Recipient Investigator

IRB Review → Recipient Agreement
Sample Informed Consent Certificate of Confidentiality Assurance of Compliance
Local Policies
Informed Consent

- If the samples were collected for research purposes or
- Are associated with information that can identify the donor, then
- Informed consent must be obtained from the donor unless appropriately waived by the IRB
Informed Consent Requirements

A clear description of
- the operation of the cell repository;
- the specific types of research to be conducted;
- the conditions under which data and specimens will be released to recipient-investigators; and
- procedures for protecting the privacy of subjects and maintaining the confidentiality of data
Informed Consent Requirements (cont’d)

- When human genetic research is anticipated, information should include possible consequences of genetic testing (e.g., insurance risks, misattributed paternity)
Informed Consent: Other Considerations

- A statement regarding 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).

- A statement regarding the length of time that samples will be stored. If storage time is indefinite, so state.

- A statement regarding subjects' access to information learned from the research, if they so choose.
Informed Consent: Other Considerations

- A statement regarding secondary uses of the samples. For example,
  - there will be secondary use only after the banked samples have been stripped of identifiers,
  - there will be no secondary use,
  - subjects have option of allowing secondary use, or
  - subjects will be contacted for additional consent in the future for secondary use.
Authorization:
HIPAA Privacy Rule

- Authorization must include “A description of each purpose of the requested use or disclose” [45 CFR 164.508]
- May not be for future unspecified research
- Uses and disclosures for future research using data/specimens from a repository requires additional Authorization, except as permitted without Authorization (e.g. waiver of Authorization by an IRB or Privacy Board, or a limited data set.)
OHRP Guidance: Usage Agreements

- Recipient-investigators should not be provided access to the identities of donors or to information through which the identities of donors may readily be ascertained; **thus not conducting human subjects research (HSR)**.

- If recipient-investigators receive identifiable, private information they are engaged in HSR and need to obtain an Assurance of Compliance and IRB review of the proposed research.
Applicability of the HHS Regulations

Research [45 CFR 46.102(d)]?

Human subjects [45 CFR 46.102(f)]?

Exempt [45 CFR 46.101(b)]?
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)]
Identifiable Private Information

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

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

[45 CFR 46.102(f)]
Under 45 CFR part 46, if an investigator obtains for research purposes private information about, or biologic samples that have come from, living individuals and the private information or biologic sample retains a link to individually identifying information, such private information ordinarily would be considered by OHRP to be individually identifiable to the investigator.
However, OHRP does not ordinarily consider coded information or biologic samples to be individually identifiable to the investigator if, for example:

- (1) 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, or
- (2) there are other legal requirements prohibiting the release of the link to the investigator.
Therefore, research on such samples or information does not involve human subjects because investigators cannot readily ascertain the identity of the individuals.
Research Using Coded Data/Biologic Samples

- Additional caveats for when research using coded data/biologic samples is not considered to involve human subjects:
  
  - Person(s) doing coding of data/samples and person(s) holding codes are not part of research team.
  - Samples/data not being obtained for the specific research in question by an interaction or intervention with living individuals.
OHRP plans to update current guidance on repositories and databases