Tissue Banking and Repositories – Human Subject Protections Privacy Protections

Medical Research Summit

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Friday March 7 – 9:15 am

Human Subject Protections
45 CFR Part 46

Repository Research – Human Subject Protections

- Requirement for IRB Review
- Requirement for Informed Consent
- Complicated by
  - Multiple Collection and Recipient Sites
  - Multiple IRBs
  - Multiple Future Uses
  - Unknown Future Uses

Repository Research – Human Subject Protections

- One Approach (OHRP Guidance)
- Key Role of Repository IRB for Review of
  - Collection criteria
    => Sample Consent Document
    => Written Collector Agreement
  - Privacy / confidentiality => Repository Procedures
  - Sharing parameters with/without additional review
    => Confidentiality requirements
    => Written Recipient Agreement

Repository Research – Human Subject Protections

- Collection Site
  - IRB review
  - Informed consent
- Recipient Site
  - Agreement
  - IRB review per institutional policy

Required Elements of Informed Consent -- §46.116(a)(1)

- Involves research
- Explanation of purposes
- Expected duration
- Description of procedures
- Experimental procedures

Required Elements of Informed Consent -- §46.116(a)(2),(3)

- Description of reasonably foreseeable risks
  - includes social and psychological risks
- Description of reasonably expected benefits

Required Elements of Informed Consent -- §46.116(a)(5),(7)

- Confidentiality protections
- Contact for information about the research activity
- Contact for information about subjects' rights

Required Elements of Informed Consent -- §46.116(a)(8)

- Participation is voluntary
- Refusal involves no penalty or loss of entitled benefits
- Discontinue at any time without penalty

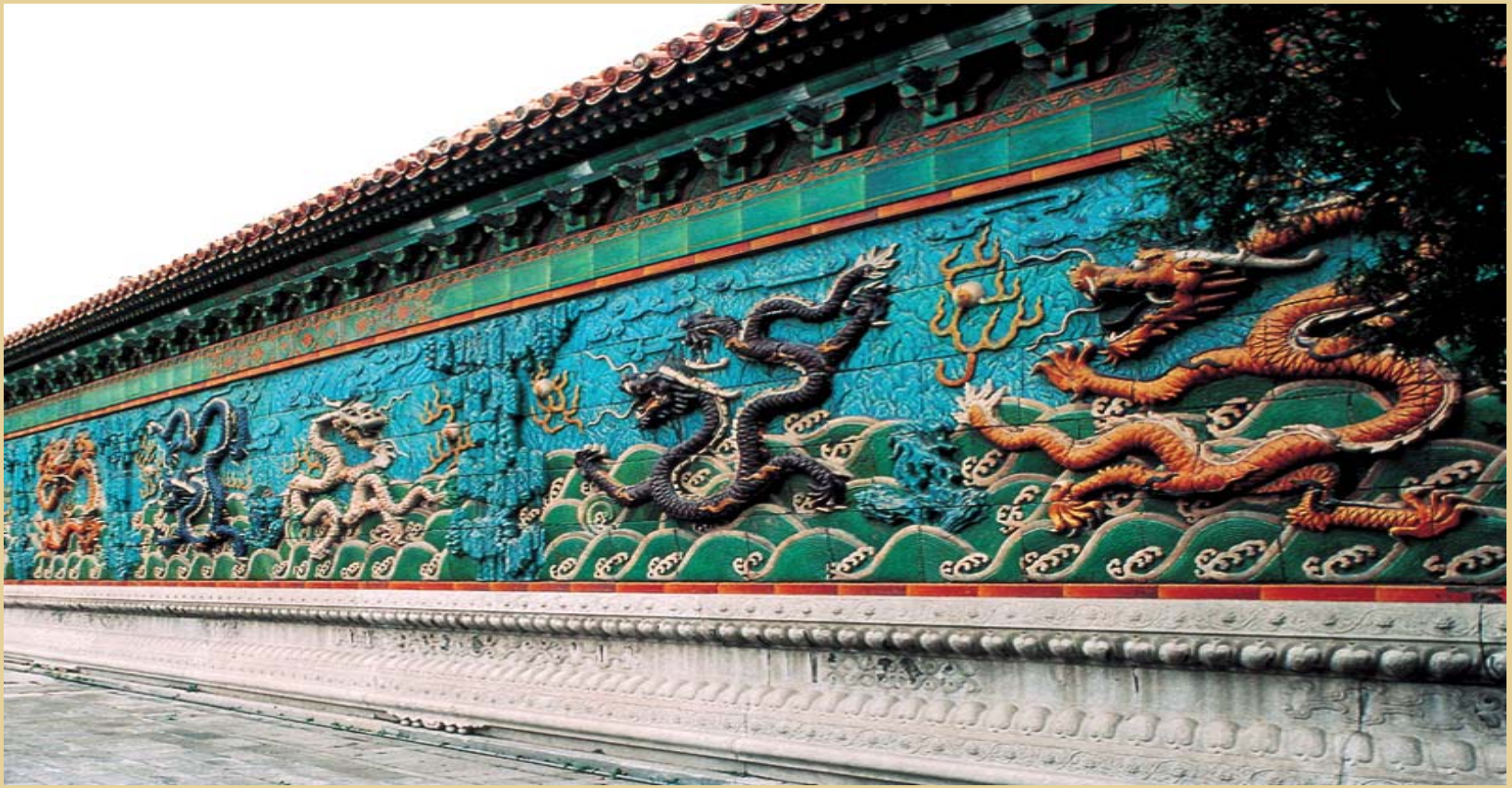
Informed Consent

- Minimize the possibility of coercion or undue influence
- Understandable language
- Written/signed documentation

Informed Consent

- No Exculpatory Language
  - No waiver or appearance of waiver of subjects' legal rights
- Future Products / Profit -- State facts
  - "Products may be developed …"
  - "No plans to share profits …"

HIPAA Privacy Rule
45 CFR Part 160 & Part 164



PricewaterhouseCoopers

HIPAA Privacy Rule
Research Use and Disclosure of PHI

- **Authorization**
- **Waiver of Authorization**
- **De-identified Information**
- **Limited Data Sets**
- Reviews Preparatory to Research
- Research on Decedents' Information

NOTE: Non-identifiable tissues are not subject to HIPAA

Authorization = Most Advantageous Route to Research

- No Representations (Assurances) Required
- No Privacy Board Review Required
- No Accounting of Disclosures Required
- No “Minimum Necessary” Limitations

Authorization Requirements

1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion
2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
3. The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

Authorization Requirements (cont)

4. A description of each purpose of the requested use or disclosure. The statement ‘at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

Authorization Requirements (cont)

5. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. **The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use and disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.**

Authorization Requirements (cont)

6. Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

Authorization Requirements (cont)

Additional Required Elements:

7. The individual's right to
   - Revoke the authorization in writing
     and
   - A description of how to revoke it
     and
     - (i) Exceptions to the right to revoke
       or
     - (ii) if appropriate, reference to the institution's privacy notice.

Authorization Requirements (cont)

8. The ability to condition research participation on the signing of an authorization.
9. The authorization must be written in plain language.
10. The individual must be provided with a copy of the signed authorization.

Research without Authorization: 1. Waiver of Authorization

Waiver Criteria:

(A) The use or disclosure of protected health information involves no more than **a minimal risk** to the privacy of individuals, based on, at least, the presence of the following elements:

(1) An adequate plan to protect the identifiers from improper use and disclosure;

and

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for regaining the identifiers or such retention is otherwise required by law;

and

Research without Authorization: 1. Waiver of Authorization

(3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research, study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

and

(B) The research could not practicably be conducted without the waiver or alteration;

and

(C) The research could not practicably be conducted without access to and use of the protected health information.

Research without Authorization: 2. De-identified Information

Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information. (164.514(a))

- De-identification may be achieved through:
  - Statistical Determination

    or
  - Removal of Specific Identifiers

Research without Authorization: 2. De-identified by Statistical Expert

Information is de-identified only if:

(1) A person with appropriate knowledge and experience with generally accepted statistical and scientific principles and methods for rending information not individually identifiable:

- (i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information;

  and

- (ii) Documents the methods and results of the analysis that justify such determination;

Research without Authorization: 2. De-identified by Removal of Identifiers

Information is de-identified only if:

(1) … *or*

(2)(i)The following identifiers of the individual or of relatives, employers, or household members of the individual are removed:

(A) Names;

Research without Authorization: 2. De-identified by Removal of Identifiers

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

Research without Authorization: 2. De-identified by Removal of Identifiers

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

Research without Authorization: 2. De-identified by Removal of Identifiers

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle Identifiers and serial numbers, including license plate numbers;

Research without Authorization: 2. De-identified by Removal of Identifiers

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs)

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images;

and

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section;

and

Research without Authorization: 2. De-identified by Removal of Identifiers

and

(2)(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

Research without Authorization: 2. De-identified Information May Include

- Gender
- Age Under 90
- Codes for Re-identifying the Information

Research without Authorization: 2. Re-identification of De-identified Info

A covered entity may assign a code or other means of record identification to allow de-identified information to be re-identified by the covered entity provided that:

(1) Derivation: The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; (*meaning: you can't use the ss # or address or date of birth as the code for re-identification*)
and

(2) Security: The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

Research without Authorization: 3. Limited Data Sets

Criteria for Use:

- Limited data set meeting regulatory requirements for removal of specific identifiers
- Data set recipient
- Data Use Agreement

Research without Authorization: 3. Limited Data Sets

The Limited Data Set May **NOT** include:

(i) Names

(ii) Postal address information, other than town or city, state, or 5-digit zip code (Note: LIMITED DATA SETS can include city, state, and 5-digit zip code but DE-IDENTIFIED information cannot)

(iii) Telephone Numbers

(iv) Fax numbers

(v) Electronic mail address

Research without Authorization: 3. Limited Data Sets

The Limited Data Set May **NOT** include:

(vi) Social security numbers

(vii) Medical record numbers

(viii) Health plan beneficiary numbers

(ix) Account numbers

(x) Certificate/license numbers

(xi) Vehicle identifiers or serial numbers, including license plate numbers

Research without Authorization: 3. Limited Data Sets

The Limited Data Set May **NOT** include:

(xii) Device identifiers or serial numbers

(xiii) Web Universal Resource Locators (URLs)

(xiv) Internet Protocol (IP) addresses

(xv) Biometric identifiers, including finger and voice prints

or

(xvi) Full face photographic images or any comparable images.

Research without Authorization: 3. Limited Data Sets

The Limited Data Set **MAY** include:

- City, state, and 5-digit zip code
- Dates

Research without Authorization: 3. Limited Data Sets

- The Data Use Agreement must state that the limited data set recipient will only use or disclose the protected health information for limited purposes.
- The Data Use Agreement must meet certain content requirements.

Research without Authorization: 4. Research on Decedents' Information

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

ISSUE: What if the information about the decedent is identifiable back to living individuals and affects their individually identifiable health information?

Research without Authorization
5. Reviews Preparatory to Research

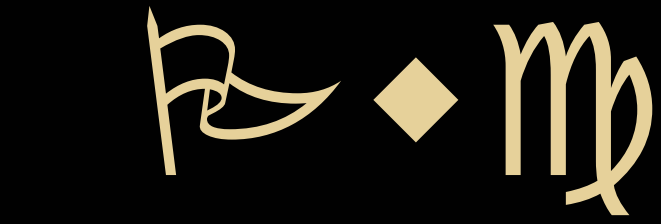
(A) Representation (assurance) by the investigator to the covered entity that the use or disclosure is being sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes "preparatory to research."

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

Authorization = Most Advantageous Route to Research

- No Representations (Assurances) Required
- No Privacy Board Review Required
- No Accounting of Disclosures Required
- No “Minimum Necessary” Limitations



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