



POLICY ON USE OF EXISTING DATA OR SPECIMENS IN RETROSPECTIVE RESEARCH

10/14/04

Introduction. Existing data and specimens are an important source of material for research studies. These data/specimens may have been collected in the past for clinical, quality improvement (QI), or research purposes for which consent and authorization (C/A) was not given for use in the specific research study under consideration. When existing data/specimens are to be used in a study, one of the following options is required: exemption of the study from IRB review, C/A, or waiver or alteration of C/A.

Option 1: Exemption from IRB review. Exemption is possible under the following conditions:

1. When there are no identifiers, i.e., all 18 Health Insurance Portability and Accountability Act (HIPAA) identifiers [45CFR164.514(b)(2)(i)] are removed, usually by a person not involved in the research project, and there are no codes or other links to the identity of the research subject [45CFR46.101(b)(4) or 45CFR46.102(f)], or
2. When no HIPAA identifiers are retained, but a code is retained by an independent person that links data/specimens to identifiable individuals, i.e., the holder of the link to the code, who is not involved in the research, declares that he/she has not shared and will not share the link with the investigator, and the investigator declares that he/she is unable to link any data/specimens to individual subjects and will not seek to do so. [These criteria for exemption are based upon the following guidances from the Office for Human Research Protections (OHRP): (a) guidance for stem cell research (paragraph 1, page 4) issued March 19, 2002 <http://www.hhs.gov/ohrp/humansubjects/guidance/stemcell.pdf>, and (b) guidance for coded private information (paragraph 4, page 3, and paragraph 2, page 4) <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>], or
3. When identifiers are retained and held by the DUHS Privacy Officer, i.e., a limited coded data set is extracted by a database keeper for use by the principal investigator, and the identifying codes are retained only by the Privacy Officer, as detailed in the DUHS IRB *Policy on Exemption of Research that Uses Coded Specimens or Coded Protected Health Information*.

Option 2: Obtaining C/A. Patients may be contacted for permission to use their past data and/or specimens for research purposes. The usual IRB procedures must be followed by having a DUHS IRB-approved protocol and strategy for obtaining C/A.

Option 3: Waiver or alteration of C/A. When the study is not eligible for exemption, and obtaining C/A is impracticable, the IRB will consider waiver of C/A based upon the federal criteria for waiver of consent [45CFR46.116(d)] and waiver or alteration of authorization [45CFR164.512(i)(1)and(2)]. (See the Attachment.)

Principal requirements for waiver:

1. No more than minimum risk,
2. No adverse effect on rights or welfare, and
3. Research cannot “practicably be carried out” without the waiver.

DUHS IRB internal guidelines for waiver of C/A for use of data and specimens in retrospective research:

1. Assurance that all data/specimens exist at the time of the IRB request for waiver: The PI must give written assurance in the protocol summary that only existing data/specimens will be used, and that those data/specimens will be only those that were collected during a time period between two specified dates in the past. Waiver or alteration of C/A for use of existing data/specimens will be approved only once per research use because care must be taken to ensure that the waiver is granted only for data/specimens that are “on the shelf” at the time of the waiver request. The continued collection of such data/specimens must occur solely for non-research purposes.
2. Sensitivity of data/specimens: C/A should not be waived for use of data or specimens that are potentially highly sensitive and are linked to patient identifiers, e.g., data on major psychiatric diagnoses and specimens for studies that could produce genetic information with potentially damaging consequences.
3. Previous C/A given for use of data/specimens in research: Consideration will be given for waiver of C/A related to specific studies in which the subjects have already given C/A for storage of the data/specimens in a research database/repository and for their use in future research related to the area of research covered by database/repository. For further information see the *DUHS Policy on Research Databases and Specimen Repositories*.
4. Practicability of obtaining C/A: At the present time there is no specific federal guidance for defining “practicably.” The DUHS IRB interprets the regulation to mean that C/A may be waived for use of data/specimens from patients who have been seen at DUHS in the past, but who are not expected to be seen at DUHS on a regular and frequent basis in the future. Patients who are expected to return soon should be asked for written C/A at their next visit.

ATTACHMENT: Requirements for Waiver of Consent and Authorization

COMMON RULE WAIVER OF CONSENT [45CFR46.116(d)]

“An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- (1) The research involves no more than minimal risk to the subjects;
- (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- (3) The research could not practicably be carried out without the waiver or alteration; and
- (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

PRIVACY RULE (HIPAA) WAIVER OR ALTERATION OF AUTHORIZATION [45CFR164.512(i)(2)(ii)]

“Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following 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;
 - (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 retaining the identifiers or such retention is otherwise required by law; and
 - (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 of disclosure of protected health information would be permitted by this subpart;

- (B) The research could not practicably be conducted without the waiver or alteration;
- (C) The research could not practicably be conducted without access to and use of the protected health information.”