

**Children's**  
Hospital & Regional Medical Center  
Office of the Vice President for Research

**OPERATING PROCEDURES/POLICIES**

Committee: Institutional Review Board  
Policy Number: IRB-31  
Effective Date: June 20, 2005

**POLICY TITLE:**

**RESEARCH USING PROTECTED HEALTH INFORMATION**

**POLICY:**

The use of identifiable protected health information for research purposes requires IRB review and approval. Permanently storing protected health information for research purposes requires IRB review and approval.

**DEFINITIONS:**

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

***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) **identifiable private information.** [45 CFR 46.102(f)]

**PROCEDURE:**

31.1 Washington state law RCW 70.02.140 and the federal Privacy Rule 45 CFR 164.502(f) consider a deceased person a human participant of research if the research uses private identifiable health information of deceased persons.

31.2 Private information must be **individually identifiable** to constitute research involving human subjects. *Private information* is individually identifiable

when it can be linked to specific individuals by the investigator(s) either directly (e.g., name, medical record number) or indirectly (e.g., through coding systems or identifiers as defined in the federal Privacy Rule (HIPAA) [45 CFR 164.514]).

- 31.3 Obtaining** identifiable information means receiving or accessing identifiable private information. Therefore, if a researcher accesses data, records or specimens that have identifiers, e.g., medical records, clinical data bases, tissue or specimen repositories, to collect research data this is considered human subjects research.
- 31.4** The level of IRB review required for research involving the use of private health information, i.e., full IRB review, expedited review, or exempt review status depends on a number of factors. Factors to be considered in determining the level of IRB review include, but are not limited to: i) risks of the research; ii) whether any identifiers will be recorded, iii) whether the records, data or specimens to be used exist at the time of IRB review of the research; and iv) plans for permanently banking the data, records or specimens for future research.

Items A.-C., below provide guidance on the level of IRB review required at Children's for a research study taking into consideration the factors noted above for determining level of IRB review:

**A. Full IRB Review for Research that involves:**

- (i) Prospective collection of individually identifiable information for research.
- (ii) Collection (prospective or retrospective) of individually identifiable, private information of a sensitive nature, e.g., psychiatric records, substance use, child abuse or neglect.
- (iii) Banking of private, identifiable, health information for future research.

**B. Expedited Review for Research that involves:**

- (i) Use of **existing**,\* individually identifiable private information for research. Research data will be coded in a confidential manner, i.e., a study code, so that data can be linked back to individuals.

\***Existing** is defined as on the shelf, in the file, at the time of IRB review.

**C. Exempt Review for Research that involves:**

- (i) Use of **existing**\*, de-identified private information for research. Research data will be recorded without any identifiers, i.e., the research data are anonymous or **de-identified**. To be de-identified

under the federal privacy rule (HIPAA), the following variables may not be collected or recorded for research purposes.

**Identifiers** based on the federal Privacy Rule:

<b>Names</b>	<b>Medical Record Numbers</b>	<b>Social Security Numbers</b>	<b>E-mail Addresses</b>
<b>Health Plan Beneficiary Numbers</b>	<b>Account Numbers</b>	<b>Telephone Numbers</b>	<b>Fax Numbers</b>
<b>All elements of dates (dates of birth, death, admission, discharge dates, service, e.g., surgery). All ages over 89</b>	<b>Geographic subdivisions smaller than a state (street address, city, county, zip code)</b>	<b>Full face photographs or comparable images</b>	<b>Biometric identifiers – finger or voice prints</b>
<b>Vehicle ID and serial numbers including license plate numbers</b>	<b>Certificate and License Numbers (including driver’s license)</b>	<b>Device identifiers and serial numbers</b>	<b>Any other unique identifying number, characteristic or code</b>
<b>Internet Protocol Address Numbers</b>	<b>Web URL</b>	<b>Surgical Pathology Number</b>	

31.5 Researchers shall complete an IRB application appropriate to the level of review required. For full IRB review, researchers shall complete the IRB-SAC application. For expedited review of research using existing data, records or specimens, researchers shall complete the IRB application for Research Involving Existing, Confidential Records, Data or Specimens. For exempt review, researchers shall complete the Request for IRB Exempt Status application.

31.6 The federal Office for Human Research Protections (OHRP) issued on August 10, 2004 a guidance document entitled “Guidance on Research Involving Coded Private Information or Biological Specimens.” (Appendix 7) Under this guidance document, OHRP clarifies that “coded” data is not considered individually identifiable if the private information or specimens are a) not collected specifically for the current research project through an interaction or intervention with living individuals; and b) the researchers will never have access to the key to the study code or the identity of the individuals whose coded private information or specimens are used.

Under this new federal guidance, no IRB review is required if all the following criteria are met:

- A. Researcher receives information or data without any of the aforementioned identifiers (31.4).

- B. Information received by the researchers may have a code as long as researchers have no access to the key to the code or the key to the code has been destroyed.
- C. No member of the research team will have access to private health information to obtain the research data. In other words, none of the research team will access records, data or specimens that include individually identifiable information, e.g., the individuals' medical records.
- D. The de-identified information or specimens used in the research are not collected specifically for the research.

The IRB, not the researcher, shall be responsible for determining if the activity is considered research and if so, the level of IRB review required.

### **Case Reports**

- 31.7 Case reports are reports of a single patient for the purpose of illustrating an unusual clinical presentation, a unique management strategy, or some other clinically important point. Case reports do not involve any analysis of data, but rather a report of the details of the case followed by a discussion.
- 31.8 Typically, case reports do not meet the federal definition of research because they do not constitute a "systematic investigation". Therefore, IRB review is not required for case reports.
- 31.9 The federal privacy rule (HIPAA) however does apply to the use of protected health information in case reports. To comply with the federal privacy rule, case reports cannot be published unless the author obtains an authorization from the parents or patient, or the published version of the case has been stripped of identifiers as defined under HIPAA.
- 31.10 Out of respect for persons, obtaining the permission of the patient or their parent is strongly encouraged for all case reports. A sample consent form has been prepared to obtain permission to publish a case report. (Appendix 13.E.)

### **Data, Tissue, or Specimen Banks or Repositories**

- 31.11 Establishing a data, tissue or specimen bank or repository for research purposes requires IRB review and approval **and** the consent and authorization of the patient or their legal representative to permanently store their protected health information in a research bank or repository.
- 31.12 The IRB will require the person responsible for the research data, tissue or specimen bank or repository to have procedures in place for releasing banked data, tissue or specimens to future researchers in a manner that protects the privacy of the individuals whose data, tissue or specimens are banked.

