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Department: Administration

Subject: PP-18 Use & Disclosure of Protected Health Information for Research

Policy Number: 18

Effective Date: August 22, 2005

Review Date: August 22, 2005

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**Context:**

The University of Washington is a hybrid entity for purposes of HIPAA. A hybrid entity is an organization whose primary business is not the delivery of health care. Thus, hybrid entities have both health care components and non-health care components. As required by the Privacy Rule, the University of Washington has designated its health care components<sup>1</sup>. Designation as a health care component depends on whether that office or unit of the University engages in activities (“covered functions”) that make the office or unit a health plan, a health care provider or a health care clearinghouse.

The University has designated UW Medicine<sup>2</sup> as a health care component because it engages in covered functions as a health care provider. A researcher, who is also a health care provider in the UW Medicine workforce, conducts research using UW Medicine facilities or patient information and/or whose research includes providing health care to UW Medicine patients, must comply with the UW Medicine Privacy and Information Security Policies.

**Policy:**

The UW Medicine policy regarding the use and disclosure of Protected Health Information (PHI) for research purposes includes the following six sections.

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<sup>1</sup>The health care component of the University of Washington includes the following: UW Medicine, Behavioral Research & Therapy Clinics, Learn Clinic, Autism Clinic, Speech & Hearing Clinic, School of Dentistry Clinics & Dental Practice Plan and Campus Health.  
<sup>2</sup> For the purpose of HIPAA, UW Medicine includes the following entities: University of Washington Medical Center and Clinics; Harborview Medical Center and Clinics; UW Medicine Neighborhood Clinics (University of Washington Physicians Network); UW Physicians Sports Medicine Clinic; UW Physicians Eastside Specialty Center; Hall Health Primary Care Center; and University of Washington Physicians.

- I. Research – Definition and Applicability
- II. Authorization and Consent Requirements
- III. Limited Data Set
- IV. De-identified Data
- V. Security Requirements
- VI. Failure to Comply

## I. Research – Definition and Applicability

For UW Medicine, "research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute "research" for the purposes of these policies, whether or not they are supported or funded under a program that is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities. This definition includes activities preparatory to the conduct of research; for example, activities conducted in support of grant or proposal preparation, pilot studies, and feasibility studies.

- A) If you are a member of the UW Medicine workforce<sup>3</sup>, and your research involves the use of human subjects (either directly or indirectly through individually identifiable health records or review of other data such as samples, specimens, or autopsy materials), your research requires review by the UW's Institutional Review Board (IRB), also known as the Human Subjects Review Committees.
- B) If you are a member of the UW Medicine workforce and you are conducting any review preparatory to research including, but not limited to screening activities, feasibility, and/ or pilot studies that involves the use of human subjects (either directly or indirectly through individually identifiable health records or review of other data such as samples, specimens, or autopsy materials), your research requires review by the IRB.
- C) Drug and alcohol abuse treatment records are subject to more stringent protections and UW Medicine will apply the more stringent requirements.<sup>4</sup> The IRB serves as the broker of access for research to these records to comply with requirements of state and federal regulations.

## II. Authorization Requirements

Individuals must authorize use of their PHI for research. When there is a patient's authorization for the use or disclosure of PHI, no accounting of

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<sup>3</sup> See "Definitions" section for further description of "workforce".

<sup>4</sup> Per RCW 70.96A.150 and 42 C.F.R. Part 2.

disclosures is required. See UW Medicine Privacy Policy: *Accounting of Disclosures of Protected Health Information (PHI)*.

UW Medicine entities accept UW IRB-approved<sup>5</sup> waivers or alterations of authorization that contain the following:

A) Statements:

- 1) Identifying the IRB and the date on which the alteration or waiver of authorization was approved.
- 2) That the IRB has determined that the alteration or waiver of authorization, in whole or in part, satisfies the following criteria:
  - a) Research is of sufficient importance to outweigh the intrusion into the privacy of the individual;
  - b) Use or disclosure of PHI involves no more than minimal risk<sup>6</sup> to the privacy of individuals, based on, at least, the presence of the following elements:
    - i. An adequate plan to protect the identifiers from improper use and disclosure;
    - ii. 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**
    - iii. 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;
  - c) The research could not practicably be conducted without the alteration or waiver, **and**
  - d) The research could not practicably be conducted without access to and use of PHI.
- 3) A brief description of the PHI for which use or access has been determined to be necessary by the IRB.
- 4) That the alteration or waiver of authorization has been reviewed and approved under either full IRB or expedited review procedures as follows:

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<sup>5</sup> UW Medicine has IRB reciprocity with Children's Hospital and Regional Medical Center, Group Health Cooperative, Swedish Medical Center/Providence Hospital– Seattle, Virginia Mason Medical Center, Fred Hutchison Cancer Research Center, Veterans Affairs Medical Centers, King County Health Department, Puget Sound Blood Center, and Oregon Health and Science University.

<sup>6</sup> See "Definitions" section for further description of "minimal risk".

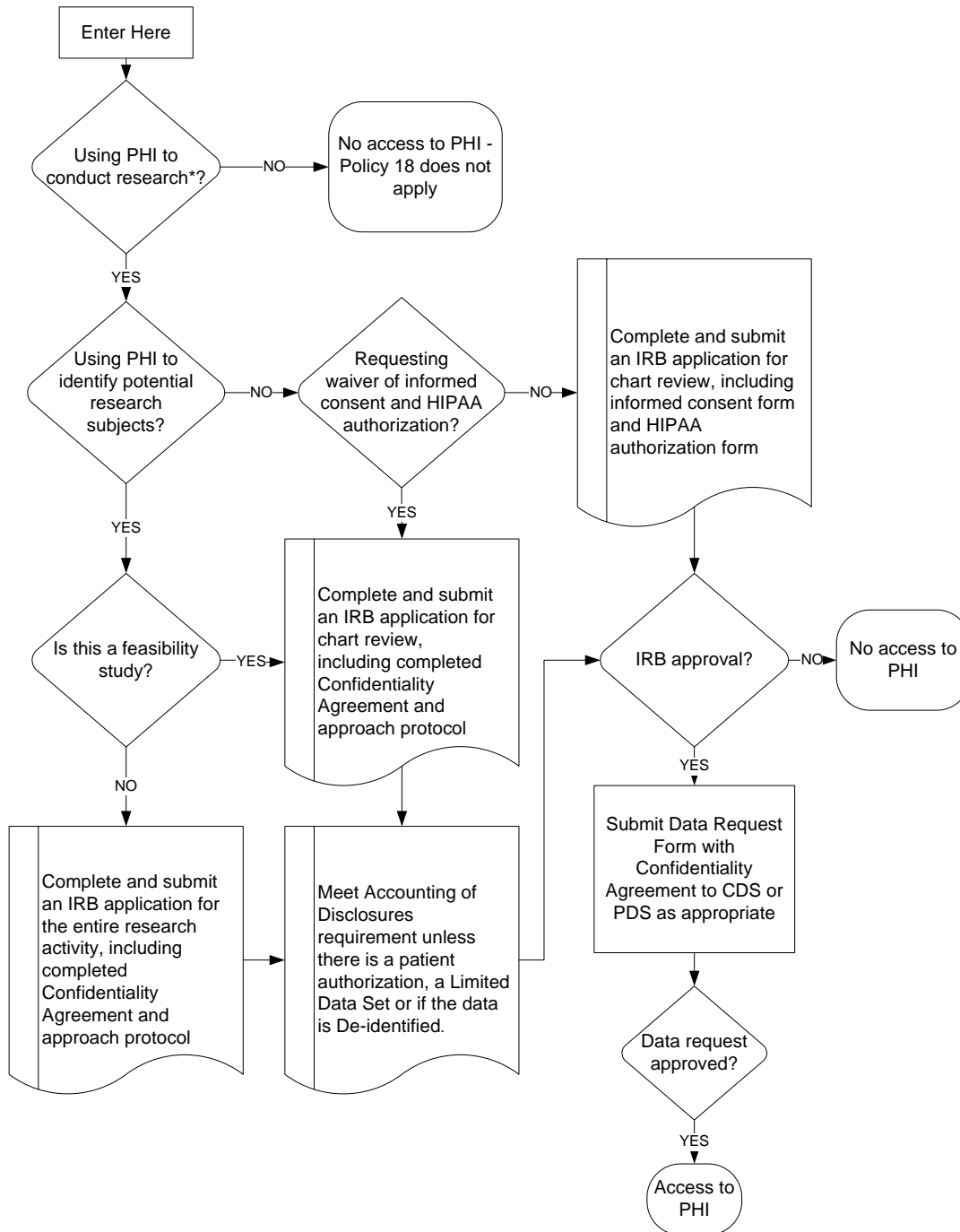
- a) UW Medicine's IRB has followed the requirements of the Common Rule, including the full IRB or expedited review procedures,<sup>7</sup> **and**
  - b) UW Medicine's IRB chair or other designated member has signed the documentation of alteration or waiver of authorization.
- B) Procedures for approaching potential research subjects (or the potential subject's legally authorized representative) identified through the use of PHI obtained under a waiver of authorization must be approved in advance by the IRB.
- Such procedures may include, but are not limited to:
- ◆ Using an intermediary<sup>8</sup> known to the potential subject to request permission for the researcher to approach the potential subject;
  - ◆ Requesting medical staff caring for the potential subject to request permission for the researcher to approach the potential subject; and
  - ◆ Requesting the potential subject's primary care or other provider to provide information to the potential subject about the study in person, by mail, by email, or by telephone.
- C) Individual(s) accessing PHI under a waiver of authorization will abide by UW Medicine requirements to meet an accounting of disclosures for all PHI accessed. See UW Medicine Privacy Policy: *PP-25 Accounting of Disclosures of Protected Health Information (PHI)*.
- D) PHI regarding Decedents: The use for research purposes of PHI about individuals who are no longer alive requires IRB review and approval. The IRB may require consent from the legally authorized surrogate or may authorize a waiver of consent in accordance with state law RCW 70.02.

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<sup>7</sup> See specific federal regulatory references under "References" sections IV. and V. of this policy.

<sup>8</sup> An intermediary may include but is not limited to someone who is known to the potential subject such as service providers, mutual friends, or representatives from support groups, task forces, committees, or societies. (Examples: Cancer Support Group, Type-2 Diabetes Task Force, School Stroke Committee, Neurological Disorders Society.)

Process Flow



\* Research includes activities that are intended to determine if it is feasible to conduct research at the University of Washington and the activities intended to identify individuals who might be potential subjects of research.

### III. Limited Data Set

UW Medicine may use or disclose a limited data set for research purposes, provided that certain criteria are met, including IRB review for creation of the

limited data set. See UW Medicine Privacy Policy: *PP-19 Protected Health Information (PHI), Limited Data Set, and De-Identification of PHI*.

**IV. De-Identified PHI**

UW Medicine may use or disclose de-identified PHI for research purposes, provided that the IRB reviews and approves the creation of the de-identified data set. See UW Medicine Privacy Policy: *PP-19 Protected Health Information (PHI), Limited Data Set, and De-Identification of PHI*.

**V. Security Requirements**

All individuals performing research must meet UW Medicine Information Security requirements. (See UW Medicine Information Security Policies and Standards, <http://depts.washington.edu/comply/security.shtml>)

**VI. Failure to Comply**

Failure to comply with the specified requirements or misuse or misappropriation of health information for research purposes may result in disciplinary action up to and including dismissal, see UW Medicine Privacy Policy: *PP-06 Sanctions for the Failure to Follow Applicable Privacy and/or Information Security Policy or for a Breach of Patient Confidentiality or Information Security*, revocation of IRB approval, and civil or criminal penalties.

**Procedures:**

**I. How to begin the review process**

Step	I. Action
1	Complete a Human Subjects Review Committee application form and submit it to the UW Human Subjects Division.
2	Include all relevant information (grant proposals, drug or device information, consent forms, questionnaires, test instruments, advertisements, debriefing statements, contact letters, etc.). Researchers seeking a waiver of authorization or consent must include statements explaining how the request satisfies the criteria at II.A.2.a-i. of this policy.

For further information, please call the Human Subjects Division at 543-0098 or visit the Human Subjects Division web site: <http://www.washington.edu/research/hsd/index.php>

**II. Obtaining Required Authorization Prior to Disclosure of PHI for Research - Consent Form Checklist**

Step	II. Action
Drafting consent form	<p>Consent forms must be drafted to include the required elements of consent in language that will be understood by the intended population of research subjects. Consent forms specifically requesting access to PHI should include the following:</p> <ul style="list-style-type: none"> <li>• The purpose for which the PHI is necessary,</li> <li>• The researcher’s plan to protect the identifiers from improper use and disclosure,</li> <li>• The researcher’s plan (including timing) for destroying the identifiers linked to the PHI, or a statement that the identifiers will be kept indefinitely,</li> <li>• An assurance that PHI will not be reused or disclosed to any other person or entity, or a description of why and to whom such information will be reused or disclosed, <b>and</b></li> <li>• A description of the content of the PHI necessary for the research.</li> </ul>

For further information, please call the Human Subjects Division at 543-0098 or visit the Human Subjects Division website: <http://www.washington.edu/research/hsd/index.php>

**References:**

- I. 45 CFR Part 160 and 164; Section 164.512(i) – “Uses & Disclosures for Which Consent, Authorization or Opportunity to Agree or Object is Not Required – Research Purposes”.
- II. RCW 70.96A.150 – Drug and Alcohol Abuse Treatment Records; 42 C.F.R. Part 2.
- III. RCW 70.02.030 – Patient Authorization of Disclosure
- IV. RCW 70.02.050 – Disclosure Without Patient’s Authorization
- V. References specific to Policy Section I. A.: 7 CFR 1c.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38

CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107 **or** 49 CFR 11.107

- VI.** References specific to Policy Section II. A. 4. – Normal Review Procedures: 7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b) **or** 49 CFR 11.108(b).
- VII.** References specific to Policy Section II. A. 4. – Expedited Review Procedures: 7 CFR 1c.110, 10 CFR 745.110, 14 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110 **or** 49 CFR 11.110.

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UW Privacy Officer: \_\_\_\_\_ Date: \_\_\_\_\_

John A Coulter, Associate Vice President for Medical Affairs

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