

<b>SOP: HI 1201</b> <b>Version No.: 04</b> <b>Effective Date: 12/7/10</b>	<b>USES AND DISCLOSURES OF          PROTECTED HEALTH          INFORMATION FOR RESEARCH</b>	<b>Supersedes          Document          Dated: 05/01/06</b>
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## 1. POLICY

Steering Committee approved 1/31/11

The Aurora IRB has been designated as the Privacy Board for Aurora Health Care. The purpose of this policy is to outline the procedures of the IRB for reviewing proposed research studies to assure that there is adequate protection of the privacy interests of participants, including compliance with the Health Insurance Portability and Accountability Act of 1996 and implementing regulations (HIPAA) and state law governing privacy of health information. This policy outlines the procedures for the IRB in approving the Use and Disclosure of Protected Health Information (“PHI”), as defined below, pursuant to one of the following mechanisms: (1) Authorization by the research subject to Use and Disclose his or her PHI; (2) determination by the IRB that the information is De-identified; (3) determination by the IRB that the information can be Disclosed and Used in the form of a Limited Data Set; or (4) Waiver or alteration of Authorization by the IRB. This policy also addresses specific requirements that must be met in order for Investigators to access PHI in preparation for research and for research on decedents’ PHI. For specific information on requests to access existing medical records, charts or databases maintained by Aurora for the purpose of research or research related activities such as recruitment, please refer to Policy SC 502.

Generally, the Authorization requirements under HIPAA for use and disclosure of Protected Health Information should be combined with the template informed consent document (see Policy IC 701). The IRB may prohibit enrollment of prospective subjects in research studies if they fail to sign the IRB-approved Informed Consent/Authorization document.

### 1.1. Definitions

The following are definitions of key terms used in this policy. Terms not defined herein shall have the meanings set forth in the Glossary.

1.1.1. “Authorization” means the signed authorization language approved by the IRB for obtaining an individual’s permission prior to Using or Disclosing that individual’s Protected Health Information for Research purposes.

1.1.2. “Data Use Agreement” is a document that specifies permitted Uses and Disclosures of PHI as part of a “Limited Data Set”, specifies who may Use or receive the data set, restricts further Use and Disclosure, and restricts re-identification of the data or contact with the individuals.

1.1.3. “Disclose, Disclosed or Disclosure” means the release, transfer, provision of access to, or divulging in any other manner of information outside the Aurora Facilities.

1.1.4. “HIPAA” means the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations governing privacy, security and code and transaction sets.

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1.1.5. “Informed Consent, or Informed Consent Form, or Consent Form” means the written form that must be provided to participants in research studies, which contains language informing the participants of the risks associated with the study.

1.1.6. “Limited Data Set” means PHI that excludes the following direct identifiers of the individual or of relatives, employers or, household members of the individual: (i) Names; (ii) Postal address information, other than town or city, state, and zip code; (iii) Telephone numbers; (iv) Fax numbers; (v) Electronic mail addresses; (vi) Social security numbers; (vii) Medical record numbers; (viii) Health plan beneficiary numbers; (ix) Account numbers; (x) Certificate/license numbers; (xi) Vehicle identifiers and serial numbers, including license plate numbers; (xii) Device identifiers and serial numbers; (xiii) Web Universal Resource Locators (URLs); (xiv) Internal Protocol (IP) address numbers; (xv) Biometric identifiers, including finger and voice prints; and (xvi) Full face photographic images and any comparable images.

1.1.7. “Privacy Standards” means the privacy regulations implemented under HIPAA, 45 C.F.R. Parts 160 and 164.

1.1.8. “Protected Health Information or PHI” means information that is transmitted or maintained in any form or medium and (i) is created or received by a health care provider, health plan, employer or health care clearinghouse; (ii) relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to the individual; or the past, present or future payment for the provision of health care to an individual; and (iii) identifies the individual (or for which there is a reasonable basis for believing that the information can be used to identify the individual). Protected Health Information excludes (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; (ii) records described at 20 U.S.C. 1232g (a)(4)(B)(iv); and (iii) employment records held by an entity governed by HIPAA in its role as an employer. In addition, the RSPP does not consider self disclosure of medical information to be PHI. However, such disclosures will be protected consistent with other research information.

1.1.9. “Sensitive Information” means PHI that specifically relates to: (i) treatment for mental health, developmental disabilities, alcohol and drug abuse; or (ii) treatment of an illness related to, or testing for the presence of, the human immunodeficiency virus (“HIV”).

1.1.10. “Use” means, with respect to Protected Health Information PHI, the sharing, employment, application, utilization, examination, or analysis of such information within the Aurora Facilities.

## 1.2. **Specific Policies**

1.2.1. For purposes of this policy, any time a research study is conducted at an

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Aurora Facility or uses PHI maintained at an Aurora Facility, the IRB will only permit Uses and Disclosures of the PHI, regardless of the source of funding of the research, in accordance with applicable requirements of the Privacy Standards of the Health Insurance Portability and Accountability Act of 1996, 45 CFR Parts 160 and 164, as provided in this policy. Specifically, the IRB will only permit Uses and Disclosures of PHI for research purposes as follows:

- If the individual who is the subject of the PHI provides prior Authorization in compliance with section 1.3, below; or
- Without prior Authorization, if the PHI is De-identified in compliance with section 1.4 below; or
- Without Authorization, and the PHI is to be Disclosed in a Limited Data Set, in compliance with section 1.4.2 below; or
- Without Authorization, and the PHI is to be Used as a Preparatory to Research activity, in compliance with section 1.7 below; or
- Without Authorization, and the PHI is to be used for research on decedents' information, in compliance with section 1.8 below; or
- Without the individual's prior Authorization if the IRB has approved a Waiver or alteration of the Authorization requirements in compliance with section 1.5 below.

1.2.2. The IRB will also ensure compliance with the Privacy Standards when:

- The Use or Disclosure of PHI is Preparatory to Research ("feasibility evaluation") and no information is removed from the Aurora Facility (see section 1.7.1, below);
- The requested Use and Disclosure is related to PHI of decedents (see section 1.8 below); or
- The Use or Disclosure of PHI is for recruitment of subjects (see section 1.7.2, below).

1.2.3. The investigator will define the purpose of the research and to whom PHI will be disclosed. The IRB should have an understanding of what PHI is going to be used or disclosed during the study.

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### 1.3. Uses and Disclosures of PHI for Research with Authorization

If the IRB determines that it is feasible to obtain Authorization of the prospective research subject, the IRB will ensure that the language in the Consent/Authorization or Authorization sets forth how the prospective research subjects' PHI will be Used or Disclosed. The template language in Form IC 701-A (the Aurora informed consent template) combines the statements required under the Privacy Standards with the statements required by other federal and state laws related to consent to participate in research so that the subjects have to sign only one form when possible. Generally, the position of the IRB is that an Authorization must be obtained and that it will be incorporated into the informed consent document for research. A written request for the use of a separate authorization (see Form 1201-A) will be considered by the IRB on a case-by-case basis provided that there is sufficient justification.

If the IRB allows the investigator to restrict research subjects' access to their research records during the research study, the IRB shall require that a statement is included in the approved informed consent /authorization document indicating the restrictions on an individual's access to their research records.

1.3.1. The IRB conditions all enrollment in a research study on the prospective research subject's execution of an Authorization. In the event a prospective research subject refuses to sign an Authorization, and the IRB requires an Authorization, the individual cannot be enrolled in the research study.

1.3.2. If a subject withdraws his/her Authorization to Use or Disclose his/her PHI during the course of a research study, the subject will be withdrawn from the research study.

1.3.3. If the research subject's Authorization is obtained, his or her PHI can be used in any way that is consistent with the terms of the Authorization language contained in the IRB-approved Informed Consent/Authorization document. If the investigator wishes to Use or Disclose PHI for a purpose not set forth in such Authorization, the investigator is responsible for ensuring that he/she obtains another authorization and such authorization is approved by the IRB, unless an IRB Waiver is obtained in accordance with section 1.5 below.

1.3.4. The language in the Authorization must include the elements set forth in 45 CFR 164.508 and 45 CFR 164.514 (see the Office for Civil Rights' web site ([www.hhs.gov/ocr/hipaa/](http://www.hhs.gov/ocr/hipaa/)) for a link to HIPAA regulations).

1.3.5. If the IRB becomes aware of unauthorized use or disclosure of PHI related to a research study in violation of an IRB-approved informed consent/authorization document, the IRB shall promptly report such violations deemed to meet the Policy definition of Serious Noncompliance to Aurora's Chief Privacy Officer.

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#### 1.4. Use and Disclosure of PHI for Research Without Authorization

##### 1.4.1. Without Authorization if Information Can Be De-identified

If obtaining an Authorization is not feasible for any reason, the investigator must complete Form SC 502-A. The IRB will consider whether the data requested could be collected without identifiers (i.e., if the purpose of the research can be accomplished with de-identified data).

**Note: Prior to implementation of the Privacy Standards, it was often common for investigators or sponsors to consider information to be “de-identified” if the names, alone, were removed. The Privacy Standard’s de-identification requirements are much more stringent.**

(A) To determine whether it will be feasible to de-identify the data, the IRB must determine whether the removal of identifiers set forth in 45 CFR 164.514(b)(2) is feasible.

(B) De-identified information will still be considered “de-identified” if a code is assigned to the de-identified information to allow such information to be re-identified by the applicable Facility, provided that the following criteria are satisfied: (1) the code is not derived from information about the prospective research subject and is not otherwise capable of being translated so as to identify the individual (e.g., the individual’s initials, the last four digits of the individual’s social security number, etc. may not be used); (2) the code is not used or disclosed for any other purpose; and (3) the code is not disclosed to the investigator that requested the de-identified information (in accordance with Aurora IRB’s Honest Broker Policy 1202).

##### 1.4.2. Without Authorization in the Form of a Limited Data Set

If the IRB determines that it is not feasible to de-identify the PHI, it will next determine whether it is feasible to use or disclose a Limited Data Set (defined in Section 1.1 above) for the research.

If the IRB determines that it is feasible to use or disclose a Limited Data Set for the proposed research study, the IRB will refer the investigator to the Aurora Chief Privacy Officer for the execution of a Data Use Agreement.

If it comes to the IRB’s attention that there is unauthorized Disclosure or Use of the Limited Data Set(s), the IRB shall promptly report this activity to the Aurora Chief Privacy Officer. This would also be considered an Unanticipated Problem (per Aurora IRB SOP RR 403) and reviewed accordingly.

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**1.5. Request for Waiver of Authorization**

There may be instances where it is not possible or practicable to obtain an Authorization, to de-identify information, or to use a Limited Data. The Aurora Facility will permit Use or Disclosure of PHI maintained at the Aurora Facility without Authorization if the IRB grants an approval of a Waiver of Authorization.

The IRB will review the research proposal and the request for a Waiver or alteration of Authorization and will only issue such Waiver or alteration if it determines that the following criteria are met:

1.5.1. The Use or Disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on the fact that the investigators have provided the following:

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

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

(C) There are adequate written assurances by the investigator that the PHI 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 PHI would be permitted by the Privacy Standards;

1.5.2. The research could not practicably be conducted without the Waiver or alteration of Authorization;

1.5.3. The research could not practicably be conducted without access to and use of PHI;

1.5.4. The use and disclosure of PHI complies with applicable state laws;

1.5.5. In the case of research involving retrospective patient health care records review the requirements of Policy SC 502 are satisfied; and

1.5.6. If the IRB approves the Waiver or alteration of Authorization, the IRB will provide the applicable Aurora Facility with a copy of the approved SC 502-A form.

**1.6. Accounting of Disclosures of PHI pursuant to an IRB Waiver**

Each Aurora Facility is required to provide an individual accounting of Use or Disclosures

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for research any time the IRB grants an IRB Waiver of Authorization. Accordingly, any time the IRB grants such IRB Waiver of Authorization, the RSPP office will indicate that such Waiver has been granted to the investigator in the approval letter and/or by an approved SC 502-A form. The IRB's approval letter and/or the approved SC 502-A form will indicate that such an IRB Waiver of Authorization has been granted.

The IRB shall report such approved Waiver to the Health Information Management/Medical Records department of the applicable Aurora Facility that maintains or will maintain the PHI by providing a copy of Form SC 502-A to them. The Health Information Management/Medical Records department is responsible for ensuring compliance with the HIPAA accounting of disclosures requirement for research-related disclosures. The following are circumstances (but not an exhaustive list) in which the Aurora IRB may grant Waiver of Authorization and therefore be required to report such Waiver to the patient health care records department:

1.6.1. Planned emergency research interventions in which informed consent cannot be obtained (see Policy SC 503);

1.6.2. Retrospective review of patient health care records in accordance with Policy SC 502 for which an IRB Waiver of Authorization has been granted; and

1.6.3. Any other research study for which the IRB grants an IRB Waiver of Authorization pursuant to this section.

**1.7. Review of PHI in Preparation for Research**

1.7.1. Feasibility Evaluation.

In the event that the IRB determines that access to PHI is needed solely to determine research feasibility at one or more Aurora Facilities, the IRB may permit investigators to access PHI without individuals' prior authorization and without IRB approval of a Waiver of Authorization, if the requirements of section 1.7.3 are met.

1.7.2. Identify potential research subjects.

In the event that the IRB determines that access to PHI is needed to identify potential research subjects, the IRB may permit investigators to access PHI without individual prior authorization and without IRB approval of a Waiver of Authorization if the requirements in section 1.7.3 are met.

Contact of potential research subjects is not allowed unless and until the IRB has reviewed and approved the proposed recruitment process to ensure compliance with federal regulations and Policy RR 406.

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1.7.3. The IRB must ensure that the investigators complete and sign Form SC 502-A. By signing Form SC 502-A, the Investigator will provide the following representations to the Aurora Facility:

- (A) Review of PHI will be limited as necessary to prepare for research;
- (B) The investigator will not remove identified PHI from the Aurora Facility; and
- (C) Review of PHI is necessary for the research

1.7.4. The Health Information Management/Medical Records department of the particular Aurora Facility is responsible for ensuring that only those individuals identified by the investigator on the approved SC 502-A form will have access to PHI, and for ensuring compliance with HIPAA accounting of disclosures requirements.

**1.8. Research on PHI of Decedents**

In the event that the IRB (acting as the Privacy Board) determines that access to PHI is needed solely to conduct research on the PHI of decedents, the IRB may permit investigators to access PHI without Authorization and without the IRB approval of a Waiver of Authorization, if the investigators sign Form SC 502-A indicating that the research will be on PHI of decedents. In signing Form SC 502-A, the investigators will provide the following representations to the Aurora Facility:

- (A) Review of PHI will be limited to research on decedents;
- (B) Review of PHI is necessary for the research and
- (C) The investigator will provide documentation of death of the individuals whose PHI will be reviewed at the Aurora Facility's request.

**1.9. Collection, Use and Disclosure of Sensitive Information**

The IRB will review all research proposals to determine whether the Use and Disclosure of Sensitive Information complies with state law in accordance with this policy.

**2. SCOPE**

This policy applies to all research studies conducted at any Aurora Facility or any research study in which PHI maintained by an Aurora Facility is to be accessed for such research study. This policy does not apply when the research does not occur at an Aurora Facility or the PHI is maintained at a non-Aurora Facility.

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### **3. APPLICABLE REGULATIONS, GUIDELINES AND STANDARDS**

45 CFR part 160 and 164

45 CFR 46.111(7)

21 CFR 56.111(7)

AAHRPP Elements II.3.D. and II.3.E.

### **4. REFERENCES TO OTHER APPLICABLE SOPS**

SOP 302

SOP 401

SOP 406

SOP 501

SOP 502

SOP 503

SOP 701