

SOP: SC 502 Version No.: 5 Effective Date: 12/3/10	REQUEST TO ACCESS EXISTING MEDICAL RECORDS, CHARTS OR DATABASES FOR RESEARCH	Supersedes Document Dated: 7/24/06
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Steering Committee approved 10/17/11

1. POLICY

The Aurora IRB, acting as the HIPAA Privacy Board, is required to review any request for access to medical records, charts or databases maintained by any Aurora Facility for the purpose of conducting research. Any individual, including but not limited to, physicians, healthcare providers, students, or employees of Aurora who are requesting to access patient medical records, charts or databases must request such access by submitting Form SC 502-A entitled “Request to Review Patient Medical Records, Charts or Databases for Research Purposes.” Unless written authorization from the subject has been obtained or unless the data will be de-identified (please refer to Policy HI 1201), anyone who is not “Affiliated with an Aurora Facility” (defined below) must also obtain a Facilitator as set forth in Policy FO 301. The IRB shall review all such requests to ensure compliance with state and federal law regarding patient privacy.

1.1. Definitions

Terms used in this policy, but not defined herein shall have the meanings set forth in the Glossary.

1.1.1. **“Affiliated with an Facility”** means any individual who is an employee, a member of medical staff or an allied health professional on the medical staff, of such Facility. This term includes any individual conducting research who is an employee, a member of the medical staff or an allied health professional on the medical staff of a hospital, clinic, physician group or other entity that has entered an affiliation agreement with the Facility.

1.1.2. **“Behavioral (mental) health records”** means records generated by a hospital unit or clinic that provides treatment of alcoholic, drug dependent, mentally ill or developmentally disabled persons and is a “treatment facility” under Wisconsin Statutes, Chapter 51.

1.2. Specific Policies

1.2.1. Request to Access Existing Medical Records, Charts or Databases for Research or Related Activities.

An investigator who desires to access medical records, charts or databases for research or in a manner preparatory to research (e.g. to determine the feasibility of conducting a research protocol or identify prospective research subjects) must submit to the IRB a Form SC 502-A. Approval of Form SC502-A must be obtained prior to accessing the medical records, charts and/or databases. The following information will be requested:

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- (A) The titles/roles of individuals who will have access to the Protected Health Information (PHI)
- (B) A detailed description of the purpose of the research study or research activity;
- (C) The specific PHI being requested (e.g., the age, sex, diagnosis, dates of admission, device number, lab data and other information necessary for the study.);
- (D) Whether the protected health information being used and disclosed is de-identified;
- (E) Whether the investigator is Affiliated with the Aurora Facility where the medical records, charts and databases are maintained;
- (F) Whether the access is preparatory to research (if so the investigator must comply with Section 1.7 of Policy HI 1201);
- (G) Whether the investigator is solely accessing protected health information of decedents. (If so, the investigator is required to meet the requirements set forth in Section 1.8 of Policy HI 1201.);
- (H) Whether the investigator is requesting a waiver of authorization by the research subjects in accordance with Section 1.5 of Policy HI 1201;
- (I) Whether the investigator intends to publish the results of the research study to a third party or the public;
- (J) Provide written assurances of compliance with Section 1.4 of Policy HI 1201- when the subject’s authorization is not being obtained prior to accessing the protected health information. (See also Section 1.2.3.C below.)

1.2.2. Behavioral Health Records

When dealing with records from a “treatment facility” (for a listing of these facilities within Aurora Health Care see the Guidance Document On Using Mental Health Records for Research on the Aurora IRB web site), the authorization to use/disclose patient information must specifically include authorization for mental health and AODA (Alcohol and Other Drug Abuse) records and comply with applicable legal requirements.

1.2.3. Investigators Eligible to Request Access to Medical Records, Charts and Databases for Research or Research Related Activities.

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Unless written authorization from the subject has been obtained or the data will be de-identified, only investigators who are Affiliated with the Aurora Facility at which the patient health care records are maintained may request access to the PHI for research purposes.

(A) Expedited versus Full IRB Review. The Senior IRB Chair or his/her designee will review the Form SC 502-A and shall conduct, or appoint an IRB member to conduct, an expedited review of the proposed research activity in accord with Policy RR 401, or place the request to access PHI on the agenda to be reviewed by all members of the Aurora IRB at its next meeting.

(B) Review Under HIPAA. The Aurora IRB will first review the request in accordance with Policy HI 1201 to determine whether the information sought can be used or disclosed pursuant to one of the following: (A) a patient's authorization; (B) consideration as to whether the information requested could be de-identified; (C) consideration as to whether the information requested could be a limited or data sets; or (D) a determination that an IRB waiver of authorization can be granted.

(C) Review Under State Law. The Aurora IRB will not require an investigator to obtain the authorizations from the patients to access patient health care records when conducting a records research study if such access is allowed pursuant to HIPAA and Wis. Stat. 146.82(2)(a)(6) or 51.30(4)(b)3 of the Wisconsin Statutes and Policy HI 1201.

(D) Notification of Final IRB Determination. The IRB will notify the investigator in writing of its decision in accordance with Policy RR 402. If approved, the IRB may request that the investigator submit an annual continuing review report as set forth in Policy RR 404. However, unless requested by the IRB, an annual continuing review report is not required. The IRB shall send the Health Information Management (Medical Records) Department of the respective Aurora Facility a completed Form SC 502-A indicating IRB approval and other information that needs to be relayed to the Health Information Management Department.

The Health Information Management (Medical Records) department of the particular Aurora Facility is responsible for ensuring that only those positions/individuals identified by the investigator on the approved SC 502-A form will have access to PHI.

1.2.4. Re-Disclosure of PHI or Limited Data Sets by Investigator Once Access by an Aurora Facility Has Been Permitted.

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(A) Limited Data Sets. If an investigator has obtained access to one or more Limited Data Sets pursuant to a Data Use Agreement, only those releases which comply with the Data Use Agreement are permitted.

(B) PHI. An investigator may re-release PHI he/she has obtained which has been de-identified in accordance with Section 1.4.1 of Policy HI 1201 or pursuant to an authorization signed by the subject or his/her legally authorized representative.

Caveat* If the investigator’s access was determined by the IRB to be “preparatory to research” the investigator may not remove PHI from the Aurora Facility and consequently may not re-disclose the PHI. (see Policy HI 1201 section 1.7).

1.2.5. Disclosure of Final Product.

In any event, any final product of the research study (i.e., article or case report) that is intended to be published to the public generally or specific third parties must be de-identified in accordance with Section 1.4.1 of Policy HI 1201.

2. SCOPE

This SOP applies any time a request for access to PHI of an Aurora Facility is made for the purpose of research.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR part 160 and 164

45 CFR 46.111(7)

21 CFR 56.111(7)

WI 146.82(2)6.

WI 51.30(4)(b)3.

The list of certified mental health facilities can be found on the WI DHFS Website (http://dhfs.wisconsin.gov/bqaconsumer/AODA_MH/AODAmhFacility.pdf)

4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 401

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SOP 402

SOP 404

SOP 1201