

SOP: SC 1202 Version No.: 3 Effective Date: 7/23/07	HONEST BROKER	Supercedes Document Dated: 5/17/07
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1. POLICY

It is the policy of the Research Subject Protection Program (RSPP) of Aurora Health Care to comply with the Health Insurance Portability and Accountability Act (HIPAA) and Wisconsin state law as they relate to the use and disclosure of protected health information (PHI), and the de-identification of PHI for the purpose of research. Terms used in the policy, but not otherwise defined, shall have the same meaning as those terms in 45 CFR §160.103 and §164.501

1.1. Definitions

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

1.1.1. **“Honest Broker”** means an individual who will collect and provide de-identified PHI to research investigators in such manner whereby it would not be reasonably feasible for the investigators or others to identify the patients/participants directly or indirectly.

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

1.1.3. **“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 a entity governed by HIPAA in its role as an employer.

1.2. Specific Policies

1.2.1. HIPAA and Wisconsin law permit Aurora to de-identify PHI. Once de-identified, this information may be used and disclosed to principal and sub-investigators for the purpose of research following review and acknowledgment by the Aurora Institutional Review Board (“IRB”).

1.2.2. PHI shall be de-identified by an Aurora Honest Broker. An Honest Broker is an individual who will collect and provide de-identified PHI to research investigators in such manner whereby it would not be reasonably feasible for the

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investigators or others to identify the patients/participants directly or indirectly. Re-identification linkage codes may be incorporated by the Honest Broker that would permit information collation or the incorporation of additional information, however the information linking the re-identification code to the patient's identity must be maintained by the Honest Broker and may not be disclosed to the recipient of the de-identified information.

1.2.3. PHI may also be provided to an investigator in the form of a limited data set, following approval by the Aurora IRB. A limited data set may include certain identifiers that would be excluded in a fully de-identified data set. A limited data is PHI, which excludes specific direct identifiers of the individual, or of relatives, employers, or household members of the individual. See SOP 1201. If a limited data set is to be provided to an investigator, the investigator must first execute a Data Use Agreement with Aurora. This agreement must be approved and signed by Aurora's Chief Privacy Officer.

1.2.4. It is possible that the data provided by the Honest Broker may lead the Investigator to the development of a separate research protocol for which this subset of patients may qualify. In such cases, the Investigator will submit a research protocol to the Aurora IRB for review. If the protocol is approved, it is possible for the Honest Broker, acting as an agent of Aurora Health Care, to approach this patient subset, seeking the patient's authorization to be contacted by a member of the research team who in turn will inquire whether that patient would be interested in learning more about the research protocol. This activity is analogous to a "Preparatory to Research" activity, however only the Honest Broker has access to the patient's protected health information until such time as that patient authorizes a contact from the research staff.

1.3. Procedure

1.3.1. For an individual to act as an Honest Broker for Aurora, the individual must be certified pursuant to the following process:

(A) The individual must be an Aurora employee.

(B) The individual must submit an Honest Broker Request to Review Medical Records for Research Purposes to the Aurora IRB, form SC 1202-A. The Aurora IRB will review the form. By signing the Honest Broker Request to Review Medical Records for Research Purposes to the Aurora IRB the honest broker assures he/she will abide by all relevant Aurora and IRB policies and procedures, including adherence to the Honest Broker certification criteria.

(C) Aurora's Chief Privacy Officer will confirm that the Honest Broker applicant has completed the following requirements:

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(1) Completion of training regarding de-identification and limited data sets.

(2) Written documentation of the processes and/or systems that will be used to develop de-identified data sets and limited data sets.

(3) Written documentation regarding the security and management of PHI in the Honest Broker's possession during the performance of Honest Broker duties.

(4) Written documentation of the processes that will be used to create and retain documentation related to all Honest Broker duties performed (IRB approval, recipient of information, what was provided, etc.).

1.3.2. The Honest Broker shall adhere to the following requirements:

(A) Upon receipt of a request for de-identified data or a limited data set, the Honest Broker shall confirm the study has been reviewed and acknowledged by the Aurora IRB.

(B) An Honest Broker must adhere to all the terms and conditions specified by the Aurora IRB.

(C) If a limited data set is requested, the Honest Broker must obtain and retain a copy of the signed Data Use Agreement.

1.3.3. An Honest Broker's failure to abide by this policy may result in disciplinary action pursuant to Aurora Health Care Policy #4, Disciplinary Policy, and IRB Policy 601, Noncompliance Policy.

2. SCOPE

This policy applies to any research studies conducted at any Aurora Facility in which an Honest Broker will collect and provide de-identified PHI to research investigators.

3. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR part 160 and 164

4. REFERENCES TO OTHER APPLICABLE SOPS

SOP 1201