AURORA Research Subject Protection Program (RSPP) GUIDANCE DOCUMENT

Obtaining a Waiver of Authorization for the Use and/or Disclosure of Protected Health Information for Research

PURPOSE
To provide guidance on the process for requesting a waiver or alteration of authorization for research purposes from the Aurora Institutional Review Board (IRB).

REQUIREMENTS
1. Per Aurora Health Care (AHC) system policy #140 [USE AND/OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH] Aurora may use and/or disclose, or allow a researcher to use and/or disclose a research subject’s PHI for the purpose of research or research-related activities when
   a. authorization is obtained from the research subject or their legally authorized representative;
   b. a waiver or alteration to obtain authorization meeting the requirements at 45 CFR 164.512(i)(1)(i)(A&B) is obtained from a privacy board or Institutional Review Board (“IRB”) for a specific research activity;
   c. a representation that the use and/or disclosure of PHI for a review preparatory to research is obtained;
   d. a representation that the use and/or disclosure of PHI for research on decedents;
   e. the PHI disclosed is a limited data set and Aurora enters into a DUA with the data recipient; or
   f. the PHI is de-identified in accordance with 45 CFR 164.514(b) and system policy #141 [USE AND OR DISCLOSURE OF PROTECTED HEALTH INFORMATION].

2. To request a Waiver or alteration of Authorization, the researcher must complete RSPP Form 502.3 [Waiver or Alteration of Authorization Request] and submit it to the Aurora IRB.
   a. Adequate information must be provided by the researcher in response to the questions on this form for the IRB to determine that the waiver of authorization criteria at 45 CFR 164.512(i)(2) are met.

GUIDANCE

Waiver or Alteration of Authorization Request.

To request a waiver or alteration of authorization of the Aurora IRB, RSPP form 502.3 [Waiver or Alteration of Authorization Request] must be accurately and appropriately completed, and submitted to the Aurora RSPP office.

NOTE: For exempt research submissions, the current Aurora Exempt form (v. 8/6/18) includes a waiver of authorization request. You do not need to include a separate Form 502.3 should you wish to request a waiver or alteration of authorization for such studies.

   a. A waiver or alteration of authorization may be requested when the use and/or disclosure of PHI involves no more than a minimal risk to the privacy of research subjects, the research could not practicably be conducted without the waiver, and the research could not practicably be conducted without access to PHI.
For example, waivers of authorization are most often used in research that solely includes the use (viewing/collection) of non-sensitive patient medical records for a large number of patients with whom you do not have direct contact (that is, chart review studies). These studies often meet the regulatory criteria for a waiver of informed consent.

Alterations of authorization most often include situations where it is impracticable to obtain the subject’s documentation of authorization – that is, when the signature of the subject on the authorization cannot be obtained. An example of such would include the use of a phone consent/authorization. An alteration of authorization typically coincides with a request for an altered informed consent process.

b. Waivers or alterations of authorization are typically not approved by the IRB when the subject’s PHI is to be used in the research AND the researcher has face-to-face contact with the subject.

c. The responses provided on Form 502.3 should be related to the research study under review. Care should be taken so that accurate information is provided. Submissions will be returned if inaccurate or non-study specific responses are provided.

d. Form 502.3 requires that the submitter:

i. describe the patient health information that will be used to complete the research activity.

1. Categories of patient information should be listed. For example, patient demographic information, lab/test results, hemodynamic data, scheduling information, etc may be listed.

   Approximate/general time frames should be provided in the description of the patient information – for example: lab results related to the patient’s diagnosis of cancer, lab results for the last 10 years, hemodynamic data related to the previously conducted right heart catheterization, information about the patient’s next scheduled visit, etc.

2. A response that “the entire patient medical record” will be used is NOT typically acceptable. If you feel that you must use the entire patient medical record in order to complete the research activity, you must provide a justification of the need. Remember HIPAA requires that only the “minimum necessary” PHI may be used/disclosed in any research activity. You will need to justify why the entire medical record is the “minimum necessary”.

ii. consider the type/amount of PHI that is being requested to be used in the research activity. The submitter will be asked to document that the requested PHI is the “minimum necessary” to meet the goals of the research activity.

iii. provide justification as to why it is not feasible (practicable) to conduct the study without the use of PHI.

   1. A response that indicates that the PHI is “required by the research protocol” is not sufficient.

   2. Consider the research activity to be completed under the waiver of authorization (e.g. determining eligibility). Then consider the categories of
patient information that are listed in question “F”. Then justify why that information is needed. For example, if the research activity under review is eligibility determination, the patient’s use of prohibited medication must be ascertained. This requires that the patient’s current medications be reviewed.

iv. provide justification as to why it would not be feasible (practicable) to conduct the research without the waiver or alteration of authorization.

1. Practicability should not be determined solely by considerations of convenience, cost, or speed. That is, you should not request a waiver of authorization merely because it is faster/easier than contacting the potential subject(s), and obtaining his/her authorization for the PHI use/disclosure.

2. Examples are provided on the form. Please give careful consideration to the options listed, and provide the best response(s) for your study.

v. provide the plan for protecting subject identifiers from improper use/disclosure, as well as the plan for destruction of subject identifiers at the earliest opportunity.

1. This question addresses the requirement for the IRB to determine that the use/disclosure involves no more than minimal risk to the privacy of the subject.

2. Examples are provided on the form. Please give careful consideration to the options listed, and provide the best response(s) for your study.

e. If PHI is to be released to a non-Aurora team member (a disclosure of PHI) under the waiver of authorization, there are questions on the form that must be addressed.

i. Disclosures under a waiver of authorization or representation must be accounted for per System Policy 140, section 5.7.

f. By signing Form 502.3, the researcher is representing that:

i. the use and/or disclosure of PHI is needed to conduct the research;

ii. the PHI that will be used or disclosed is the minimum necessary to conduct the research; and

iii. the PHI will not be reused or disclosed to another person or entity except as permitted by the HIPAA Privacy Rule.

REFERENCES

Aurora RSPP informed consent/authorization template

HHS HIPAA for Professionals: https://www.hhs.gov/hipaa/for-professionals/index.html

System Policy 140 - Use and/or Disclosure of Protected Health Information for Research

RSPP Form 502.3 - Waiver or Alteration of Authorization Request