TITLE: Institutional Review Board Waiver of Authorization
WA 1002 Request for Waiver of Authorization Submission Requirements

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Documentation submitted by Investigators for determination of Waiver or Alteration of Authorization must provide IRB members with enough information about a study, the information to be accessed, collected, stored and distributed to assess if it adequately meets the criteria for Waiver or Alteration of Authorization as outlined in the regulations at 45 CFR 164.512(i)(2)(i-v) (See attachment WA 1001 A).

A request for waiver or alteration of waiver will be reviewed when the Office of the IRB staff has determined that the information and materials submitted present an adequate description of the proposed research.

GENERAL PROVISIONS:
Submission Requirements for Initial Review

A request for Waiver or alteration of Authorization must include enough information so the IRB can determine if the use, access to, or disclosure of identifiable health information meets the regulatory criteria for Waiver or alteration of Authorization and is the minimum necessary to accomplish the object of the research.

Therefore, Investigators applying for Waiver or alteration of Authorization must submit:

- Completed initial application with the indication that a waiver or alteration of Authorization is being requested along with completion of the additional questions required to request a waiver or alteration of authorization
- Research protocol or supplemental documentation that includes all elements required for approval of a waiver or alteration of authorization.

A waiver in whole occurs when the IRB determines that no Authorization will be required for a covered entity to use or disclose PHI for a particular research project because certain criteria set forth in the Privacy Rule have been met (see section 164.512(i) of the Privacy Rule). For example, if a study involved the use of PHI pertaining to numerous individuals where contact information is unknown, and it would be impracticable to conduct the research if Authorization were required, an IRB could waive all of the Authorization requirements for research participants if the IRB determined that all of the Privacy Rule waiver criteria had been satisfied. If the IRB approves such a waiver, the receipt of the requisite documentation of the approval permits a covered entity to use or disclose PHI in connection with a particular research project without Authorization. A partial waiver of the Authorization requirements of the Privacy Rule might be requested, for instance, to allow a researcher to obtain PHI as necessary to recruit potential research subjects. For example, even if an IRB does not waive the Authorization requirement for the entire research study, an IRB may partially waive the Authorization requirement to permit a covered entity to disclose PHI to a researcher for the purposes of contacting and recruiting individuals into the study.

An IRB may also approve a request that removes some, but not all, required elements of an Authorization (an alteration). For example, an IRB may alter the Authorization to remove the element that describes each purpose of the requested use or disclosure where, for example, the identification of the specific research study would affect the
results of the study. Before a covered entity could use or disclose PHI pursuant to the altered Authorization, however, it must receive documentation that an IRB determined that all of the Privacy Rule waiver criteria at section 164.512(i)(2)(ii) had been satisfied. Any subsequent use or disclosure of PHI by a covered entity for a different research study would require an additional Authorization, except as permitted without Authorization under section 164.512(i) (e.g., with a waiver of Authorization) or 164.514(e) (i.e., as a limited data set with a data use agreement).

The Privacy Rule establishes the criteria to be evaluated by an IRB in approving an Authorization waiver or alteration. Furthermore, the criteria for an IRB waiver or alteration of the Authorization are consistent with the criteria for IRB waiver of the informed consent requirements contained in the HHS Protection of Human Subjects Regulations. For a covered entity to use or disclose PHI under a waiver or an alteration of the Authorization requirement, it must receive documentation of, among other things, the IRB or Privacy Board's determination that the following criteria have been met:

- The PHI use or disclosure involves no more than minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the IRB to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

- The research could not practicably be conducted without the requested waiver or alteration.

- The research could not practicably be conducted without access to and use of the PHI.

When acting upon a request to waive or alter the Authorization requirement, an IRB must follow the procedural requirements of the HHS Protection of Human Subjects Regulations and/or, if applicable, FDA regulations, including using either the normal review procedures (review by the convened IRB) or the expedited review procedures. The FDA Protection of Human Subjects Regulations also require the IRB to follow its established written procedures whether a request for a waiver or an alteration of the Authorization requirement is considered by a convened IRB or by an IRB under the expedited review procedures.

**Action Taken If Documentation is not Adequate or Additional Information is Required**

If the Office of the IRB staff determines that the submitted documents are not adequate, Investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. Incomplete requests for Waiver of Authorization will not be reviewed.

**REFERENCE:**

45 CFR 164.512(i)(2)(i-v)
OCR Guidance Explaining Significant Aspects of the Privacy Rule http://www.hhs.gov/ocr/hipaa/privacy
21 CFR 56.108
45 CFR 46.108
21 CFR 56.110
45 CFR 46.110

**ATTACHMENTS:**

WA 1002-A Request for Waiver of Authorization (part of the initial application)

**PROCEDURE:**

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<td>IRB Specialist/IRB Coordinator</td>
<td>1. Ensure that the submission materials are complete and there is enough information available to review the request for waiver of authorization.</td>
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IRB Chairperson (or designee)

1. Confirm the submitted materials are complete and there is enough information available to review the request for waiver of authorization.
2. Request return of incomplete submissions to the investigator with notice outlining missing materials or information.
3. Assign and route through appropriate review process depending on the type of study and request. IRB Chairperson (or designee) may complete review process as outlined in WA 1003.

IRB Committee

1. Only review submitted materials if they are complete and there is enough information available to review the request for waiver of authorization.

CONCURRENT CONSENTS:

Institutional Official