

UNIVERSITY AT BUFFALO
HUMAN RESEARCH PROTECTIONS PROGRAM
AUTHORIZATION VALIDITY CHECKLIST
REQUIREMENTS CHECKLIST AND EXAMPLES

This checklist, derived from the Federal HIPAA Privacy regulations, forms the instrument which will be used by the University at Buffalo IRB to determine the validity of authorization forms submitted to it for review. The checklist has been organized according to the sections appearing in the UB HIPAA "Authorization Template" document. They appear below as numbered and bold sections. The checklist also includes example language that may be used in preparing an authorization. All items identified as a *Requirement* must be present in a valid authorization. You should also review the separate "Investigator Guidelines" document for important information on how to use the HIPAA authorization.

Requirement: The authorization must be written in plain language.

1. What protected health information will be collected about you as part of this research study?

Requirement: *Provide a description of the individually identifying information to be used or disclosed that identifies the information in a specific and meaningful fashion.*

Requirement: *Provide a description of each purpose of the requested use or disclosure. (NB: Unspecified future research is not permitted as a purpose under the regulations.)*

Recommended: *Also provide a description of the health information to be accessed or created as part of the research study.*

Recommended: *Describe whether and in what manner the personal identifiers and the health information will be associated. This allows the subject better evaluate how a 'disclosure' of this information may impact their privacy, and will assist in acquiring this information from covered entities when necessary by documenting authorization to collect it.*

Recommended: *Be sure to define general categories of information (e.g., lab results) in addition to any specific details. If you provide only specific details about the information you will be collecting, you will not be permitted to collect any additional information without obtaining additional authorization.*

Method: *Include all of the identifiers from the list below that you will be using with respect to the research subject or of relatives, employers, or household members of the research subject:*

- Names
- Any geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
 - (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
 - (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
- Any elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
- Telephone numbers
- Fax numbers
- Electronic mail addresses
- Social security numbers

- Medical record number
- Health plan beneficiary numbers
- Account numbers
- Certificate / license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic, or code

- information from your medical records:
- new Health Information created from study related tests, procedures, visits, and/or questionnaires as described in the attached consent form.

General description of information:

Example 1 (General description of information):

Individually identifiable information that will be collected about you for the purposes of this study will include your first, middle and last names; the zip code of your primary residence; a telephone number where we may contact you if necessary; and tissue samples that will be labeled with a code that we can use to identify them as coming from you. We will be collecting the following information related to your state of health [*insert: tissue samples, structural images, functional images, lab results, blood samples*]. Your personal information will be combined and stored with your health information.

Example 2 (General description of information):

Individually identifiable information that will be used in this research study includes your name, date of birth and phone number. Your medical records will be reviewed and researchers may need to discuss your health information with your treating physicians, if applicable. Researchers will also generate new health information about you, in the form of _____, as a result of the study. Your personal information will be kept in a locked file in case we need to contact you at a future date. Your personal information will not be part of the research database. Therefore, if the information described in this section were acquired by other entities, they would not directly identify you as the source of this information.

2. Who is authorized to provide and collect this information?

- Requirement:** *The name or other specific identification of the person(s), or class of persons, authorized by this document to make the requested use or disclosure [who is being authorized in this document to release information to the researcher].*

Note: *Be as specific as possible here. The people and in particular the covered entities listed for this requirement must be identified sufficiently to permit them to rely on this HIPAA to release information to the investigator. If covered entities are not listed in this section, the HIPAA regulations prohibit them from using this authorization to provide the requested information.*

- Requirement:** *The name or other specific identification of the person(s), or class of persons, permitted to receive the requested use or disclosure [who on the researcher's team is authorized in this document to request and receive the information from the entity releasing the information].*

Note: *For this section, list classes of people whenever possible. The entities "authorized by this document to make a use or disclosure" (above) can only disclose to the people who are "authorized to make a requested use or disclosure". The HIPAA regulations prohibit covered entities from accepting a request for release of protected health information from anyone not listed in this section.*

- KALEIDA Health, Buffalo NY
 Principal Investigator or listed designee
- ECMC Healthcare Network, Buffalo NY
 University at Buffalo School of Dental Medicine
- Other: _____

Example 1 (Other):

Your information will be obtained directly from you, from your primary physician, Dr. X., or from medical records maintained by Hospital Y. The lead researcher on this project, Dr. Z., may release information collected or generated as part of this study to individuals and organizations listed in question (3) below.

Example 2 (Other):

Dr. X, the researcher responsible for the conduct of this study, or a member of the research staff as designated in writing by Dr. X, may request this information from the places checked above or from the XYZ clinic in Philadelphia, PA. Dr. X. may also release information collected or generated as part of this study to individuals and organizations listed in question (3) below.

3. With whom may your protected health information be shared?

- Requirement:** *The name or other specific identification of the person(s), or class of persons, authorized to receive the requested use or disclosure [who is being authorized in this document to release information to the researcher].*
- Required Statement:** *The authorization must include a statement that there can be no guarantee that identifiable health information will not be re-disclosed by a recipient.*

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

- clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
- the sponsor of this research study, list specific sponsor, cooperative group, etc., or its agents **[insert list]:**
- other medical investigators/centers/institutions participating in this research study **[insert list of centers, institutions]:**
- the following **[insert list of all other specific organizations, people, etc.]**:

Your information may also be shared with individuals responsible for general oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

[Required] All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health

information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

4. How long will this information be kept by the Principal Investigator?

Requirement: An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement "end of the research study," "none", or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

Note: The authorization is no longer valid after the expiration date or event.

Example 1:

<input type="checkbox"/> This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing. [-or-]
<input type="checkbox"/> This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you. [-or-]
<input type="checkbox"/> This authorization will expire and your protected health information collected for the purposes of this study will be destroyed by [date]
[check if applicable] <input type="checkbox"/> Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

5. What are your rights after signing this authorization?

Requirements: The authorization must contain statements adequate to place the individual on notice of the following:

- A statement of the individual's right to revoke the authorization in writing
 - Recommended: a description of how the individual may revoke the authorization.
 - Recommended: a description of how to revoke the authorization with any 3rd party entities relying on it to release PHI
- A statement of exceptions to the right to revoke, if any AND a description of how the individual may revoke the authorization.
 - Permitted exceptions (select one or both):
 - Exception to right to revoke to the extent that the covered entity has taken action based on authorization.
 - Exception to the right to revoke to the extent that the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.
 - A description of how the individual may revoke the authorization.
 - Recommended: a description of how to revoke the authorization with any 3rd party entities relying on it to release PHI

Example 1:

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should

know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

[Insert name and address of individual or position associated with the research study that will be responsible for handling such requests.]

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information. You may also withdraw this authorization directly with those institutions by writing to the following:

[Insert name, address of Privacy Officers of any covered entities from which information is being acquired (information not being provided directly by subject) from #2 above.]

6. What will happen if you decide not to sign this authorization?

Requirement: *State the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on authorization.*

- Circumstances where a condition may be stipulated (select one or more)
 - *A covered health care provider may condition the provision of research related treatment on provision of an authorization for the use or disclosure of protected health information, provided that the consequences to the individual of a refusal to sign the authorization are stated.*
 - *If treatment (payment or health plan enrollment / eligibility) will not be conditioned contingent on signing this authorization, the form must state that “we may not condition treatment, payment, enrollment or eligibility for benefits on receiving this authorization”*
 - *If treatment is provided solely on behalf of a third party, failure to sign this authorization to permit information release to that third party is sufficient reason to deny the treatment.*

Recommended: A statement that the individual has a right not to sign this authorization.

Example 1:

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

#7 is a situational question – must be included if marketing directly to the individual is part of this research protocol:

7. How may your identifiable health information be used to market directly to you?

Note: “Marketing” in this context is using the information to identify and target the individual who is authorizing the disclosure of their individual health information. The term does not apply to general marketing campaigns in which the individual is not targeted via use of the information they disclose with this authorization, or to using the results of the study for general marketing purposes. For more information, see the specific definition of marketing in the instructions.

Requirement: *an authorization must be obtained for any use or disclosure of protected health information is for marketing purposes:*

Requirement: *If any component of the research involves marketing activities for a 3rd party, and there is direct or indirect compensation being provided to support the research as a result, the authorization must state that such remuneration is involved.*

Recommended: Although a HIPAA authorization provides investigators with the authorization to receive information, there is no requirement that a covered entity fulfill requests made by investigators. However, a covered entity is obligated (except in special circumstances) to fulfill a direct request from the subject of the information. Therefore it is strongly recommended that language implementing such a request accompany an authorization. A covered entity generally has 30 days to either fulfill the request, or provide a written explanation of why it will not. Failure to fill a request in accordance with HIPAA requirements constitutes a violation of the regulations. Note that an entity is permitted to charge a fee related to such requests, but fee must be limited to reasonable costs (e.g., labor and supplies to copy, postage).

Example This document constitutes a direct request on my part to the entities identified above to provide the protected health information described in this document in accordance with 45 CFR 164.524 'Access of individuals to protected health information', and authorizes the release of this information to the authorized recipients identified above. Furthermore this document authorizes the recipients identified above to act on my behalf as my personal representative in seeking this information.

Signature requirements

Requirement: Authorization is not valid until signed and dated by the individual or their personal representative.

Requirement: If a personal representative is executing the document, a description of the representatives authority to act for the individual whose protected health information is being authorized for release must provided.