

INVESTIGATOR GUIDELINES

Authorization for the Use of Individually Identifiable Health Information For Research Purposes

Federal regulations require that research subjects sign an "authorization" granting permission to use and disclose their individually identifiable health information for research purposes. The regulations are intended to provide enhanced protection with respect to the privacy and security of an individual's health information. The regulations are contained in the Privacy Rule section of the Health Insurance Portability and Accountability Act (HIPAA).

Individually Identifiable Health Information is defined in the regulations as: a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

The UB IRB website has a list of demographic information considered to be 'identifiers' by HIPAA.

A detailed listing of all requirements of a valid authorization is also available in a document titled "Authorization Validity Checklist" is also available at the UB IRB website. The "Authorization Validity Checklist" delineates the criteria by which the UB IRB will determine the validity of authorization forms submitted to it for review.

Important note: New York State Law sets additional requirements on the disclosure of certain types of information by health care workers, including but not limited to: Cancer Information, Communicable Diseases within New York City, HIV/AIDS, Tuberculosis, Sexual Abuse, Drug Abuse, Births and Deaths, Early Intervention Services, Genetic Information, Alcohol and Substance Abuse, and Mental Health. In situations where research involves such information, State Law requirements, in addition to HIPAA requirements need to be considered. A HIPAA compliant authorization *does not* remove the need to understand and comply with any additional requirements governing disclosures associated with these types of information.

After having an authorization validated by the IRB, there are additional steps an investigator must be aware of regarding the use and processing of authorizations.

These investigator guidelines will help you to:

- choose the authorization option (stand alone or embedded in an informed consent) that will work best for you;
- understand the required elements of a valid authorization
- understand your obligations with respect to "covered entities"
- develop a valid authorization containing all of the required elements using an authorization

Authorization Options

There are several authorization options that will be accepted by UB IRBs for review:

- Researchers may develop an authorization form based directly on the UB and Hospital (KALEIDA Health, ECMC Healthcare network) approved authorization template form and associated investigator instructions.

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- Researchers may choose to include authorization requirements within the body of an expanded informed consent form. There is one exception to the option of combining elements of authorization and informed consent in one document: an authorization seeking access to psychotherapy notes cannot be combined with an informed consent. The researcher should consider the implications of doing this given that
 - The authorization does not expire until its stated expiration date (if any) or the subject revokes.
 - Covered entities are required to maintain copies of individually signed HIPAA authorization. This copy would include the informed consent if the two are combined.
- Each individual research protocol requires a separate authorization (separate, or combined with the informed consent) to be approved by the IRB. A form approved for use in one research protocol *cannot* be used for another research protocol, even if the only change in the form anticipated is the title of the research protocol. New protocols being submitted for approval to the IRB, which are relying on the authorization mechanism, will not be approved without an accompanying authorization also being submitted for review and approval.
- All elements of the authorization must be filled in and fixed, with the form in its final state and ready to accept subject signature, prior to submission for IRB approval. Researchers may not modify the form after receiving IRB approval by checking additional boxes, adding information elements being authorized for disclosure, or in any other way altering the authorization form after it has been approved by the IRB.
- Research subjects must sign both the HIPAA specific *authorization for use of individually identifiable health information* and the customary *informed consent to participate in a research study* forms when the authorization is not combined with an informed consent.
- Sponsor-developed authorization forms or combined informed consent/authorization forms only are acceptable in lieu of the UB template authorization form. These submissions will also require review and approval by the IRB for compliance with the HIPAA Privacy Rule using the “authorization validity checklist” (available separately).

Required Elements of a Valid Authorization

Detailed instructions and examples for determining the validity of an authorization are available in the separate document “Authorization Validity Checklist”. In brief, a valid authorization must address the following Privacy Rule requirements:

- A description that identifies the health information and individual identifiers to be used or disclosed in a specific and meaningful fashion.
- A description of each purpose of the requested use or disclosure, including for the creation and maintenance of a research database or research repository.
- The name of the person(s) or class of persons authorized to make the requested use or disclosure [the covered entity providing the individually identifiable health information, the investigator, etc.];
- The name of the person(s) or class of persons to whom the covered entity may make the requested use or disclosure [the investigator, entities the investigator may disclose the individually identifiable health information to, etc.];
- A statement that individually identifiable health information collected with the authorization may be re-disclosed by a recipient and no longer be protected;
- An expiration date or expiration event for the authorization that relates to the purpose of the use or disclosure.
- The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization. Conditioning of treatment can only occur under specific circumstances.
- The signature and date of the research subject or their personal representative, including a description of a personal representatives authority to act for the subject.

- The individual's right to revoke the authorization in writing and the exceptions to the right to revoke, together with a description of how the individual may revoke the authorization;

The regulations also note that the authorization should be written in plain language and that the researcher is obligated to provide the research subject with a copy of the signed authorization (and informed consent if combined with authorization) form.

Authorization Requirements with Respect to a "Covered Entity"

HIPAA regulations define a **Covered Entity** as a health plan, a health care clearinghouse or a health care provider who engages in any one of a set of electronic transactions defined in the regulations. See the UB IRB WEB site for a listing of commonly encountered covered entities. If you will be using the authorization to access individually identifiable health information from a covered entity there are several critical considerations:

- If an entity will be relying on an authorization to provide individually identifiable health information for a study, the regulations mandate that the entity(ies) must receive a copy of this authorization before they are permitted to disclose individually identifiable health information to the researcher. In general a copy of the entire, fully executed authorization should be delivered to the covered entity's "HIPAA Privacy Officer" unless otherwise indicated:
 - KALEIDA Health: provide copies of signed authorizations to the Supervisor of Health Information Management at each KALEIDA site supplying PHI to the researcher (as of 4/9/2003).
 - ECMC Healthcare Network: HIPAA Privacy Officer, ECMC, 462 Grider Street, Buffalo, NY, 14215 (as of 3/2003)
 - School of Dental Medicine: contact Mike Breene, the HIPAA project manager for SDM, as to appropriate procedure (as of 3/2003)
 - Research occurring in a non-covered entity: PI should maintain signed authorizations on file along with signed informed consent
- Entities relying on an authorization to provide individually identifiable health information for the study must be provided with a dated copy of any written revocation of this authorization that the subject provides to the researcher. Both the researcher and the entities providing individually identifiable health information must halt the flow of individually identifiable health information to the researcher for a subject when they receive a written revocation of this authorization from the subject. It is possible that the entity providing individually identifiable health information will receive the revocation directly from the subject without the researcher's knowledge.
- Entities relying on an authorization to provide individually identifiable health information will not be able to release that individually identifiable health information unless *all* of the required elements in this authorization are present.
- The authorization may not be used to acquire individually identifiable health information after the expiration date or event listed (if any) and is no longer valid after that time.
- This authorization may be used to collect only the individually identifiable health information detailed described 'in a specific and meaningful fashion' in the authorization.
- This authorization is invalid if any of the statements are known to be false by the researchers. Additionally, an entity providing the individually identifiable health information may not release that information based on an authorization that it knows contains false information.