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## **INSTRUCTIONS FOR HIPAA INDIVIDUAL AUTHORIZATION**

A Privacy Rule Authorization is an individual's signed permission to allow a covered entity, including Public Health (DPH), Ambulatory Care Network (ACN) and Health Services Administration (HSA) or any DPH, ACN or HSA employee, to use or disclose the individual's protected health information (PHI) that is described in the Authorization for the purpose(s) and to the recipient(s) stated in the Authorization. This is in addition to an informed consent document which is an individual's agreement to participate in the research study. Federal law permits an Authorization to be embedded within an informed consent document but the IRB recommends that a separate, stand-alone Authorization document be used. The use or disclosure of PHI for the research must be consistent with the Authorization.

The IRB has adopted a suggested form for use in obtaining individual authorizations. This form is included in the IRB's packet of materials for HIPAA compliance. Using this form (deleting any sections that do not apply, as indicated on the form itself) is likely the easiest route. However, you may modify it further or design your own form, as long as it complies with the requirements described below.

The Authorization must be written in plain language. A copy of the signed Authorization must be provided to the individual signing it if the covered entity itself is seeking the Authorization. The Privacy Rule does not specify who must draft the Authorization, so a researcher could draft one suitable to the particular study and study population. The Privacy Rule specifies core elements and required statements that must be included. An Authorization is not valid unless it contains all of the required elements and statements. An Authorization form may also, but is not required to, include additional, optional elements so long as they are not inconsistent with the required elements and statements and are not otherwise contrary to the Authorization requirements of the Privacy Rule.

**Authorization Core Elements** (see Privacy Rule, 45 C. F. R. § 164.508(c)(1))

Description of PHI to be used or disclosed.

1. Names
  2. All geographic subdivisions smaller than a state including street address, city, county, precinct, full zip code
  3. All dates except year including date of birth (with the exception of individuals over the age of 89), admission date, date of diagnosis, discharge date, date of death.
  4. Telephone numbers
  5. Fax numbers
  6. Electronic mail addresses
  7. Social Security numbers
  8. Medical record numbers
  9. Health plan beneficiary numbers
  10. Account numbers
  11. Certificate/license numbers
  12. Vehicle identifiers and serial numbers, including license plate numbers
  13. Device identifiers and serial numbers
  14. Web universal resource locators (URLs)
  15. Internet protocol (IP) address numbers
  16. Biometric identifiers, including finger and voice prints
  17. Full face photographic images and any comparable images
  18. Any other unique identifying number, characteristic or code.
- The name(s) or other specific identification of the person(s) or class of persons authorized to make the requested use or disclosure.
  - The name(s) or other specific identification of the person(s) or class of persons who may use the PHI or to whom the covered entity may make the requested disclosure.
  - Description of each purpose of the requested use or disclosure. Researchers should note that this element must be research study specific, not for future unspecified research.
  - Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms “end of the research study” or “none” may be used for research, including the creation and maintenance of a research database or repository).
  - Signature of the individual and date. If the Authorization is signed by an individual’s personal representative, a description of the representative’s authority to act for the individual.
  - The individual’s right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke his/her Authorization or (2) reference to the corresponding section(s) of the covered entity’s Notice of Privacy Practices.
  - Notice of the covered entity’s ability or inability to condition treatment, payment, enrollment, or eligibility for benefits on the Authorization, including research-related treatment, and, if applicable, consequences of refusing to sign the Authorization.<sup>1</sup>

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<sup>1</sup> In other words, the Authorization must make clear whether or not any treatment or services will or will not be given if the individual exercises his/her right not to sign the Authorization. If the research centrally involves a treatment, then such research-related treatment may reasonably be withheld from a person who does not sign an Authorization (just as it would be

- The potential for the PHI to be re-disclosed by the recipient and no longer protected by the Privacy Rule. This statement does not require an analysis of risk for re-disclosure but may be a general statement that the Privacy Rule may no longer protect health information.<sup>2</sup>

**Additional California-specific Required Elements.** The HIPAA Privacy Rule was intended to provide a national minimum standard for privacy protection and does not invalidate any previously existing and more stringent privacy protections afforded by state law or local statute. Therefore, a valid California Authorization must include, if applicable, a separately initialed consent to release:

- HIV test results.
- Mental health treatment records governed under state law (including mental health records relating to involuntary or voluntary mental health treatment).
- Substance abuse (drug and alcohol) treatment records.

A research subject may revoke his/her Authorization at any time. However, a covered entity may continue to use and disclose PHI that was obtained before the individual revoked his or her Authorization to the extent that the entity has taken action in reliance on the Authorization. In cases where the research is conducted by the covered entity, this would permit the covered entity to continue using or disclosing the PHI as necessary to maintain the integrity of the research, as, for example, to account for the subject's withdrawal from the research study, to conduct investigations of scientific misconduct, or to report adverse events.

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if the person refused to sign an informed consent). If on the other hand the research does not involve treatment or when the covered entity is not providing health care solely for the purpose of collecting PHI for research purposes, then treatment or care cannot be withheld from anyone who declines to sign an Authorization (again similar to a person who declines to consent to participate in a research study at a health care provider).

<sup>2</sup> If an Authorization permits disclosure of PHI to a person that is not a covered entity (such as a sponsor or funding source of the research), the Privacy Rule does not continue to protect the PHI disclosed to the noncovered entity. However, other applicable Federal and State laws as well as agreements between the disclosing covered entity and the PHI recipient may establish continuing protections for the disclosed information.