

Authorization Guidance

The Privacy Rule permits the use and disclosure of protected health information for research purposes when a research participant authorizes the use or disclosure of information about him or herself. For example, a research participant's authorization will typically be sought for most clinical trials and some records research.

To use or disclose protected health information with authorization by the research participant, the covered entity must satisfy the requirements of 45 CFR 164.508, which are contained in the authorization form and described below.

1. **Description of the information to be used and disclosed.** List all of the protected health information* to be collected for this protocol/study. This includes demographic information, results of physical exams, blood tests, x-rays, and other diagnostic and medical procedures as well as medical history.
2. **Who may use or disclose this information.** List who may use and/or disclose PHI (e.g. Principal Investigator, study coordinator)
3. **Who may receive the information.** List who may receive the PHI, (e.g., sponsoring company, FDA, IRB, publications, monitors from the sponsoring company, collaborators etc.) this list needs to be inclusive because it will be necessary to account for any disclosures outside the list.
4. **Purpose of the use or disclosure.** You may utilize statements from the purpose section of the consent. (Modify this list as appropriate- delete or add items as necessary)
5. **Expiration date or event.** No expiration date would be used in the case of a research study utilizing a database or repository.
6. **Right to revoke authorization.** The privacy rule requires that a subject have the ability to revoke a previously signed authorization. Researchers must honor the request, except to the extent they have already relied on the permission. Researchers may continue to use data that was obtained prior to the revocation to maintain the integrity of the study or if the data has already been included in analysis, this analysis can be maintained. The researcher and the IRB must be notified of such revocation. Failure to honor a revocation results in noncompliance subject to IRB policy.
7. **Statement that re-disclosures are no longer protected by the HIPAA Privacy Rule**
While efforts will be made to ensure privacy and confidentiality of health information once it is disclosed to a third party it may be re-disclosed by the recipient and no longer protected.
8. **Right to refuse to sign authorization**
The subject may not participate in a research study if they refuse to sign the authorization. Treatment associated with the research may be conditioned on signing the authorization. Treatment, payment or enrollment in any health plan or eligibility for benefits will not be affected if they refuse to sign the authorization.
9. **Suspension of right to access personal health information**
The right to access PHI will be suspended during the course of the study. This access will be reinstated at the conclusion of the study.
10. **Notice of Privacy Practices** If the individual has not received a Notice of Privacy Practices they must be provided one and the acknowledgement placed in the medical record, if no medical record exists the acknowledgement should be placed in the research record.

If you have questions please contact the HS IRB office: 882-3181 or C IRB 882-9585.

* PHI: Individually Identifiable health information transmitted or maintained in any form (electronic, paper or oral communication) that relates to the past, present or future physical or mental health or conditions of an individual.