



WORKSHEET: HIPAA Authorization

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The purpose of this checklist is to provide support for IRB staff when evaluating whether a HIPAA authorization is valid. IRB staff are to consult this worksheet to review HIPAA authorizations. This worksheet is to be used. It does not need to be completed or retained.

1 CORE ELEMENTS (Check if “Yes”. All must be checked)

<input type="checkbox"/>	A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
<input type="checkbox"/>	The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
<input type="checkbox"/>	The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.
<input type="checkbox"/>	A description of each purpose of the requested use or disclosure.
<input type="checkbox"/>	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.)
<input type="checkbox"/>	Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual must also be provided.

2 REQUIRED STATEMENTS (Check if “Yes”. All must be checked)

<input type="checkbox"/>	The individual’s right to revoke the authorization in writing.
<input type="checkbox"/>	The authorization either: <ul style="list-style-type: none"> • Describes the exceptions to the right to revoke the authorization. • References the Notice for Privacy Practices for Protected Health Information which describes the exceptions to the right to revoke the authorization.
<input type="checkbox"/>	The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either of the following: <ul style="list-style-type: none"> • The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization. • The consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.
<input type="checkbox"/>	The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this authorization.

3 OTHER REQUIREMENTS (Check if “Yes”. All must be checked)

<input type="checkbox"/>	The authorization is written in plain language.
<input type="checkbox"/>	The individual will be provided with a copy of the signed authorization.
<input type="checkbox"/>	If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.
<input type="checkbox"/>	The authorization is either a separate document or incorporated into the written consent document for research.
<input type="checkbox"/>	No material information in the authorization is known to be false.