



WORKSHEET: HIPAA Authorization		
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HRP-330	10/13/2017	1 of 1

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)

- A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.
- The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.
- 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.
- A description of each purpose of the requested use or disclosure.
- 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.)
- 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)

- The individual's right to revoke the authorization in writing.
- The authorization either:
 - 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.
- The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either of the following:
 - 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.
- 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)

- The most recent version of the UM HIPAA Authorization (Form B) is included.
- The authorization is written in plain language.
- The individual will be provided with a copy of the signed authorization.
- 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.
- The authorization is either a separate document or incorporated into the written consent document for research.
- No material information in the authorization is known to be false.
- If using UM HIPAA Authorization (Form B), the study team has completed all required sections appropriately:
 - Header populated with identifying information for the study (pages 1 and 2)
 - Sites indicated (UM, JHS, other) consistent with study protocol and new study application (pages 1 and 2)
 - Types of health information to be used or disclosed indicated in Section 1 consistent with study protocol
 - Recipients of PHI listed as per Sections 2 and 4
 - Study team contact information included in Section 7