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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. | |
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| 1. CORE ELEMENTS. A valid authorization under this section must contain at least the following elements: (All must be “Yes”) | |
| Yes  No | A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion. |
| Yes  No | The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure. |
| Yes  No | 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. |
| Yes  No | A description of each purpose of the requested use or disclosure. (The statement “at the request of the individual” is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.) |
| Yes  No | 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.) |
| Yes  No | 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. |
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| 1. REQUIRED STATEMENTS. In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following: (All must be “Yes”) | |
| Yes  No | The individual's right to revoke the authorization in writing. |
| Yes  No | Either of the following is YES:   * The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or * To the extent that the information in statement (A) above is included in the “Notice of Privacy Practices for Protected Health Information.”. |
| Yes  No | 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 when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or * The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization. |
| Yes  No | 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. |
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| 1. OTHER REQUIREMENTS: (All must be “Yes”) | |
| Yes  No | The authorization is written in plain language. |
| Yes  No | The individual will be provided with a copy of the signed authorization. |
| Yes  No | 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. |
| Yes  No | The authorization is either a separate document or incorporated into the written consent document for research. |
| Yes  No | No material information in the authorization is known to be false. |