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| The purpose of this checklist is to help you evaluate your proposed HIPAA Authorization before IRB submission. | |
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| 1. CORE ELEMENTS. All these elements must be included in your HIPAA Authorization: | |
|  | 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. (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.) |
|  | 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. |
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| 1. REQUIRED STATEMENTS. In addition to the core elements, your authorization must inform potential participants of the following: | |
|  | The individual's right to revoke the authorization in writing. |
|  | * 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 above is included in the “Notice of Privacy Practices for Protected Health Information.”, a reference to the covered entity’s notice |
|  | 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 164.508 applies; or * The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of section 164.508, 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. |
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| 1. OTHER REQUIREMENTS | |
|  | The authorization must be written in plain language. |
|  | You must provide the individual with a copy of the signed authorization. (State this in your 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 (for non-VA studies; see VA rules for VA studies) |
|  | No material information in the authorization is known to be false. |