

WORKSHEET: HIPAA Waiver of Authorization

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This worksheet is used to grant a waiver or alteration of authorization to use or disclose protected health information for <Research as Defined by HHS>.

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1. Criteria for Waiver or Alteration of Authorization (see Footnote 1) *45 CFR §164.512(i)(1)(ii)*

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| 1.1 | <input type="checkbox"/> | The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals. |
| 1.2 | <input type="checkbox"/> | There is an adequate plan to protect the identifiers from improper use and disclosure. |
| 1.3 | <input type="checkbox"/> | There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law. |
| 1.4 | <input type="checkbox"/> | There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the protected health information would be permitted. |
| 1.5 | <input type="checkbox"/> | The research could not practicably be conducted without the waiver or alteration. |
| 1.6 | <input type="checkbox"/> | The research could not practicably be conducted without access to and use of the protected health information. |
| 1.7 | <input type="checkbox"/> | Access to the protected health information is necessary. |

2. Notes

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3. Footnotes

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| 3.1 | <input type="checkbox"/> | Communicate to the covered entity the following documentation of the alteration or waiver of authorization signed by the <IRB Chair> or <Designated Reviewer>: (i) A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved; (ii) A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the above criteria; (iii) A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph 45 CFR §164.512(i)(2)(ii)(C); of this section; |
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