



Description of Technical Amendment (February 22, 2017) to VHA Handbook 1200.05: Requirements for the Protection of Human Subjects in Research

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| <p>Description of Amendment: Removes requirement in Paragraph 23(4) of VHA Handbook 1200.05 for the IRB to review the HIPAA authorization to ensure that the consent document, protocol, and authorization are consistent. This was a VA specific requirement that was removed to address issues with VA Facilities using IRBs that do not review written HIPAA authorizations, such as the National Cancer Institute (NCI) Central IRB.</p> | |
| <p>Non-Amended VHA Handbook 1200.05</p> | <p>Amended (February 22, 2017) VHA Handbook 1200.05</p> |
| <p><u>Paragraph 23. HIPAA AUTHORIZATION:</u></p> <p>a. <u>Written Authorization.</u> In accordance with the HIPAA Privacy Rule at 45 CFR 164.508, a written authorization signed by the individual to whom the information or record pertains, is required when VA medical facilities need to access, collect, develop, use, or disclose individually-identifiable health information for a purpose other than treatment, payment, or health care operations (e.g., research) unless there is legal authority (e.g., waiver, limited data set with data use agreement, etc.) to disclose such information (see VHA Handbook 1605.1). (1) VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research, must be used to document the authorization. The authorization may not be embedded in the consent form;</p> <p>(2) The information in the authorization must not contradict any provisions of the protocol, informed consent, or other documents submitted for IRB approval;</p> <p>(3) All potential disclosures to a non-VA entity must be listed within the authorization;</p> | <p><u>Paragraph 23. HIPAA AUTHORIZATION:</u></p> <p>a. <u>Written Authorization.</u> In accordance with the HIPAA Privacy Rule at 45 CFR 164.508, a written authorization signed by the individual to whom the information or record pertains, is required when VA medical facilities need to access, collect, develop, use, or disclose individually-identifiable health information for a purpose other than treatment, payment, or health care operations (e.g., research) unless there is legal authority (e.g., waiver, limited data set with data use agreement, etc.) to disclose such information (see VHA Handbook 1605.1). (1) VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research, must be used to document the authorization. The authorization may not be embedded in the consent form;</p> <p>(2) The information in the authorization must not contradict any provisions of the protocol, informed consent, or other documents submitted for IRB approval;</p> <p>(3) All potential disclosures to a non-VA entity must be listed within the authorization;</p> |

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| <p>(4) The IRB does not approve the authorization but does review it to ensure the consent document, protocol, and authorization are consistent;</p> <p>(5) The PO must review the HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements before the PI can begin to use or collect the individual's information based on an approved research protocol (see VHA Handbook 1605.1);</p> <p>(6) Data disclosed under a properly executed HIPAA authorization must be securely transferred according to VA information security requirements;</p> | <p>(4) The PO must review the HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements before the PI can begin to use or collect the individual's information based on an approved research protocol (see VHA Handbook 1605.1);</p> <p>(5) Data disclosed under a properly executed HIPAA authorization must be securely transferred according to VA information security requirements;</p> |
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The amended VHA Handbook 1200.05 can be found at http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3052 and on the VHA Publications Websites:

<http://vaww.va.gov/vhapublications/>

<http://www.va.gov/vhapublications/>

Please send any questions regarding this technical amendment to the ORD Regulatory Mailbox at VHACOORDRegulatory@va.gov.