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| **VA HIPAA Authorization Requirements When Using an Independent (Commercial) IRB****June 28, 2023**The following instructions with language for VA HIPAA authorizations for research when combined with the informed consent document (ICD) have been provided in this table. Please use this table to also determine if a standalone written HIPAA authorization for research (VA Form 10-0493) is required or whether the authorization language can be combined with the ICD. **VA Facilities must include the VA authorization language into the informed consent document as a replacement for the model authorization language where applicable or use the VA Form 10-0493 as part of independent IRB application requirements. If there are questions regarding this language, please email** **vhacoordregulatory@va.gov****.** **If the study involves a standalone written HIPAA authorization (VA Form 10-0493),** **do not submit the VA Form 10-0493 to the independent (commercial IRB)** |
| **Policy or Law** | **Citation and Topic** | **Policy Language**  | **Language Provided to the Independent IRBs** | **Comments** |
| VHA Directive 1200.05(2)VHA Directive 1605.03 (2) | Paragraph 23.a.(1)Appendix D, Paragraph 1.k.(5)(b)(2)(f)Authorization Requirements and Authorization language when the ICD and authorization is combined: entities for use or disclosure of protected health information. | (1) Authorization must meet all VHA Privacy requirements detailed in VHA Directive 1605.01. The written HIPAA authorization may either be a standalone document or combined with the research informed consent approved by the IRB. If a standalone document is used as the written HIPAA authorization, VA Form 10-0493: Authorization for Use and Release of Individually Identifiable Health Information Collected for VHA Research located at <http://vaww.va.gov/vaforms/medical/pdf/10-0493-fill.pdf>must be used (NOTE: This is an internal VA Web site that is not available to the public. | When the Authorization Language is combined with the informed consent to be approved by the IRB, the following authorization language is provided:There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your ‘authorization,’ for the use and disclosure of information protected by the Privacy Rule.The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, date of birth, and information from your medical records such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment.  | Authorization language may only be combined with the informed consent to be approved by the IRB if either condition is met:#1. No optional banking of identifiable data or biospecimens is involved, OR#2. The IRB does not approve the use of subject’s legally authorized representatives (LARs) to consent for the subject. **If there is optional banking of identifiable data or biospecimens, the HIPAA authorization language for research cannot be combined with the informed consent document.** **If the IRB has approved the use of subjects’ LARs to consent, the HIPAA authorization language for research cannot be combined with the informed consent document.**  |
| **Policy or Law** | **Citation and Topic** | **Policy Language** | **Language Provided to the Independent IRBs** | **Comments** |
|  | Authorization language when the ICD and authorization is combined: entities for use or disclosure of protected health information. |  | The research team may also need to disclose the information to others as part of the study progress. Others may include the following: ***{MODIFY AS APPROPRIATE: ... Food and Drug Administration, Office (FDA), Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO); Sponsors; Contractors, Affiliates as appropriate}****,* the Institutional Review Board, and the local VA medical facility Human Research Protections Program.Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.  |  |
|  | Authorization language when the ICD and authorization is combined: access to research records when the study is being conducted. |  | ***Include the following language verbatim depending upon the choice made:***While this study is being conducted you ***(Choose one of the below to complete the sentence)***will have access to your research related health records ***OR***will not have access to your research related health records.This will not affect your VA healthcare, including your doctor’s ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed. |  |
| **Policy or Law** | **Citation and Topic** | **Policy Language** | **Language Provided to the Independent IRBs** | **Comments** |
|  | Authorization language when the ICD and authorization is combined: revocation. |  | You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility, or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.If you revoke this authorization, **(insert name of VA Site Investigator)** and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time. |  |