Veterans Health Administration
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VA Specific Requirements for Informed Consent and HIPAA Authorizations When Using a Commercial IRB
September 14, 2020

The following instructions with language for VA informed consent and VA HIPAA authorizations have been provided to commercial IRBs approved by the VHA Office of Research and Development to review and approve VA research. VA Facilities are to include VA informed consent language into the commercial IRB informed consent document, where applicable. It is the responsibility of the VA Facilities to include the language prior to uploading their local VA Facility informed consent documents and HIPAA authorizations as part of the application process.

Policy or Law	Citation and Topic	Policy Language	Language Provided to the Commercial IRBs	Comments
VHA Directive 1200.05	Paragraph 17.d.(10) VA Treatment for Research-Related Injuries	A statement that VA will provide treatment for research related injury in accordance with 38 CFR 17.85. **NOTE:** *VA's statutory requirement in 38 CFR 17.85 apply regardless of inclusion of the information as part of the informed consent process.*	If you are a VA study participant, the VA (not you or your insurance) will provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the (***insert local name***) VAMC or arrangements may be made for contracted care at another facility. You have not released this institution from liability for negligence. In case of research related injury resulting from this study, you should contact your study team. If you have questions about compensation and medical treatment for any study related injuries, you can call the medical administration service at this VA Medical Center at (***insert phone number***). If you want to speak to someone who is not a member of the study to discuss problems, ask questions or voice concerns, you can call (***fill in numbers***).	This ORD policy requirement is a VA-specific element of informed consent. Do not include this language if the VA informed consent document is required to include the VA required language consistent with the PREP Act; the PREP Act informed consent language addresses this policy requirement for COVID-19 related research involving medical countermeasures.

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VHA Directive 1200.05	Paragraph 17.e.(10) Costs for Study Participation	When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research. ***NOTE:*** *Some Veterans are required to pay copayments for medical care and services specifically related to their medical care provided by VA. These co-payment requirements will continue to apply to medical care and services that are not part of the research procedures or interventions.*	If you are a VA study participant, you or your insurance will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, these co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.	
VHA Directive 1200.05	Paragraph 17.k. Consent for Photographs, Video, or Audio Recordings	The informed consent for research must include information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes; how the photographs, video, and/or audio recordings will be used for the research; and whether the photographs, video, and/or audio recordings will be disclosed outside VA.	No language provided by ORD.	Study-specific information on use of photographs, video, and/or audio recordings must be provided by the study team in both the informed consent document and HIPAA Authorization section or separate VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research.

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VHA Directive 1200.05	Paragraph 17.k. Consent for Photographs, Video, or Audio Recordings	(1) An informed consent to take a photograph, video and/or audio recording cannot be waived by the IRB. (2) The consent for research does not give legal authority to disclose the photographs, video, and/or audio recordings outside VA. A HIPAA Authorization is needed to make such disclosures.		
VHA Directive 1200.05	Paragraph 22.c.(1) Certificates of Confidentiality (CoCs)	(1) For studies in which information about the subject's participation will be included in the subject's VHA medical record, information must be given to the prospective subjects as part of the informed consent process that information regarding study participation will be included in the medical record.	Your study doctors will put information about your participation in this study in your VA medical record for your safety. It is important for other health care providers taking care of you to know any study drugs or study treatments you are receiving.	Many consent documents include language describing that information about the subject's participation will be included in his or her VHA medical record. Only include this language or a modification of it if the informed consent document does not include statements.

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VHA Directive 1200.05	Paragraph 22.c.(2) Certificates of Confidentiality (CoCs)	(2) For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality. ***NOTE:*** *The HHS agencies that issue Certificates of Confidentiality usually have guidance specific to the issuing agency on statements that must be included in informed consent documents describing Certificates of Confidentiality.*	This study has a Certificate of Confidentiality.	Only include this statement if the informed consent document does not already include statements that the study has a Certificate of Confidentiality (CoCs) Most studies with CoCs use language as described in NIH's example for CoCs at https://grants.nih.gov/policy/humansubjects/coc/helpful-resources/suggested-consent.htm.

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PREP Act	HHS Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19	Please refer to HHS Declaration published in the Federal Register (Vol. 85, No. 52) on March 17, 2020: https://www.govinfo.gov/content/pkg/FR-2020-03-17/pdf/2020-05484.pdf	A new public health law under the Public Readiness and Emergency Preparedness Act was issued by the Department of Health and Human Services on March 10, 2020. This law limits your ability to sue if you are in a COVID-19 research study. If this study uses a drug, device or vaccine designed to treat, diagnose, cure or prevent COVID-19, you cannot sue the manufacturers, the study sponsor, healthcare providers or other professionals involved in the study for injury or harm (i.e., getting hurt) unless the injury or harm was on purpose. You may be compensated for injury or harm through a Department of Health and Human Services program called the Countermeasures Injury Compensation Program (CICP). For more information about this program, please contact the Health Resources and Services Administration's CICP by phone at 855-266-2427 or online at https://www.hrsa.gov/cicp/about/index.html. VA will still provide necessary medical treatment should you be injured by being in this study. You will be treated for the injury at no cost to you. This care may be provided by the local VAMC or arrangements may be made for contracted care at another facility. In case of research related injury resulting from this study, you should contact your study team. If you have questions about medical treatment for any study related injuries, you can call the operator at this VA Medical Center and ask for medical administration. You still have the right to hold VA responsible for negligence that is not related to a COVID-19 research study.	The PREP Act language for informed consents is only to be used when the VA study involves a medical countermeasure (e.g., drug, device or vaccine) designed to treat, diagnose, cure or prevent COVID-19. The PREP Act informed consent language includes statements to cover the ORD policy requirement in VHA Directive 1200.05, Paragraph 17.d.(10) addressing research-related injuries.

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VHA Directive 1200.05	Paragraph 23.a.(1)	(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.	<u>When the Authorization Language is combined with the informed consent to be approved by the IRB, the following authorization language is provided</u>: 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 both conditions are met: #1. No optional banking of identifiable data or biospecimens is involved, and #2. The IRB does not approve the use of subject's legally authorized representatives (LARs) to consent for the subject. **If either of the above conditions are not met, a VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research, must be used.**
VHA Directive 1605.03	Appendix D, Paragraph 1.k.(5)(b)(2)(f) Authorization Requirements VA Form 10-250	Determine if data-banking or tissue-banking is part of the protocol (if the banking involves identifiable data or identifiable tissue). Depending on whether the banking is optional or mandatory, ensure authorization is completed correctly. Does the study include tissue or data banking for future use? If yes, a combined Research Informed Consent with Research HIPAA Authorization is not permitted. VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research, MUST be used.		

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			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.	

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			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.	

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			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.	