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| **VA Specific and** **Selected 2018 Common Rule Informed Consent Requirements When Using an Independent (Commercial) IRB****June 28, 2023** The following instructions with language for VA informed consent documents (ICDs) are provided in this table.  VA specific informed consent requirements, as applicable, must be included in all ICDs submitted during the application submission to the independent IRBs.If the study is funded by industry, please also insert the applicable selected 2018 Common Rule requirements if the model informed consent does not contain the requirements.  |
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| **Policy or Law** | **Citation and Topic** | **Policy Language**  | **Language Provided to the Commercial IRBs** | **Comments** |
| VHA Directive 1200.05(2) | 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.*  | As 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***). | **The study is not required to 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.** Please note that the terms of the current PREP Act declaration for COVID -19 countermeasures, PREP Act coverage will end if the public health emergency and all other emergency declarations end, and there is no federal agreement relevant to the activity.It is preferred (but not required by ORD policy) that sponsors remove their template language addressing research-related injuries if present.  |
| **VA Specific informed Consent Document Requirements**  |
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| VHA Directive 1200.05(2)  | 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.*  | As 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. | If a sponsor requests to alter the language, please send the query to VHACOORDRegulatory@va.gov prior to submitting the informed consent document to the commercial IRB. It is preferred (but not required by ORD policy) that sponsors remove their template language for costs for study participation if present.  |
| VHA Directive 1200.05(2) | 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.**Please note that the research-specific use or collection of photographs, video, and/or audio recordings would almost always be a protocol requirement when a photograph, video, and/or audio recording is obtained or collected for protocol purposes only. If your VA participating site is seeking use of photographs, video, and/or audio recordings only when it is not required by protocol, your site must submit a site-specific amendment for the reviewing IRB to evaluate; the IRB will determine whether the site-specific amendment can be approved. | This basic element is only required if applicable to the study.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(2) | Paragraph 17.k. Consent for Photographs, Video, or Audio Recordings (cont.). | 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.
 | **No language provided by ORD.** |  |
| VHA Directive 1200.05(2) | 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.  | **This is one of two ORD policy requirements specific to studies with certificates of confidentiality and only applies if the study already has a COC.** If the study with a CoC involves a medical intervention (administration of a drug, use or implanting a medical device), information about the VA subjects’ participation in the study must always be placed in the medical record for patient safety reasons. 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.  |
| **VA Specific informed Consent Document Requirements**  |
| **Policy or Law** | **Citation and Topic** | **Policy Language** | **Language Provided to the Commercial IRBs** | **Comments** |
| VHA Directive 1200.05(2) | Paragraph 22.c.(2)Certificates of Confidentiality (CoCs) | 1. 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.  | **This is the second of two ORD policy requirements specific to studies with certificates of confidentiality and only applies if the study already has a COC.** 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>.**If your site is a participating study site, do not submit an application for a CoC for the study.**  |
| **VA Specific informed Consent Document Requirements**  |
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| PREP Act | HHS Notice of Declaration Under the PublicReadiness and EmergencyPreparedness Act for MedicalCountermeasures 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**.Please note that the terms of the current PREP Act declaration for COVID -19 countermeasures, PREP Act coverage will end if the public health emergency and all other emergency declarations end, and there is no federal agreement relevant to the activity.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.  |
| **PLEASE PROCEED TO THE NEXT TABLE IN THIS DOCUMENT IF THE STUDY IS INDUSTRY FUNDED.**  **If the study is funded by industry**, please also insert the selected 2018 Common Rule requirements if the model informed consent does not contain the  requirements. If you or the sponsor have questions regarding this requirement, please email vhacoordregulatory@va.gov. |
| **Policy or Law** | **Citation and Topic** | **Policy Language** | **Comments** |
| 2018 Common Rule  | 38 CFR §16.116 (a)(5)(i)Key Information | Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.  | This is a **required element** of informed consent. It must be included with the submission to the IRB.  |
| 2018 Common Rule | 38 CFR §16.116 (b)(9)Future use of information and/or specimens | One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:(i) A statement that identifiers might be removed from the identifiable privateinformation or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or(ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. | This is a **required element** of informed consent. However, the Common Rule does not require the statement to be made “verbatim” as per the regulation. Many times this is included in the model informed consent. **If you are unsure whether to include it, mark “na” on your checklist.** The IRB will determine whether it is applicable. |
| 2018 Common Rule | 38 CFR §16.116 (c)(7)Specimens for Profit  | A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit; | This is an **additional element** of informed consent. **If you are unsure whether to include it, mark “na” on your checklist.** The IRB will determine whether it is applicable. |
| 2018 Common Rule | 38 CFR §16.116 (c)(8)Return of Results | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. | This is an **additional element** of informed consent. **If you are unsure whether to include it, mark “na” on your checklist.** The IRB will determine whether it is applicable. |
| 2018 Common Rule | 38 CFR §16.116 (c)(9)Whole Genome Sequencing | For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). | This is an additional element of informed consent. Do a word search of the model informed consent form for “WGC” or “whole genome sequencing”. **If you are unsure whether to include it, mark “na” on your checklist**. The IRB will determine whether it is applicable. |