**Checklist for VA Facilities Using Independent (Commercial) IRBs:**

**Inclusion of Required Language into Informed Consent Documents (ICDs) and**

**Combined ICD/HIPAA Authorization Documents**

**Instructions**

This document is a checklist tool for VA Investigators to assist them when submitting informed consent documents (ICDs) in the initial applications of VA research studies to ORD-approved independent (commercial) IRBs. The checklist is to be used in conjunction with the applicable ORD tables listed in the applicable sections to help ensure that required language is included in the applicable ICDs and combined ICD/HIPAA authorizations submitted for independent IRB review. The checklist is not required to be used nor should it be submitted with independent/commercial IRB applications by VA Investigators.

1. **Project Information**

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| **VAIRRS Project Number** |       |
| **Facility** |       |
| **Title of Project** |       |
| **Local Site Investigator** |       |
| **Name of Independent/Commercial IRB** | [ ]  Advarra [ ]  Sterling [ ] WCG |

# **Informed Consent Requirements: VA Specific Elements**

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| The study team has included the following content in the informed consent form to be submitted to the independent/commercial IRB using the following ORD table:**VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using An Independent (Commercial) IRB located on** [**ORD’s website**](https://www.research.va.gov/programs/orppe/irb_relationships.cfm)**.** |
| 1. VA Treatment for Research-Related Injuries

*Note: Please use the specified language in the table. If a sponsor wishes to alter the language, please email* *vhacoordregulatory@va.gov* *for a consultation prior to submitting the informed consent for IRB review.*  | [ ]  Yes [ ]  No |
| 1. Costs for Study Participation
 | [ ]  Yes [ ]  No |
| 1. Consent for Photographs, Video, or Audio Recordings
 | [ ]  Yes [ ]  No [ ]  N/A |
| 1. Certificates of Confidentiality (CoCs)
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|  | 1. If information about the subject’s participation will be included in the medical record for a study with a CoC, statement regarding the fact that study participation will be included in the medical record.
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | 1. If the study has a CoC, a statement that the study has a Certificate of Confidentiality.
 | [ ]  Yes [ ]  No [ ]  N/A |
| 5. PREP ACT | [ ]  Yes [ ]  No [ ]  N/A |
| Comments:        |

# **Informed Consent Requirements: Selected 2018 Common Rule Informed Consent Requirements for Industry-Funded Studies**

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| 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 hasquestions regarding this requirement, please email vhacoordregulatory@va.gov. Please use the following table:**VA Specific and Selected 2018 Common Rule Informed Consent Requirements When Using An Independent (Commercial) IRB located on** [**ORD’s website**](https://www.research.va.gov/programs/orppe/irb_relationships.cfm)**.** |
| 6. Key Information presented up front *Note: 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*.  *Note: The five (5) list of topics that would generally satisfy the requirement*  *includes:*  *1. The fact that consent is being sought for research and that participation is*  *voluntary* *2. The purposes of the research, the expected duration of the prospective*  *subject’s participation, and the procedures to be followed in the research* *3. The reasonably foreseeable risks or discomforts to the prospective subject* *4. The benefits to the prospective subject or to others that may reasonably*  *be expected from the research* *5. Appropriate alternative procedures or courses of treatments, if any, that* *might be advantageous to the prospective subject.* | [ ]  Yes [ ]  No |
| 7. Future use of information and/or specimens*Note: 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.* | [ ]  Yes [ ]  No [ ]  N/A |
| 8. Biospecimens and Commercial Profits*Note: 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*. | [ ]  Yes [ ]  No [ ]  N/A |
| 9. Return of Research Results to Subjects*Note: 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.* | [ ]  Yes [ ]  No [ ]  N/A |
| 10.Statement that research involves Whole Genome Sequencing *Note: 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.*  | [ ]  Yes [ ]  No [ ]  N/A |
| Comments:       |

# **4. VA HIPAA Authorization Document Requirements When the HIPAA Authorization Document is Combined with the Informed Consent Document**

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| The study team has included the following content in the combined VA HIPAA authorization form to be submitted to the independent/commercial IRB unless the VA Form 10-0493 must be used. Please use the following table:**VA HIPAA Authorization Requirements When Using an Independent (Commercial) IRB located on** [**ORD’s website.**](https://www.research.va.gov/programs/orppe/irb_relationships.cfm)   |
| 11. The VA HIPAA authorization language for research is combined with the informed consent document to be approved by the IRB. *Note: 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.* | [ ]  Yes [ ]  No If “No”, VA Form 10-0493  must be used. Do not  proceed with further  checklist items for this  section.   |
| 12. The VA HIPAA authorization language for research when combined with the informed consent language to be approved by the IRB includes:  |  |
|  | a. List of disclosures | [ ]  Yes [ ]  No  |
|  | b. Statement whether research subject will or will not have  access to his/her research records during the research. | [ ]  Yes [ ]  No  |
|  | c. Revocation language | [ ]  Yes [ ]  No  |
| Note: If any of the above in question #12 responses are marked “no”, please consult with your privacy officer. Do not submit the combined informed consent document/HIPAA authorization to the IRB unless all responses are “yes”.  Comments:       |
| **PLEASE DO NOT SUBMIT THE STANDALONE HIPAA AUTHORIZATION FORM FOR RESEARCH****(VA FORM 10-0493) TO THE COMMERCIAL (INDEPENDENT) IRB UNLESS SPECIFICALLY INSTRUCTED TO DO SO BY THE IRB.** |