Consent – Reviewer Checklist



|  |  |
| --- | --- |
| **VAPORHCS PI Name:** |  |
| **Study/Project ID#:** |  |
| **Current Regulatory Requirements Subject to:** | [ ]  Pre-2018 Common Rule [ ]  2018 Requirements  |

**IRB Reviewer:       Review Date:**

*Reviewer attestation: by entering my name above, I am confirming that I completed this review and did not have a conflict of interest with this protocol.* ***NOTE:***If you have a conflict of interest in reviewing this protocol, please contact an IRB Analyst via pvamc-irb@va.gov immediately, so that this review may be reassigned.

This form is to be used for review of signed Informed Consent forms, as well as a guide for review of Research Information Sheets e.g., consent scripts or written statements for participants accompanying Request for Waiver of Informed Consent Documentation).

This checklist covers all required elements, as well as other elements prompted in the ICF template, as applicable. However, other statements may be needed, as appropriate and determined by the IRB/designated reviewer. This checklist is not the final word on whether or not a consent form or research information sheet should be approved.

**Key for Regulatory Elements Required for Approval (where noted):**

**GENREQ** = General Requirements for Informed Consent

**BRE** = Basic Required Elements

**AERV** = Additional Elements Required by VA, per VHA Directive 1200.05 and/or VAPORHCS-specific policy

**AEA** = Additional Elements when Appropriate

***NOTE:******If 2018 Common Rule is checked above****, see highlighted yellow sections for requirements per 2018 Common Rule and/or revised VHA directive 1200.05.*

|  |  |  |
| --- | --- | --- |
| **General Criteria for Informed Consent (GENREQ)*****NOTE:*** *For some relatively simple research studies with limited risks or benefits, the entire informed consent document may be relatively brief and still satisfy if it satisfies the criteria in #1 & #2 below without following the Summary of Key Information section exactly. However, all Basic and applicable additional elements must be included in the ICF or Research Information Sheet, if applicable.*  | **Yes** | **No** |
| 1. Informed consent begins 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 research. **(GENREQ)**
 | [ ]  | [ ]  |
| 1. Key information section is organized and presented in a way that facilitates comprehension. **(GENREQ)**
 | [ ]  | [ ]  |
| **Summary of Key Information (GENRREQ)*****NOTE:*** *All Basic and applicable additional elements must be included in the ICF or Research Information Sheet, if applicable.*  |
| **WHO SHOULD I CONTACT?** | **Yes** | **No** |
| 1. An explanation of whom to contact for answers to questions about the research. **(BRE)**
 | [ ]  | [ ]  |
| 1. Who to contact if there are research-related injuries and/or privacy/confidentiality concerns. **(BRE)**
 | [ ]  | [ ]  |
| 1. Who to contact for information regarding research subjects’ rights. **(BRE)**

***NOTE:*** *At least one contact's name and phone number must be for someone other than the investigator or study personnel.* | [ ]  | [ ]  |
| **WHAT AM I BEING ASKED TO DO?** | **Yes** | **No** |
| 1. Includes a statement that the study involves research. **(BRE)**
 | [ ]  | [ ]  |
| 1. Includes a statement explaining who is funding/sponsor of the research. **(AEA)**
 | [ ]  | [ ]  |
| **TAKING PART IN THIS STUDY IS YOUR CHOICE** | **Yes** | **No** |
| 1. A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. **(BRE)**
 | [ ]  | [ ]  |
| **WHY IS THIS STUDY BEING DONE?** | **Yes** | **No** |
| 1. Summarizes in the form of a simple question the study’s primary objective. **(GENREQ - see item #1 above)**
 | [ ]  | [ ]  |
| **WHAT IS THE USUAL APPROACH TO MY <INSERT CONDITION>?** | **Yes** | **No** |
| 1. Includes a brief description of a usual approach, which should not be overly specific or detailed, allowing the research to be placed into context. **(AEA)**
 | [ ]  | [ ]  |
| **WHAT ARE MY CHOICES IF I DECIDE NOT TO TAKE PART IN THIS STUDY?** *Alternative section* |
| 1. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. **(BRE)**
 | [ ]  | [ ]  |
| **WHAT WILL HAPPEN IF I DECIDE TO TAKE PART IN THIS STUDY?** | **Yes** | **No** |
| 1. Major study procedures, tests, exams, and if any test(s) include(s) genetic testing. **(GENREQ - see item #1 above)**
 | [ ]  | [ ]  |
| 1. Includes a statement about the expected duration of the subject’s participation. **(BRE)**
 | [ ]  | [ ]  |
| **WHAT ARE THE RISKS AND BENEFITS OF TAKING PART IN THIS STUDY?** |
| 1. Summarizes most important expected risks of participation. **(GENREQ - see item #1 above)**
 | [ ]  | [ ]  |
| 1. Summarizes any reasonable foreseeable/potential benefits of participation. **(GENREQ - see item #1 above)**
 | [ ]  | [ ]  |
| **IF I DECIDE TO TAKE PART IN THIS STUDY, CAN I STOP LATER?** |
| 1. A statement that significant new findings which may relate to this subject's willingness to continue participation will be provided to the subject. **(AEA)**
 | N/A [ ]  | [ ]  | [ ]  |
| 1. A statement of the consequences of a participant’s decision to withdraw from the research. **(AEA)**
 | N/A [ ]  | [ ]  | [ ]  |
| 1. Procedures for the orderly termination of participation of the subject. **(AEA)**
 | N/A [ ]  | [ ]  | [ ]  |
| **ARE THERE OTHER REASONS WHY I MIGHT STOP BEING IN THE STUDY?** |
| 1. A statement of anticipated circumstances under which the subject’s participation might be terminated by the investigator without regard to the subject’s consent. **(AEA)**
 | N/A [ ]  | [ ]  | [ ]  |
| **END OF SUMMARY OF KEY INFORMATION**  |
| **MAIN INFORMED CONSENT** |
| **WHAT IS THE PURPOSE OF THIS STUDY?** | **Yes** | **No** |
| 1. An explanation of all the purpose(s) of the research. **(BRE)**
 | [ ]  | [ ]  |
| 1. A statement whether the research will (if known) or might include whole genome sequencing. **(AEA)**
 | N/A [ ]  No biospecimen included | [ ]  | [ ]  |
| **DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL, OR OTHER INTEREST?** *Conflict of Interest (COI) Section* |
| 1. If a COI is reported to the IRB by the Research Office, this section is included, and information is disclosed here. **(AERV)**
 | N/A [ ]  | [ ]  | [ ]  |
| 1. If any investigator on the study may also be the subject’s health care provider, an appropriate statement is included (i.e., see ICF template for boilerplate language). **(AERV)**
 | N/A [ ]  | [ ]  | [ ]  |
| **HOW MANY PEOPLE WILL PARTICIPATE?** |
| 1. The number of subjects to be recruited from VAPORHCS. **(AEA)**
 | [ ]  | [ ]  |
| 1. Number of subjects to be recruited across other sites. **(AEA)**
 | N/A [ ]  | [ ]  | [ ]  |
| **WHAT WILL HAPPEN DURING THIS STUDY?** *Description of Study Procedures* |
| 1. A description of the procedures to be followed. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. Description of those procedures being done for research. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. The study includes procedures that are part of “usual” care?
 | [ ]  | [ ]  |
| * 1. If YES, are the procedures appropriately identified as “usual” care?
 | **[ ]**  | **[ ]**  |
| * 1. If YES, is there a statement advising subjects to review the risks of such “usual care” with their health care providers?
 | **[ ]**  | **[ ]**  |
| 1. Identification of any procedures that are experimental. **(BRE)**
 |  N/A [ ]  | **[ ]**  | **[ ]**  |
| **WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF PARTICIPATION?**  | **Yes** | **No** |
| 1. Statement that the research may involve risks which are unforeseeable. **(AEA)**
 | N/A [ ]  | **[ ]**  | **[ ]**  |
| 1. A description of any reasonably foreseeable risks or discomforts. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. If applicable, a statement that if the subject is or becomes pregnant, the particular treatment or procedure might involve currently unforeseeable risks to the embryo or fetus. **(AEA)**
 | N/A [ ]  | **[ ]**  | **[ ]**  |
| 1. If the study will use tissue collected solely for research purposes and exempt from Pathology and Laboratory Medicine Service (P&LMS) examination, a statement that such a release may potentially impair ability to obtain definitive diagnosis, obtain prognostic data or guide therapy. **(AERV-VAPORHCS-specific policy)**
 | N/A [ ]  | **[ ]**  | **[ ]**  |
| **HOW WILL MY CONFIDENTIALITY BE PROTECTED?**  |
| 1. A statement describing the extent to which confidentiality of records/information identifying the subject will be maintained. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. A statement describing which and how subject identifier(s) will be used, (*regardless of whether they will be shared outside the VAPORHCS*).
 |  N/A [ ]   no identifiers | **[ ]**  | **[ ]**  |
| 1. A statement that identifiers might be removed from information and/or biospecimens and used for future research. **(AERV-VAPORHCS-specific policy)**
 |  N/A [ ]   no identifiers used | **[ ]**  | **[ ]**  |
| 1. A statement describing how subject information and/or specimens shared outside the VAPORHCS will be labeled/identified.
 |  N/A [ ]   not shared outside VAPORHCS | **[ ]**  | **[ ]**  |
| 1. A description of the transfer of ownership for any identifiable (directly or with a key to the code) information and/or specimens that will be disclosed, stored or shared outside VAPORHCS.
 |  N/A [ ]   not shared outside VAPORHCS | **[ ]**  | **[ ]**  |
| 1. The consent form is consistent with the HIPAA Authorization.
 |  N/A [ ]   no PHI | **[ ]**  | **[ ]**  |
| 1. If video/audio tapes or photographs will be collected, the ICF includes language regarding their collection, purpose(s) and disclosure(s). **(AERV)**
 |  N/A [ ]   no audio video/photos | **[ ]**  | **[ ]**  |
| 1. A statement indicating that the FDA may inspect research records including identifiable medical records. (required for FDA regulated research)
 |  N/A [ ]   not FDA-regulated  | **[ ]**  | **[ ]**  |
| 1. A statement indicating there is a description of the clinical trial on <http://www.ClinicalTrials.gov> (required for trials of drugs or biologics other than Phase I trials)
 |  N/A [ ]   not FDA-regulated and/or Phase I  | **[ ]**  | **[ ]**  |
| **WILL I BE TOLD ABOUT ANY STUDY RESULTS?**  |
| 1. Statement regarding whether clinically relevant research results, including individual research results will be shared with the subject, and if so, under what conditions. **(BRE)**
 | **[ ]**  | **[ ]**  |
| **WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**  |
| 1. A statement that neither subjects nor their insurance will be charged for any costs related to the research (but that they may be for their standard medical care costs). **(AERV)**
 |  N/A [ ]  | **[ ]**  | **[ ]**  |
| 1. Explanation of any additional costs. **(AEA)**
 |  N/A [ ]  | **[ ]**  | **[ ]**  |
| **WILL I BE PAID? (section not required if subjects will not be paid)** |
| 1. Information concerning the amount of payment to subjects.
 |  N/A [ ]  | **[ ]**  | **[ ]**  |
| 1. Information concerning the schedule of payments to subjects.
 |  N/A [ ]  | **[ ]**  | **[ ]**  |
| 1. If compensation will be prorated, an explanation of how the compensation will be prorated.
 |  N/A [ ]  | **[ ]**  | **[ ]**  |
| **WILL ANYONE PROFIT FINANCIALLY FROM THIS STUDY? (section not required if study does NOT collect/bank biospecimens, even if identifiers are removed)** |
| 1. A statement that the subject’s biospecimen(s) may be used for commercial profit and whether the subject will/will not share in any commercial profit. **(AEA)**
 |  N/A [ ]  No biospecimen  | **[ ]**  | **[ ]**  |
| **WHAT WILL HAPPEN IF I AM HURT?** *Liability Section* |
| 1. An explanation as to whether any medical treatments are available if injury occurs and if so, what they consist of, or where further information may be obtained. **(BRE- for research involving more than minimal risk)**
 | **[ ]**  | **[ ]**  |
| 1. A statement that the VA must provide necessary medical treatment for research-related injuries, in accordance with applicable federal regulations. **(AERV)**
 | **[ ]**  | **[ ]**  |
| 1. An explanation as to whether compensation is available if injury occurs. If compensation is available when injury occurs, an explanation as to what it consists of or where further information could be obtained. **(BRE- for research involving more than minimal risk)**
 | **[ ]**  | **[ ]**  |
| 1. If COVID-19 study involving a covered countermeasure, ORD approved liability statement is included. **(AERV) *NOTE:*** *For guidance and to determine if study requires liability statement, please see ORD Guidance document dated 8/17/20 located at:* <https://www.research.va.gov/resources/policies/guidance/Implementation-PREP-Act-COVID19.pdf>
 | N/A **[ ]**  | **[ ]**  | **[ ]**  |
| **WHAT DO I NEED TO DO TO DROP OUT (WITHDRAW) AFTER I SIGN THIS CONSENT FORM?** |
| 1. Procedures for withdrawing participation in the study by the subject. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. If the subject requests, procedures for requesting to have specimen(s) destroyed.
 | N/A **[ ]**  | **[ ]**  | **[ ]**  |
| **SIGNATURE OF CONSENT SECTION:** |
| 1. Signature line for person obtaining the consent.
 | N/A [ ]  No physical interaction | **[ ]**  | **[ ]**  |
| 1. Statement that the study has been explained (should not say “I understand,” but can say “I have been told…”).
 | **[ ]**  | **[ ]**  |
| 1. If no adults with impaired decision making will be involved, the signature line for legally authorized representative (LAR) has been removed.
 | [ ]  LAR required | **[ ]**  | **[ ]**  |
| 1. The IRB may require a witness (e.g., if a study involves an invasive intervention or an investigational drug or device). If a witness is not required, the signature line for witness has been removed.
 | [ ] Witness required | **[ ]**  | **[ ]**  |
| 1. Date lines are present for all required signatures.  **(AERV-VA requires that these signatures be dated.)**
 | **[ ]**  | **[ ]**  |
| **ADDENDUM FOR BANKING: (***For optional data/specimen contribution to a repository.)* ***NOTE:*** *Items in this section should be throughout main ICF if banking is required.* [ ]  **N/A** - study does not have contribution of data/specimens to a repository ***(skip to 78)*** | **Yes** | **No** |
| 1. Description of the type of data, specimens and/or identifiers to be contributed. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. General location for the repository receiving data, specimens and/or identifiers.
 | **[ ]**  | **[ ]**  |
| 1. Statement regarding how the data, specimens and/or identifiers will be used, including the type(s) of future research. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. A statement whether the future research on biospecimens will (if known) or might include whole genome sequencing. **(AEA)**
 | N/A **[ ]** No biospecimen included | **[ ]**  | **[ ]**  |
| 1. A description of any reasonably foreseeable risks or discomforts. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. A statement regarding future genetic research (including possible inherited disorders) and risk of conflict with family members. **(AEA)**
 | N/A **[ ]** No future genetic research | **[ ]**  | **[ ]**  |
| 1. Description of The Genetic Information Nondiscrimination Act (GINA) and Oregon Genetic Privacy Law. **(AEA)**
 | N/A **[ ]** No future genetic research | **[ ]**  | **[ ]**  |
| 1. A statement that the subject’s biospecimen(s) may be used for commercial profit and whether the subject will/will not share in any commercial profit. **(BRE)**
 | N/A **[ ]** No biospecimen included | **[ ]**  | **[ ]**  |
| 1. Statement regarding how long data and/or specimens will be stored.
 | **[ ]**  | **[ ]**  |
| 1. Statement regarding whether clinically relevant research results, including individual research results will be shared with the subject, and if so, under what conditions. **(BRE)**
 | **[ ]**  | **[ ]**  |
| 1. Consequences of withdrawal from the repository and procedures for the withdrawing contributed data, specimens and/or identifiers from the repository by the subject. **(AEA)**
 | **[ ]**  | **[ ]**  |
| 1. If the subject requests, procedures for requesting to have specimen(s) destroyed.
 | **[ ]**  | **[ ]**  |
| 1. Signature line for person obtaining the consent.
 | [ ]  N/A  | **[ ]**  | **[ ]**  |
| 1. Statement that the study has been explained (should not say “I understand,” but can say “I have been told…”).
 | **[ ]**  | **[ ]**  |
| 1. If no adults with impaired decision making will be involved, the signature line for legally authorized representative (LAR) has been removed.
 | [ ]  LAR required | **[ ]**  | **[ ]**  |
| 1. The IRB may require a witness (e.g., if a study involves an invasive intervention or an investigational drug or device). If a witness is not required, the signature line for witness has been removed.
 |  [ ] Witness required | **[ ]**  | **[ ]**  |
| 1. Date lines are present for all required signatures. **(AERV - VA requires that these signatures be dated.)**
 | **[ ]**  | **[ ]**  |
| **Additional General Criteria for Informed Consent (GENREQ)** | **Yes** | **No** |
| 1. The language in the consent form is at an appropriate reading level based on the potential population.
 | **[ ]**  | **[ ]**  |
| 1. The consent form does NOT include any exculpatory language, e.g., “I understand.”
 | **[ ]**  | **[ ]**  |
| 1. The consent form is consistent with the protocol.
 | **[ ]**  | **[ ]**  |
| 1. The consent form provides information that a reasonable person would want to have to make an informed decision about whether to participate.
 | **[ ]**  | **[ ]**  |
| 1. The informed consent as a whole presents information in sufficient detail relating to the research and is organized and presented in a way that does not merely list isolated facts, but rather facilitates understanding of reasons why one might/might not want to participate.
 | **[ ]**  | **[ ]**  |
| **If Revised Consent Form (for ongoing study that has enrolled subject(s)):** |
| 1. If this checklist is being completed for a revised informed consent form, should subjects already enrolled be re-consented/notified of the changes to the consent form? **If “Yes”,** please answer both of the following:

 1. When should reconsent/notification of changes to the consent form take place?  2. How should the notification be documented? (i.e., via signing the revised ICF, via letter, etc.)  | N/A [ ]  | **[ ]**  | **[ ]**  |

**List by number any item which received a “no” answer and what corrections are needed:**