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| Office of the Institutional Review Board  LIMITED IRB REVIEWER WORKSHEET | | | | IRB MEMBER Worksheet | | |
|  | | | | IRB Member Reviewer: | | |
|  | | | | Protocol Title: | | |
|  | | | | PI | Project Number | Date |
|  | | | |  |  |  |
|  | **Exempt Category  2(iii)  3(i)(c) 8**  *For category 8 - a broad consent document must be included with the application for review.* | | | | | |
|  | **The initial determination must be included with the application for review.** | | | | | |
| **Review Criteria for Categories 2(iii), 3(i)(c), and 8– IAW 38 CFR 16.111(a)(7)** | | | | | | |
| **Privacy and Confidentiality** | | | | | | |
| **YES**  **NO** | | Are there adequate provisions to protect the privacy of subjects? | | | | |
| **YES**  **NO** | | Are there adequate provisions to protect the confidentiality of data? | | | | |
|  | | **Proceed to Reviewer Recommendations (if Cat 8 see below)** | | | | |
| **Additional Review Criteria for Category 8 (not applicable to 2(iii) or 3(i)(c))** | | | | | | |
| **YES**  **NO** | | Is the broad consent document under which the data and/or specimens were collected included for review? | | | | |
| **YES**  **NO** | | Were all data and/or specimens obtained solely for the purpose of research under a process of broad consent IAW .116(a)(1)-(4); (a)(6); d? (see Broad Consent Section below) | | | | |
| **YES**  **NO** | | Broad consent was documented for all data and specimens IAW .117 (without waiver or alteration)? | | | | |
| **YES**  **NO** | | The planned research is within the scope of the broad consent that was signed by participants? | | | | |
| **YES**  **NO** | | The plan in this proposed research does not include the individual return of results to study particpants? | | | | |
| Broad Consent | | **Did the broad consent process meet the following elements: .116(a)(1)-(4); (a)(6); d** | | | | |
| **YES**  **NO** | | Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative  An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether to participate and that minimize the possibility of coercion or undue influence.  The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.  The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.  No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. | | | | |
|  | | **Does the Broad Consent Document contain the following elements:** | | | | |
| **YES**  **NO** | | A description of any reasonably foreseeable risks or discomforts to the subject;  A description of any benefits to the subject or to others that may reasonably be expected from the research;  A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;  A statement that participation is voluntary and that refusal to participate or a decision to terminate their participation will involve no penalty or loss of benefits to which the participant 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;  A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;  A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;  A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);  Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;  A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and  An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm. | | | | |
|  | | **Are the following additional elements applicable:** | | | | |
| Only if applicable; are they met?  **YES**  **NO** | | 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  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). | | | | |
| **Reviewer Recommendation or Approval (for expedited reviews)** | | | | | | |
| **EXPEDITED REVIEW**  **CONVENED BOARD REVIEW** | | | **APPROVE**  **CONDITIONALLY APPROVE**  **DEFER/TABLE**  **RECOMMEND** **DISAPPROVAL** | | | |
| **MAJOR STIPULATIONS:** | | |  | | | |
| **MINOR STIPULATIONS:** | | |  | | | |
| **ADDITIONAL COMMENTS** (INCLUDING JUSTIFICATION FOR RECOMMENDATION FOR RESEARCH DISAPPROVAL)**:** | | |  | | | |

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Include Reviewer Name: Date