Continuing Review – Reviewer Checklist

|  |  |
| --- | --- |
| **VAPORHCS PI Name:** |  |
| **Study/Project ID#:** |  | **Review Date:**  |  |
| **IRB Primary Reviewer:***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. |
| **1. Are the numbers of participants consented and/or enrolled to date consistent with the study plan and within IRB approved parameters?** [ ]  YES [ ]  NO; If **NO**, please describe & include if any PI action is required:       |
| **2.**  **Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review?** *(Obtain when there are questions about the veracity of the information provided by the investigator.)* [ ]  YES [ ]  NO **3.** **Is the consent document accurate and complete?** [ ]  YES [ ]  NO [ ]  N/A – no consent document/study closed to enrollment**4.** **If information has arisen that might affect the willingness of participants to continue to take part in the research; will it be provided to those participants?** [ ]  YES [ ]  NO [ ]  N/A – no new information |
| **RECOMMENDATIONS and/or DECISION:**[ ]  **APPROVE AS PRESENTED**[ ]  **CONTINGENTLY APPROVE****Specify all contingencies and/or review comments:** ***NOTE: Comments should be written directly to the PI/Study Staff, so the IRB Analyst is able to copy and paste them directly into the IRB Contingent Approval Letter:*** [ ]  **DEFFER** (Delays approval of the research project because **substantive** issues must be resolved. Note that the investigator’s response to the IRB cannot be reviewed outside of a convened IRB meeting.) **Specify reason(s) for deferral:** ***NOTE: Comments should be written directly to the PI/Study Staff, so the IRB Analyst is able to copy and paste them directly into the IRB Deferral Letter:***  **ASSESSMENT OF RISK** [ ]  **No Greater Than Minimal Risk**[ ]  **Moderate Risk**[ ]  **High Risk****RATIONALE FOR RISK LEVEL** **(Full-Board Reviews ONLY):****Provide the rationale for the risk level checked above** (e.g., moderate risk because the risk is greater than that encountered in daily life, high risk due to investigational drug, etc.):  |

|  |
| --- |
| **FLAG DETERMINATION (Full-Board Reviews ONLY):***The utilization of a research flag in Electronic Health Record (EHR) is typically recommended when the research involves (1) any invasive procedure, (2) interventions or clinical services used in the medical care of the subject or that could interfere with the subject’s other medical care, or (3) surveys/interviews that could provoke undue stress or anxiety, unless IRB determines the flag is not in subject’s best interests. The IRB should base the decision to implement a research flag on the study design and the interests of the participants.* **If approval is recommended, are there any changes to previous requirements to flag the medical record to protect the participant’s safety by indicating participation in the study and the source of more information on the study?**[ ]  NO: changes to previous flag determinations for this study based on continuing review (e.g., maintain previous flag determinations)[ ]  NO: flag not necessary for this study[ ]  NO: flag no longer in use (e.g., subjects have completed intervention(s)[ ]  YES: changes needed (indicate by checking appropriate boxes below) Based on the study design research flags should be initiated (entered into EHR) when: [ ]  Participants are consented, [ ]  Participants begin study treatment/intervention, [ ]  Other: (describe)        Based on the study design research flags should be removed/deactivated from EHR when: [ ]  Participants complete study treatment/intervention, [ ]  Participants study participation ends, [ ]  All study activities are completed,  [ ]  Other: (describe)      **CONTINUING REVIEW INTERVAL:**1. [ ]  **YES; Annual Continuing Review is required. Study is moderate or high risk and/or FDA- regulated and annual review is appropriate and/or study has not transitioned to 2018 Requirements/Revised Common Rule.**
2. [ ]  **YES; Annual Continuing Review would not otherwise be required per criteria above. However, annual continuing review is appropriate based on the following rationale:**
3. [ ]  **NO; Continuing Review is required at interval less than annual and recommended approval period is based upon the following assessment/level of risk:**

If **NO**, what is the recommended continuing review interval? 1. [ ]  **NO; Annual Continuing Review is not required based on the following criteria:**

[ ]  Research eligible for expedited review; **AND**[ ]  Research is **NOT** FDA-regulated; **OR**[ ]  Research has progressed to the point that it involves only one or both of the following, which are part of an IRB-approved study:[ ]  Research is NOT FDA-regulated; **AND**[ ]  Research is limited to data analysis, including analysis of identifiable private information or identifiable biospecimens; **OR**[ ]  Research is NOT FDA-regulated; **AND**[ ]  Research is limited to accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care |
| **Expedited Category(ies) for Continuing Review, if applicable (check all boxes that apply)**

|  |  |
| --- | --- |
| **[ ]**  | **Category 1:**Clinical study that involves a drug or medical device where an Investigational new drug application (IND) is NOT required (for a drug study) OR, for a device study, an Investigational device exemption (IDE) application is NOT required, or the medical device is cleared/approved for marketing and will be used in accordance with its cleared/approved labeling (see IRQ Appendix E or HUD Application). |
|  |
| **[ ]**  | **Category 2:**Research involves the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture, where either: blood samples will be collected from healthy, non-pregnant adults who weigh at least 110 pounds and the amount of blood drawn will be less than 550ml in an 8-week period and blood collection will occur no more than twice per week,**or**blood samples will be collected from adults and/or children with consideration of age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected, and in addition, the amount of blood drawn from these individuals will not exceed the lesser of the following: 50ml or 3ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. |
|  |
| **[ ]**  | **Category 3:**The research proposes the prospective collection of biological specimens for research purposes by non-invasive means. *Examples of noninvasive means of biological specimens can be found in Appendix 1 of the IRB Policy & Procedure, located at http://www.portland.va.gov/Research/documents/irb/irb-sop.pdf.*  |
|  |
| **[ ]**  | **Category 4:**This research includes the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing (studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). *Examples of noninvasive means of data collection can be found in Appendix 1 of the IRB Policy & Procedure, located at http://www.portland.va.gov/Research/documents/irb/irb-sop.pdf.* |
|  |
| **[ ]**  | **Category 5:**This research involves materials (data, documents, records, or specimens) that have been collected for any purpose, including previous research, or that will be collected solely for non-research purposes (such as medical treatment or diagnosis). *(Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects at 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt. (See Category 4 of Certification of Exemption at* (<http://www.va.gov/portlandresearch/piservices/rd_forms.asp#alphabetical>).  |
|  |
| **[ ]**  | **Category 6:**This research involves the collection of data from voice, video, digital, or image recordings made for research purposes. |
|  |
| **[ ]**  | **Category 7:**This research involves individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior); ***OR***research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.  |
|  |
| **Category 8: Continuing review of study previously approved by a convened IRB (check one):** |
| **[ ]**  | **Category 8(a):** **All** **of the following are true:*** The research is permanently closed to the enrollment of new subjects; **and**
* All of the subjects completed all research-related interventions; **and**
* The research is active only for long-term follow-up of subjects
 |
| **[ ]**  | **Category 8(b):** No subjects have been enrolled and no additional risks have been identified. |
| **[ ]**  | **Category 8(c):** The remaining research activities limited to data analysis. |
|  |
| [ ]  | **Category 9: Continuing review of study previously approved by a convened IRB**Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. |

 |

**Additional Review Comments:**