IRB Initial - Reviewer Checklist

2018-Requirements

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| --- | --- | --- | --- |
| **VAPORHCS PI Name:** |  | | |
| **Study ID# :** |  | **Review Date:** |  |
| |  |  | | --- | --- | | **Type of Review:** | Initial  Re-Review |   **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](mailto:pvamc-irb@va.gov) immediately, so that this review may be reassigned. | | | |

*Critical areas for the review of human subjects research are listed below.* ***The questions in bold reflect the regulatory requirements which must be met in order to grant approval.*** ***The items in red reflect VA-specific information that must be present in the protocol, as required by VHA directive 1200.05.*** Review all project materials, including the protocol, IRB Application, consent form, etc., to make your determinations. *Please contact an IRB Analyst if you need any additional correspondence or forms to be able to answer the questions below*.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | | | **Yes** | | | **No** | |
|  | | * **Does the research protocol include information regarding relevance of the research to the mission of the VA and the Veteran population?** * **If the information provided raises any concerns and/or reasons why the research should NOT be conducted at VAPORHCS,**   **please describe:**  **N/A – no concerns** | | |  | | |  | |
|  | | *Take into consideration:* | | |  | | |  | |
| * ***VA Mission Statement:*** *To fulfill President Lincoln’s promise, “To care for him who shall have borne the battle, and for his widow, and is orphan” by serving and honoring the men and women who are America’s Veterans.* | | | |  | | | |  | |
| * *VA’s five core values underscore the obligations inherent in VA’s mission: Integrity, Commitment, Advocacy, Respect, and Excellence.* | | | |  | | | |  | |
| * ***Integrity****: Act with high moral principle. Adhere to the highest professional standards. Maintain the trust and confidence of all with whom I engage* * ***Commitment****: Work diligently to serve Veterans and other beneficiaries. Be driven by an earnest belief in VA’s mission. Fulfill my individual responsibilities and organizational responsibilities.* * ***Advocacy****: Be truly Veteran-centric by identifying, fully considering, and appropriately advancing the interests of Veterans and other beneficiaries.* * ***Respect****: Treat all those I serve and with whom I work with dignity and respect. Show respect to earn it.* * ***Excellence****: Strive for the highest quality and continuous improvement. Be thoughtful and decisive in leadership, accountable for my actions, willing to admit mistakes, and rigorous in correcting them.* | | | |  | | | |  | |
|  | | | | **Yes** | | | | **No** | |
| * **Does the protocol include all required information as indicated in the** [**Sample Protocol Template**](http://www.va.gov/portlandresearch/documents/PIResources/Sample-Research-Protocol.doc)**?** (If **NO,** please contact an IRB Analyst for additional guidance.)   ***NOTE:*** *The protocol template is designed to ensure the protocol, informed consent documents, and other protocol-related documents are consistent and in compliance with VA requirements. If the main study protocol was written by a third party (i.e., the sponsor, the coordinating center, etc.), please assure the protocol template was used to create a local protocol addendum that addresses specifically how the required items will be conducted/addressed at the VA Portland Health Care System (VAPORHCS).* | | | |  | | | |  | |
|  | |  | | | **Yes** | | | **No** | |
| **1** | | **Are the risks to subjects (physical, social, psychological, economic, and legal risks) minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose the subjects to risk?** | | |  | | |  | |
| *Additional thoughts to consider regarding the minimization of risks:* | | | | | | | | | |
| * *Do the investigators and research staff have the appropriate training and qualifications to conduct the research project?* | | | | | | | | | |
| * *Are all appropriate histories, physical exams, and lab tests being conducted on the patient and are there qualified co-investigators in place to interpret the laboratory/study data?* | | | | | | | | | |
| * *Does the protocol involve “usual care”?* | | | | | | | | | |
| * *If yes, does the protocol clearly differentiate risks of the study intervention(s) from risks associated with the “usual care”?* | | | | | | | | | |
| **1a** | | | **Are the risks to subjects (physical, social, psychological, economic, and legal risks) minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes, whenever appropriate?** | |  | | |  | |
|  | | |  | | **Yes** | | | **No** | |
| **2** | | | **Are the risks to subjects (physical, social, psychological, economic, and legal risks) reasonable in relation to any anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result?** | |  | | |  | |
| * *Consider only those risks and benefits that may result from the research.* | | | | | | | | | |
| * *Do not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the IRB’s purview.* | | | | | | | | | |
|  |  | | | | **Yes** | | | **No** | |
| **3** | **Is the selection of subjects equitable?** | | | |  | | |  | |
| *Take into consideration:* | | | | | | | | | |
| * *The purpose of the research and the setting in which the research will be conducted.* | | | | | | | | | |
| * *Special problems of research involving categories of populations who are vulnerable to coercion or undue influence such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.* | | | | | | | | | |
| * *Does the study exclude any classes of persons who might benefit from the research?* | | | | | | | | | |
| * *Are the inclusion and exclusion criteria for subject selection appropriate?* | | | | | | | | | |
| * *Recruitment and enrollment procedures* | | | | | | | | | |
| * *Influence of payments to participants* | | | | | | | | | |
|  | | | | | | | | | |
|  | | | | | | | | | |
| **3a** | | | If this study focuses on a disease, disorder or condition that disproportionately affects women and/or members of minority groups, are appropriate efforts being made to include women Veterans and/or Veterans of applicable minority groups?  N/A – study does not focus on such a disease, disorder or condition | |  | | |  | |
|  | | |  | | **Yes** | | | **No** | |
| **4** | | | **Will informed consent be sought from each prospective participant or the participant’s legally authorized representative (LAR) in this study?** (If **NO,** skip to 6.) | |  | | |  | |
| **4a** | | | If **YES** to 4**,** are all of the following true? (If **YES** to 4a, proceed to 5; if **NO,** explain under comments.) | |  | | |  | |
| * The circumstances of the consent process provide the prospective participant or the LAR sufficient opportunity to consider whether to participate. | | | | | | | | | |
| * The circumstances of the consent process minimize the possibility of coercion or undue influence. | | | | | | | | | |
| * The individuals communicating the information to the participant or LAR during the consent process provide the information in language understandable to the participant or the LAR (language is at an appropriate reading level). | | | | | | | | | |
| * The information communicated to the participant or the representative during the consent process does **not** include exculpatory language through which the participant or LAR is made to waive or appear to waive any of their legal rights. | | | | | | | | | |
| * The information communicated to the participant or LAR during the consent process does **not** include exculpatory language through which the participant or representative releases or appears to release the investigator, the sponsor, the organization, or its agent from liability for negligence. * The information communicated to the participant or the LAR during the consent process includes 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.The information communicated to the participant or the LAR during the consent process begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR 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. * Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR’s understanding of the reasons why one might or might not want to participate. | | | | | | | | | |
| **5** | | | **Will informed consent be documented? (check “Long form” or “Short form” as applicable for this study).** (If **NO,** skip to 5a.) | | **Yes** | | | **No** | |
| **Long form – the consent meets all the criteria outlined on the Informed Consent Form Checklist**  **Short form *(for use in conjunction with a detailed oral presentation of required consent elements)***   * + The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant’s legally authorized representative.   + A written summary embodies the basic and appropriate additional elements of disclosure.   + There will be a witness to the oral presentation.   + For participants who do not speak English, the witness is conversant in both English and the language of the participant.   + The participant or the participant’s legally authorized representative will sign and date the consent document.   + The witness will sign and date both the short form and a copy of the summary.   + The person actually obtaining consent will sign and date a copy of the summary. * A copy of the signed and dated short form will be given to the participant or the representative. | | | | | | | | | |
|  | | | | | | | | | |
| **5a** | | | If informed consent will be obtained, but will not be documented (e.g., consent is implied by completing a questionnaire), and the answer to 5 was NO, is one of the following true (i.e. a waiver of *documentation* of informed consent is appropriate)? | | |  | | |  |
| 1. The only record linking the subject to the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality and the research is not FDA-regulated? (Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern.); ***OR*** | | | | | |  | | |  |
| 1. The research presents no more than minimal risk of harm and involves no procedures for which written consent is normally required outside of the research context. (May be FDA-regulated); ***OR*** | | | | | |  | | |  |
| 1. The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and an appropriate alternative mechanism for documenting informed consent was obtained will be used. | | | | | | |  | | | |  |
| **5b** | | | If it is appropriate to waive documentation of informed consent (as per 5a), should a written statement (informational sheet) or an oral presentation regarding the research be provided to the subject?  N/A – no documentation waiver requested | | |  | | |  |
|  | | |  | | |  | | |  |
| **5c** | | | If **YES** to 5b, did the investigator submit a sufficient informational sheet or oral script? | | |  | | |  |
| **6** | | | **If NO to 4, does the study meet the criteria for a waiver of informed consent *process* (i.e. no consent of any kind will be conducted or documented) outlined in 6a *or* 6b, and, if applicable, 6c?** | | | **Yes** | | | **No** |
| **6a** | | | The research involves no more than minimal risk to the subjects. | | |  | | |  |
|  | | | The waiver or alteration of informed consent will not adversely affect the rights and welfare of the subjects. | | |  | | |  |
|  | | | The research could not practicably be carried out without the waiver. | | |  | | |  |
|  | | | The research involves using identifiable private information or identifiable biospecimens, and the research could not practicably be carried out without using such information or biospecimens in an identifiable format.  N/A | | |  | | |  |
|  | | | Whenever appropriate, the subjects will be provided with additional pertinent information after participation. | | |  | | |  |
|  | | | The research is not FDA-regulated. | | |  | | |  |
| **6b** | | | This is a research/demonstration project subject to the approval of state or local government officials and is designed to study, evaluate or examine any of the following: public benefit or service program, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. | | |  | | |  |
|  | | | The research could not practicably be carried out without the waiver of informed consent. | | |  | | |  |
|  | | | The research is not FDA-regulated. | | |  | | |  |
|  | | | | | | | | | |
| **6c** | | | For research following a DOD Addendum, the following must also be true: | | |  | | |  |
|  | | | The research does not involve an intervention or interaction with the subject for the primary purpose of obtaining data regarding the effect of either ***OR*** a waiver has been granted by the Secretary of Defense.  N/A – no DOD Addendum | | |  | | |  |
|  | | | | | | | | | |
| **7** | | | Should the requirement to include subjects’ names on a master list be waived, because it would pose an additional, potential risk to subjects from a breach of confidentiality?    N/A - a waiver of *consent process* is appropriately used for the study, so a master list is not required. | | | **Yes** | | | **No** |
|  | | |  | | | **Yes** | | | **No** |
| **8** | | | **Does the research protocol make adequate provision for monitoring the data collected to ensure the safety of subjects?** | | |  | | |  |
|  | | | If the research is under a Dept. of Defense (DOD) addendum, answer 8a and 8b.  N/A | | |  | | |  |
| **8a** | | | If the research is greater than minimal risk, has a research monitor has been named? | | |  | | |  |
| **8b** | | | If the research is not greater than minimal risk, should a research monitor be named for all or any part of the research? | | |  | | |  |
| **8c** | | | Does the protocol describe the data and safety monitoring plan and include all of the following elements (as applicable)? If **NO**, please attach a list of elements that need to be included.  For interventional studies, the following are **REQUIRED** elements:   * What safety information will be collected including serious adverse events and unanticipated problems involving risk. * How the safety information will be collected (e.g., case report forms, at study visits, by telephone, etc.). * The frequency of data collection including when safety data collection starts. * The frequency or periodicity of review of cumulative safety data. * If there will not be a data monitoring committee, and if applicable, what statistical tests will be used to analyze safety data and determine if harm is occurring? * Who will oversee safety data. * Which conditions would trigger an immediate suspension of the research, if applicable.   *For retrospective studies, including studies involving pre-existing data and biological specimens, there needs to be a description included of potential study outcomes that may have an effect on the subject’s health or well-being and a procedure to determine when and how to notify individual subjects or their health care providers of findings that may affect the subjects’ health.* | | |  | | |  |
|  | | |  | | | **Yes** | | | **No** |
| **9** | | | **Are there adequate provisions to protect the privacy of subjects?** | | |  | | |  |
|  | | |  | | | **Yes** | | | **No** |
| **10** | | | **Are there adequate provisions to maintain the confidentiality of the data?** | | |  | | |  |
|  | | |  | | |  | | |  |
| **11** | | | **List any subjects included in the study population who may be vulnerable to coercion or undue influence (e.g., children\*, prisoners\*, interventional or invasive monitoring of pregnant women\*, individuals with impaired decision-making capacity\*, economically or educationally disadvantaged persons, or those with a serious illness).**  N/A – no vulnerable subjects are included, OR  The following populations are/may be included: | | |  | | |  |
|  | | | **If any of the vulnerable populations in 11 are/may be included, please review the research protocol, and then answer the following questions:** | |  | | |  | |
|  | | |  | | **Yes** | | | **No** | |
| **11a** | | | Has the Principal Investigator listed in the protocol additional safeguards to protect the rights and welfare of the vulnerable subjects? | |  | | |  | |
| **11b** | | | Are any there any further additional safeguards that should be required (e.g., involvement of subject advocates, independent consent monitoring, formal capacity assessment, waiting periods, etc.) as part of the research plan to protect subjects? If YES, please specify in Comments or attach a separate list of recommended additional safeguards. | |  | | |  | |
|  | | | | | | | | | |
| **11c** | | | If the research involves persons with impaired decision-making capacity, please answer the following questions: | |  | | |  | |
| 1. At least one of the following three conditions is met? | | | | |  | | |  | |
| 1. The research is no greater than minimal risk to the subject; ***OR*** | | | | |  | | |  | |
| 1. The research presents a greater probability of direct benefit to the subject than harm to the subject; ***OR*** | | | | |  | | |  | |
| 1. The research presents greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition that is of vital importance for the understanding or amelioration of the subject’s disorder or condition. | | | | |  | | |  | |
|  | | | | |  | | |  | |
| 1. At least one of the following two conditions is met? | | | | |  | | |  | |
| a. The research cannot be performed solely with persons who possess decision-making capacity and the focus of the research is the disorder leading to the subjects’ lack of decision-making capacity, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke); ***OR*** | | | | |  | | |  | |
| b. The subject of the research is not directly related to the subjects’ lack of decision-making capacity but the investigator has presented a compelling argument for including such subjects (e.g., transmission of methicillin-resistant staphylococcus aureus infections in a nursing home where both individuals with and without decision-making capacity are affected). | | | | |  | | |  | |
|  | | | | |  | | |  | |
| 1. **Surrogate Consent:** The investigator has indicated in the protocol and/or IRQ Appendix A that when a potential subject is determined to lack decision-making capacity, that the following conditions will be met? | | | | |  | | |  | |
| 1. Consent will be obtained from the LAR of the subject (i.e., surrogate consent). | | | | |  | | |  | |
| 1. If feasible, the investigator will explain the proposed research to the prospective research subject even when the surrogate gives consent.   ***NOTE:*** *Although unable to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.* | | | | |  | | |  | |
| 1. The subject will not be forced to participate against their wishes, and, if feasible, will be asked for their assent. | | | | |  | | |  | |
| 1. LARs will be told that their obligation is to try to determine what the subjects would do if able to make an informed decision. | | | | |  | | |  | |
| 1. If the potential subjects’ wishes cannot be determined, the LARs will be told they are responsible for determining what is in the subjects’ best interest. | | | | |  | | |  | |
| 1. Should any additional safeguards be required (e.g., involvement of subject advocates, independent consent monitoring, formal capacity assessment, waiting periods, etc.) as part of the research plan to protect subjects? If **YES**, please attach a list of recommended additional safeguards. | | | | |  | | |  | |
|  | | |  | | | **Yes** | | **No** | |
| **12** | | | Does the protocol and/or IRQ indicate that the study has obtained or will obtain a Certificate of Confidentiality (CoC) in order to protect research subjects from whom personally identifiable, sensitive information is collected? (If **YES**, skip to 13) ***NOTE:*** *Sensitive information for purposes of a Certificate of Confidentiality includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.* | | |  | |  | |
| **12a** | | | If **NO** to 12, should the investigator be urged to consider the use of a CoC, given the information to be collected from subjects as part of the research? | | |  | |  | |
|  | | |  | | | **Yes** | | **No** | |
| **13** | | | **Does this study propose to enroll non-veterans? (**If **NO**, skip to 14) | | |  | |  | |
| **13a** | | | If **YES** to 13, The protocol includes appropriate justification for the inclusion of non-veterans (e.g., insufficient number of Veterans, survey of VA employees, study of active-duty military, etc.). | | |  | |  | |
|  | | |  | | |  | |  | |
| **13b** | | | If **YES** to 13, must a patient record be established in the Electronic Health Record (EHR) for each non-veteran because they will be seen as in-patients, treated as outpatients, or the research procedures are used in the medical care of the subject at a VA facility? | | |  | |  | |
|  | | |  | | | **Yes** | | **No** | |
| **14** | | | **Is this a multi-site study?** (If conducted at OHSU and VAPORHCS, it is multi-site.) | | |  | |  | |
| **14a** | | | If **YES** to 14, is the management of information, relevant to the protection of subjects at all sites, adequate? (See IRQ and the Multi-Site Study Concerns and Data and Safety Monitoring Plan sections of the Local Protocol, if applicable.) | | |  | |  | |
| **14b** | | | If **YES** to 14, has the PI clearly differentiated what will occur at the VAPORHCS versus other sites (including OHSU)? | | |  | |  | |
|  | | |  | | | **Yes** | | **No** | |
| **15** | | | **Based on review of the protocol and any other documents, is the project scientifically valid?** | | |  | |  | |
| **15a** | | | Does the research use procedures consistent with sound research design? | | |  | |  | |
| **15b** | | | Is the research design sound enough to yield the expected knowledge? | | |  | |  | |
|  | | |  | | | **Yes** | | **No** | |
| **16** | | | Does this study involve evaluating the safety and/or effectiveness of a device(s)? (if NO, skip to 17) (If YES to 16, see IRQ Appendix E and answer the following questions) | | |  | |  | |
| **16a** | | | Does the device already have a status with the FDA (e.g. IDE, 501(k), HDE, etc.)? | | |  | |  | |
| **16b** | | | If NO to 16a, does the device meet criteria to be Exempt from IDE Requirements (see list of criteria on IRQ Appendix E)? | | |  | |  | |
| **16c** | | | If NO to 16b, does the device meet criteria for a Non-Significant Risk Device (see risk-related questions on IRQ Appendix E) and the Abbreviated IDE Requirements (also listed on IRQ Appendix E)? | | |  | |  | |
|  | | | **Points to Consider for NSR determinations (from FDA Guidance):**  <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf> | | |  | |  | |
|  | | | * The risk determination needs to be based on the proposed use of a device in an investigation, and not on the device alone. * What is the nature of harm that may result from use of the device? Significant Risk (SR) studies are those that present a potential for serious risk to the health, safety, or welfare of a subject. * Will the subject need to undergo an additional procedure(s) as part of the investigational study? IRBs should consider the potential harm the procedure(s) could cause, as well as the potential harm caused by the device. | | |  | |  | |
| **16d** | | | Are any changes/clarifications needed regarding the device(s)? (If **YES**, please specify in Comments.) | | |  | |  | |
|  | | |  | | | **Yes** | | **No** | |
| **17** | | | Based on your review of the IRQ and answers from the PI at the IRB meeting (if applicable), are resources adequate?*Assessment should include, but not be limited to, money, investigator time, equipment, space, and qualified staff with adequate time to allow the research to be performed appropriately.* Specifically consider the following: | | |  | |  | |
| * The number and types of other studies the PI is supervising. | | | | | | | | | |
| * Whether there is a research coordinator for the study, what their experience and training (including Good Clinical Practice training) is, and on what other studies they are involved. | | | | | | | | | |
| * Other investigators, their role on the study, time, and whether any have the same privileges as the PI. | | | | | | | | | |

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| --- | --- | --- | --- |
| **RECOMMENDATIONS and/or DECISION:**  **APPROVE AS PRESENTED** (In order to approve the research project as presented, questions 1-3 and 8-10 must be answered “yes”, and either consent will be obtained or the study meets the criteria for a waiver of informed consent and/or a waiver of documentation of informed consent.)  **CONTINGENTLY APPROVE**(In order to approve the research project only after the described **specific** minor changes have been made by the Investigator and verified by the Primary Reviewer. Questions 1-3 and 8-10 must be “Yes”, or they will be answered “yes” as appropriate ***if*** a few **specific, minor** changes are made.)  **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*** | | | |
| |  |  | | --- | --- | |  | **DISAPPROVE – FOR FULLY CONVENED IRB ONLY** (To disapprove the research project for the documented reasons provided by the reviewer(s). The research should not be conducted, and the IRB will only reconsider if compelling reasons are presented. If the investigator is able to provide compelling reasons that the research should be conducted, the investigator’s response must be reviewed by the fully convened IRB.)  **Specify reason(s) for disapproval:**  ***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 Disapproval Letter*** |   **ASSESSMENT OF RISK *(****Check a box below – If moderate or high, review cannot be expedited)* | |
| **No Greater Than Minimal Risk**  **Moderate Risk**  **High Risk** | |
| **RATIONALE FOR RISK LEVEL**  **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**  *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, should the medical record be flagged to protect the participant’s safety by indicating participation in the study and the source of more information on the study?**  NO: flag not necessary  YES:  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**  **If approval is recommended, is an annual continuing review appropriate or required?**  *(select one of the four options below)*   1. **YES; Annual Continuing Review is required. Study is moderate or high risk and/or FDA- regulated and annual review is appropriate**      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   1. **YES; Annual continuing review would not otherwise be required per criteria above. However, annual continuing review is appropriate based on the following rationale:** 2. **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? | |
| **Expedited Category(ies) for Initial 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. |   **Additional Review Comments:** | |