| Note: **All applicable questions must be answered** | **Yes** | **No** | **NA** | **Investigator’s Comments**  (Please indicate the page numbers in the protocol or consent where information can be located for each question.) | | **Yes** | **No** | **NA** | **Reviewer’s Comments** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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| GENERAL RESEARCH INFORMATION | | | | | | | | | |
| 1. For a VA multi-site study, not only the principal researcher, but also all local site researchers, must obtain written approvals from the relevant local VA facilities’ IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements.   * Research cannot be initiated at any given site until the local researcher has obtained written notification that the research can be initiated from the local associate Chief of Staff for Research and Development.   Is this research a VA multi-site study?  If yes, have all the written approvals and notifications been obtained and submitted? |  |  |  |  | |  |  |  |  |
| **RADIATION/BIOSAFETY CONCERNS** | | | | | | | | | |
| 1. Does this study involve any **additional** radiation procedures? (i.e. x-rays)  If **yes**, documentation from the Radiation Safety Committee **must** be submitted to indicate approval for those procedures. |  |  |  |  | |  |  |  |  |
| 2. Does this study involve biosafety issues? (i.e. recombinant DNA or viral vectors)  If **yes**, documentation from the Safety/Biosafety Subcommittee **must** be submitted to indicate approval for those procedures. |  |  |  |  | |  |  |  |  |
| A. PRIVACY AND CONFIDENTIALITY | | | | | | | | | |
| 1. Does the medical record have to be flagged to protect the participant’s safety by indicating participation in the study?  The participant’s health record must be flagged if participation involves:   * Any invasive research procedure. * Interventions that will be used in the medical care of the subject, or that could interfere with other care the subject is receiving or may receive. * Clinical services that will be used in the medical care of the subject. * The use of a survey/questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interest of the subject. |  |  |  |  | |  |  |  |  |
| 2. Is the VA Data Protection Checklist attached to the submission? |  |  |  |  | |  |  |  |  |
| **B. PARTICIPANT SELECTION (JUSTICE)** | | | | | | | | | |
| 3. Will participants be paid? Payment may be permitted, with IRB approval, in the following circumstances:   * No direct subject benefit. When the standard of practice in affiliated non-VA institutions is to pay subjects in this situation. * When human subjects at a collaborating VA or non-VA institution are to be paid for the same participation in the same study. * In other comparable situations in which payment of subjects is appropriate. * When transportation expenses are incurred by the subject that would not be incurred in the normal course of receiving treatment and that are not reimbursed by any other mechanism. |  |  |  |  | |  |  |  |  |
| 4. Participant enrollment for VA research studies.   * Will non-veterans be entered into the research? For multisite protocols, this applies only to VA site recruitment. *(Non-veteran enrollment* ***must*** *be justified)* * Are there sufficient veterans available to complete the study? |  |  |  |  | |  |  |  |  |
| 5. For recruitment does protocol state that initial contact with potential subjects will be in person or by letter, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research? The initial contact must provide a telephone number or other means that the potential subject can use to verify the study constitutes VA research. |  |  |  |  | |  |  |  |  |
| 6. Will recruitment involve obtaining information from patient’s records, whether your patient or not?  ***If yes, a HIPAA waiver and Consent waiver must be submitted.*** |  |  |  |  | |  |  |  |  |
| **C. ADDITIONAL INFORMED CONSENT ELEMENTS FOR VA STUDIES** | | | | | | | | | |
| 7. Does consent contain contact information for the emergency department? |  |  |  |  | |  |  |  |  |
| 8. Does the consent contain a line for the participant’s signature or the participant’s legally authorized representative’s signature? |  |  |  |  | |  |  |  |  |
| 9. Is consent documented through the use of VA Form 10-1086? |  |  |  |  | |  |  |  |  |
| 10. Does the consent contain a statement that in the event of a research related injury the VA has to provide necessary medical treatment to a participant injured by participation? |  |  |  |  | |  |  |  |  |
| 11. Does the consent contain a statement that except in limited circumstances, the necessary care has to be provided in VA medical facilities? |  |  |  |  | |  |  |  |  |
| 12. Does the protocol or IRB application and the informed consent differentiate “usual care” from the research intervention? |  |  |  |  | |  |  |  |  |
| 13. Does the consent contain a statement that a veteran-participant will not be required to pay for care received as a participant in a VA research project except that certain veterans are required to pay co-payments for medical care and services provided by the VA? |  |  |  |  | |  |  |  |  |
| **D. COGNITIVELY IMPAIRED ADULTS** | | | | | | | | | |
| 14. Does this study include cognitively impaired adults?  **If no, skip this section.**  If yes, complete this section. |  |  |  |  | |  |  |  |  |
| 15. Only incompetent persons or persons with impaired decision making capacity are suitable as participants. |  |  |  |  | |  |  |  |  |
| 16. Competent persons are not suitable for the proposed research. |  |  |  |  | |  |  |  |  |
| 17. The investigator has demonstrated to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as participants. |  |  |  |  | |  |  |  |  |
| 18. Incompetent persons or persons with impaired decision-making capacity are not being proposed as participants simply because they are readily available. |  |  |  |  | |  |  |  |  |
| 19. The research does not impose a risk of injury, unless that research is intended to benefit that participant and the probability of benefit is greater than the probability of harm. |  |  |  |  | |  |  |  |  |
| 20. Procedures have been devised to ensure that participant’s representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity. |  |  |  |  | |  |  |  |  |
| 21. Legally authorized representatives will be told that their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant’s wishes cannot be determined, what they think is the incompetent person’s best interest. |  |  |  |  | |  |  |  |  |
| 22. Consent by a legally authorized representative will be limited to situations where the prospective participant is incompetent or has impaired decision-making capacity, as determined and documented in the person’s medical record in a signed and dated progress note. |  |  |  |  | |  |  |  |  |
| 23. If there is any question as to whether or not a potential adult subject has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision-making capacity, and the individual has not been ruled incompetent by a court of law, the investigator must consult with a qualified practitioner (who may be a member of the research team) about the individual’s decision-making capacity before proceeding with the informed consent process. Is this procedure documented in the protocol? |  |  |  |  | |  |  |  |  |
| 24. Is there a provision for re-consenting if participant regains decision-making capacity? |  |  |  |  | |  |  |  |  |
| 25. That whenever feasible, the practitioner will explain the proposed research to the prospective participant even when the surrogate gives consent. |  |  |  |  | |  |  |  |  |
| 26. Participants will not be forced or coerced to participate in a research study. |  |  |  |  | |  |  |  |  |
| Other Investigator Comments: | | | | | **Reviewer’s Recommendation (Please check)**  **Disapprove**  **Approve**  **Approve with the following modifications**.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please indicate below if you would like to have a copy of this form and your comments provided to the Principal Investigator.  **YES**  **NO**  Please indicate below if you would like to have the Principal Investigator for this study to be present at the next IRB meeting to clarify any issues or concerns that you may have had about this study.  **YES**  **NO** | | | | |