| 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 or collaborative study, not only the principal researcher, but also all local site researchers, must obtain written approvals from the relevant local VA and non-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 or collaborative 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. Is the VA Data Protection Checklist attached to the submission? |  |  |  |  | |  |  |  |  |
| **B. PARTICIPANT SELECTION (JUSTICE)** | | | | | | | | | |
| 2. 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. |  |  |  |  | |  |  |  |  |
| 3. 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** | | | | | | | | | |
| 4. Does the consent contain a line for the participant’s signature or the participant’s legally authorized representative’s signature? |  |  |  |  | |  |  |  |  |
| 5. 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? |  |  |  |  | |  |  |  |  |
| 6. Does the consent contain a statement that except in limited circumstances, the necessary care has to be provided in VA medical facilities? |  |  |  |  | |  |  |  |  |
| 7. Does the protocol or IRB application and the informed consent differentiate “usual care” from the research intervention? |  |  |  |  | |  |  |  |  |
| 8. 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? |  |  |  |  | |  |  |  |  |
| Other Investigator Comments: | | | | | **Reviewer’s Recommendation (Please check)**        \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please indicate below if you would like to have a copy of this form and your comments provided to the Principal Investigator.    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. | | | | |