

Primary Reviewer's Initial Review Checklist

Principal Investigator: _____

Name of Study: _____

Name of Primary Reviewer: _____ **Date of Review:** _____

In considering the information provided by the investigator for the initial review, please answer the questions and provide comments as needed. If an item does not apply to the protocol under review, please make note of the reason why.

1. Investigator Qualifications, Resources, and Conflict of Interests

a. Scientific training and qualifications of investigators and research staff are appropriate for the research described and the protection of human subjects. If an investigational drug is involved, the investigator is knowledgeable about FDA requirements (based on his/her experience, training, and licensure).	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. Research resources are appropriate to conduct this study according to HRPP standards and regulations	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. Conflict of Interest Forms for the investigators and study staff were submitted and there does not appear to be any potential conflict of interests that may influence their decisions and abilities to conduct the research study.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. Human subject protection training of investigators and research staff is up-to-date and appropriate to the protection of human subjects.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

2. Study Design

a. The study design and purpose is appropriate to the protection of human subjects.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. The scientific rationale is appropriate to the protection of human subjects.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

3. Subject Selection (inclusion and exclusion criteria)

a. The number of subjects to be enrolled was considered and seems appropriate	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. Subject selection criteria are equitable and are appropriate to the purposes of the research, are consistent with VA, DHHS and FDA policies.	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Equitable means that the burdens, risks, and benefits of the research are fairly distributed and do not place disproportionate burdens on any racial, ethnic, gender, vulnerable, or other disadvantaged group and do not systematically exclude persons who might benefit from the research.

4. Vulnerable Subjects

- a.** The reasons and justification for use of vulnerable subjects is appropriate to the protection of human subjects and additional protections are adequate to protect the rights and welfare of vulnerable subjects.
 Yes No Not part of the study
- b.** Vulnerable Populations are appropriately identified. Yes No Not part of the study
- c.** When incompetent individuals or persons with impaired decision-making capacity as participants are included in the study, the following items were adequately addressed:
1. The subjects were not being proposed as participants simply because they were readily available.
 2. The proposed research entailed no significant risks, tangible or intangible, or if the research presents some probability of harm, there is a greater probability of direct benefit to the participant.
 3. The research does not impose risk of injury, unless that research is intended to benefit that participant and the probability of benefit is greater than the probability of harm.
 4. Procedures are devised to ensure that participants' legally authorized representatives are well informed regarding their roles and obligations to protect incompetent participants or persons with impaired decision making capacity.
- Yes No Not part of the study

5. Risks to Subjects and Provisions for Data and Safety Monitoring

a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risks	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
b. Risks to participants are minimized, whenever appropriate, by using procedures already being performed on the subject for diagnostic or treatment purposes	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
c. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the research	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
d. The research plans makes adequate provisions for managing adverse events and for monitoring the safety of subjects and the data collected to ensure the safety of subjects	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
e. Is there a DSMB for this study?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
f. Research risks as distinguished from risks of therapeutic activities (when applicable) are acceptable	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
g. Physical risks of the research are adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study

h. Psychological risks of the research are adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
i. Social risks of the research are adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
j. Economic risks of the research are adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
k. Legal risks of the research are adequately considered	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study
l. Risks are reasonable in relation to the anticipated benefits, if any, and the importance of the knowledge that may be expected to result	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
m. The appropriateness of and rationale for elements warranting special attention (i.e. placebo; challenge studies; wash-out periods; deviations from standard care) is appropriate to the protection of human subjects	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Not part of the study

6. Subject Recruitment

a. Methods used to identify or recruit subjects are appropriate, do not create undue influence to participate, and adequately protect privacy and confidentiality. There are no “finder’s fees or bonus payments.

Yes No Not part of the study

b. Advertisement or materials used to recruit subjects does not include exculpatory language. If the study involves an investigational drug, the advertisement material does not offer a coupon good for a discount on the purchase price of the product once it had been approve for marketing.

Yes No No advertisement planned at this time

c. Methods used to obtain information about subjects are appropriate and adequately protect privacy of the participants and the confidentiality of the data.

Yes No

d. The nature and amount of compensation offered to subjects is appropriate and does not create undue influence to participate. VA Policy - The IRB will not approve payments to subjects when the research is integrated with a patient’s medical care and when it makes no special demands on the patient beyond those of usual medical care.

Yes No No payment is offered

7. Privacy (subjects’ personal space, dignity, and need for modesty)

Plans for provisions to protect subject privacy interests are adequate. Yes No

8. Confidentiality (subjects’ personal identity and health information)

a. Plans for provisions to maintain the confidentiality of data during and after study completion are adequate.

Yes No

b. The investigator completed the Data Security Checklist for Principal Investigators and signed Principal Investigator's Certification: Storage and Security of VA Research Information verifying that information is being used, stored and secured in accordance with the applicable VA and VHA policies and guidance.

Yes

No

9. Informed Consent (If there is a request for waiver of informed consent requested, go to next section)

a. Plans for assessment of a subject's capacity to consent to participate in research are adequate and plan to obtain the legally effective informed consent of the participant or the participant's legally authorized representative, using VA Form 10-1086 to document the consent.

Yes

No

b. For all studies that require informed consent, confirm that the following are disclosed in the consent form and **CHECK any items that are NOT in the consent form that SHOULD BE included:**

- A statement that the study involves research.
- An explanation of the purposes of the research.
- An explanation of the expected duration of the participant's participation.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
- An explanation of whom to contact for concerns, complaints or for answers to pertinent questions about the research and research subjects' rights.
- A statement that participation is voluntary
- A statement that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
- A statement that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
- If necessary, an explanation of any measures to prevent pregnancy that should be taken while in the study
- For FDA-regulated research, a statement that notes the possibility that the Food and Drug Administration may inspect the records.
- For studies involving greater than minimal risk, an explanation of whom to contact in the event of a research related injury; whether any compensation is available if injury occurs and if available, an explanation of what it consists of, or where further information may be obtained; whether any medical treatments are available if injury occurs and if available, an explanation of what it consists of, or where further information may be obtained.
- A statement that a copy of the signed and dated consent document would be given to the person signing the consent document.
- A place for the participant or the participant's legally authorized representative signs and dates the consent document.

g. If there is a potential that surrogate consent will be obtained, the investigator attests that specified conditions are met and the vulnerable population plan includes appropriate information regarding the additional safeguards to protect vulnerable subjects for IRB approval.

Yes No

Examples of additional safeguards that may be planned by the investigator or recommended by the IRB includes:

- *Ensuring subjects' understanding by requiring prospective subjects to take a test or to independently write or dictate their understanding of the research and risks*
- *Obtaining an independent assessment by a physician not involved in the study*
- *Employing a consent monitor to independently verify that informed consent has taken place*
- *Providing prospective subjects with an advocate during the consent process*
- *Providing additional opportunities for prospective subjects to decline to participate or to end their participation in the study*
- *Constructing an assent mechanism for subjects with limited autonomy*
- *Requiring a ceiling for level of risks of non-therapeutic procedures*
- *Requiring that research be limited to the medical conditions affecting the subjects*
- *Requiring that research not be performed on subjects who are unable to provide consent for themselves*
- *Re-consenting previous decisionally- incapable subjects who were enrolled via proxy consent, who become competent during the time of the study.*

10. Waiver of Informed Consent

Does the study meet criteria for waiver of informed consent?

Yes No Not requested

11. Altered Informed Consent

Does the study meet criteria for allowance of Altered Informed Consent or waiver of the requirements to obtain written documentation of consent?

Yes No Not requested

If waiver of the consent process or documentation is granted, does the IRB want the investigator to provide participants with a written statement regarding the research (if so, IRB must review the written statement that would be provided to participants).

Yes No Not requested

12. Alteration or Waiver of HIPAA Authorization

Does the study meet criteria for Alteration or Waiver of HIPAA Authorization?

Yes No Not requested

13. Benefits

a. Importance of the knowledge that may be reasonably expected to result from the research was evaluated and is acceptable. Yes No

b. Probable benefits to subjects were evaluated and explanation of probable benefits was appropriate and does not create undue influence to participate. Yes No

BENEFIT LEVEL (CHECK ONLY ONE):

- Prospect for direct benefit to participants
- Little prospect for benefit to participants, but likely to yield generalizable knowledge
- No prospect for direct benefit to participants, but likely to yield generalizable knowledge
- No prospect for direct benefit to participants, and unlikely to yield generalizable knowledge

14. Industry Sponsored Studies

There is a written plan (e.g. protocol, contract, sponsor memo) that demonstrates sponsors are following good clinical practice guidelines and applicable laws, regulations and guidelines and will report to investigators and regulatory authorities significant findings that could affect the safety and well being of research subjects.

- Yes No Not an industry sponsored study

15. External Site or Multi-site Research where TVAMC is lead PI (if the study does not involve external sites or multi-site research where the TVAMC is lead PI, skip this section)

When the investigator plans to conduct research at external sites, is the contact information for the site listed and is information provided on whether the site has granted permission for the research to be conducted? Yes No

Are plans described on whether or not the TVAMC IRB will be the IRB of record or state otherwise? Yes No

For multi-site studies in which TVAMC investigator is lead investigator, is information included about the management of information that is relevant to participant protections, such as:

- Unanticipated problems involving risks to participants or others
- Interim results
- Protocol modification

- Yes No

16. Tissue Banking

Tissue banking plans meet VA requirements (Note: specimens must be stored in a VA approved tissue bank).

- Yes No Not part of the study

IRB ACTION (Choose only one!)

- Approved** - As submitted - no revisions required
- Contingent Approval with Expedited Review** - Minor modifications or clarifications that are requested and may be verified by the IRB Chair or a designated IRB member.
- Contingent Approval with Convened IRB review** - Modifications that requires changes to the study protocol and review by the convened IRB.
- Tabled** - Requires significant modifications and must be re-submitted to the IRB through the normal submission scheduling procedures
- Disapproved** - Requires major protocol changes and must be re-submitted to the IRB through the normal submission scheduling procedures.

LIST contingencies, modifications or clarifications needed or reasons for table or disapproval:

RISK LEVEL (check one):

- Less than minimal**
- Minimal**
- Moderate**
- High**

CONTINUING REVIEW (check one, based on the level of risk):

- Annually**
- Every ___ months**

Signature of Primary Reviewer: _____ *Date:* _____