

UMB Human Research Protections Program

Criteria for Approval – Amendment (Full Board ONLY)

Checklist #1C

PROTOCOL NUMBER: _____

PRINCIPAL INVESTIGATOR: _____

In order to meet one of the approvable selections, the following **MUST** be YES, YES IF CONTINGENCIES MET, or N/A:

(1) Revisions to the protocol and their rationale have been adequately described and appropriately incorporated in to the BRAAN application, Informed Consent Document, and full protocol as applicable (i.e., does the PI provide adequate justification for the changes(s) requested?).
_____ Yes _____ Yes If Contingencies Met _____ No

(2) Would expected benefits to participants and potential for generalizeable knowledge remain unaffected by the proposed change?
_____ Yes _____ Yes If Contingencies Met _____ No

(3) Does the proposed change affect individual and/or cumulative risk?
One of the following is true (please check the applicable box):
 There have been no changes to participant safety (i.e., risk-benefit ratio)
 Changes in the risk-benefit ratio are more favorable than initially proposed:
 ▪ Changes do not negatively effect participant safety
 ▪ Changes should not affect a participant’s willingness to continue with the research activities.
 Changes in the risk-benefit ratio are less favorable than initially proposed and may possibly affect the participant’s decision to continue with the research activities.
_____ Yes _____ Yes If Contingencies Met _____ No

(4) If the risk-benefit ratio is less favorable, one of the following is true (Please check the appropriate box):
 The IRB finds the risk to be acceptable and mechanisms for informing participants has been addressed
 The IRB does not find the risk to be acceptable and makes appropriate determinations (i.e., request closure of the study, request Investigator to suspend the study to enrollment, requests the Investigator to suspend the study, IRB suspends the study to enrollment, the IRB suspends the study, any other action deemed appropriate by the IRB Committee).
_____ Yes _____ Yes If Contingencies Met _____ No

(5) If the risk-benefit ratio is unchanged or more favorable, one of the following is true:
 Changes to the research activities will not require changes in the informed consent document (i.e., the currently approved consent document is still accurate and complete).
 Changes to the research activities will require changes in the informed consent document and they have been adequately and appropriately incorporated (i.e., the proposed consent document is accurate and complete).
 Changes to the research activities will require changes in the informed consent document and they have NOT been adequately and appropriately incorporated.
_____ Yes _____ Yes If Contingencies Met _____ No

(6) Are all the risks and benefits documented appropriately in the consent form?
_____ Yes _____ Yes If Contingencies Met _____ No

(7) One of the following is true:
 Changes to the informed consent document will not require re-consenting of previously enrolled participants.
 Changes to the research activities will require changes to the informed consent document that will require re-consenting of previously enrolled participants and notification of participants who have completed the research interventions. The notification letter is attached and has been reviewed and approved by the IRB.
 Changes to the research activities will require notification of currently enrolled participants and notification of participants who have completed the research interventions. The notification letter is attached and has been reviewed and approved by the IRB.
_____ Yes _____ Yes If Contingencies Met _____ No

(8) Do provisions for protecting privacy (if applicable) remain adequate?

_____ YES _____ YES IF CONTINGENCIES MET _____ NO

(9) The requested change impacts on the scientific integrity of the study by (select the appropriate description):

- Increasing the scientific integrity
- Not changing the scientific integrity
- Decreasing the scientific integrity

_____ Yes _____ Yes If Contingencies Met _____ No

(10) If the change decreases the scientific integrity of the study, one of the following is true:

- The IRB has determined that the study may continue (i.e., scientific integrity is adequate)
- The IRB has requested appropriate action(s) (i.e., request closure of the study, request Investigator to suspend the study to enrollment, requests the Investigator to suspend the study, IRB suspends the study to enrollment, the IRB suspends the study, any other action deemed appropriate by the IRB Committee).
- The IRB has determined that the scientific integrity is significantly affected and the amendment is disapproved.

_____ Yes _____ Yes If Contingencies Met _____ No

(11) Vulnerable populations have been added to the protocol and one of the following is true (please check the appropriate box):

- None of the participants are likely to be vulnerable to coercion or undue influence.
- Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence.

_____ Yes _____ Yes If Contingencies Met _____ No

(12) If applicable, the changes contain information that needs to be communicated to previously enrolled participants (i.e., information that may affect the participants' willingness to continue in the study; information that would meaningfully add to the protection of the rights and welfare of participants) and provisions have been made to do so.

_____ Yes _____ Yes If Contingencies Met _____ No _____ N/A

(13) Does subject selection remain equitable?

_____ Yes _____ Yes If Contingencies Met _____ No

(14) Does recruitment remain without coercion?

_____ Yes _____ Yes If Contingencies Met _____ No

Complete #15-17 if the Study Under Review Involves the Addition of the VAHMCS as a Site, Otherwise Skip

(15) Does the medical record need to be flagged to protect the participant's safety by indicating participation in the study and the source for where more information on the study can be obtained?

The IRB considered not flagging the medical record if (choose all that apply):

- Participation in the study involved only one encounter.
- Participation in the study involved the use of a questionnaire or previously collected biological specimens.
- Identification as a participant in a particular study would place the participant at greater than minimal risk.

_____ The Medical Record should be flagged

_____ The Medical Record does not need to be flagged

(16) Recruitment (confirm all of the below):

- The initial contact with the patient is through a letter and/or in person (prior to phone contact).
- During the phone contact, research staff will not request the veteran's social security number.
- Phone and other contacts with veterans are restricted to only those procedures and data elements outlined in the protocol/application for approval.
- During the initial contact, research staff provide the veteran with a telephone number or other means that the veteran can use to verify the validity of the study.
- The informed consent document form contains information about where and how a veteran can verify the validity of a study and authorized contacts.

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(17) Does this modification involve biosafety or ionizing radiation?

- No
- Yes → Do NOT process. Notify the Director of IRB Operations. The appropriate R&D subcommittee must approve the modification before the UMB IRB reviews the transaction.

The modified research (amendment) is:

- Approved
- Approved with minor modifications/minor contingencies
- Deferred
- Disapproved

Signed _____

Dated _____

References: 45 CFR 46.111, 21 CFR 56.11, and 38 CFR 16.111 and UMB HRPP and IRB P&Ps SOP II.2.A.1