

UMB Human Research Protections Program
Criteria for Approval – New Protocol
Checklist #1A

PROTOCOL NUMBER: _____

PRINCIPAL INVESTIGATOR: _____

In order to meet one of the approvable selections, ALL of the following MUST be YES or YES IF CONTINGENCIES MET:

(1) Is the study feasible?

_____ Yes _____ Yes If Contingencies Met _____ No

(2) Do the PI & study team have the appropriate expertise?

_____ Yes _____ Yes If Contingencies Met _____ No

(3) Is the study adequately designed to meet the aims?

_____ Yes _____ Yes If Contingencies Met _____ No

(4) Are the research procedures adequately differentiated from clinical practice?

_____ Yes _____ Yes If Contingencies Met _____ No

(5) Are the inclusion/exclusion criteria explicit and justifiable and is the target participant population clear?

_____ Yes _____ Yes If Contingencies Met _____ No

(6) Are there adequate processes described to ensure that potential participants have an ongoing understanding of the consent?

_____ Yes _____ Yes If Contingencies Met _____ No

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

(7) If there is a partial HIPAA waiver, is it justified? If no partial HIPAA waiver, select N/A.

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

In order to meet one of the approvable selections, the following MUST be YES or YES IF CONTINGENCIES MET.

(8) HIPAA documentation is adequate and there are no concerns?

_____ Yes _____ Yes If Contingencies Met _____ No

In order to meet one of the approvable selections, ALL of the following MUST be YES or YES IF CONTINGENCIES MET:

(9) Is the level of risk designated by the PI appropriate?

_____ Yes _____ Yes If Contingencies Met _____ No

(10) Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

_____ Yes _____ Yes If Contingencies Met _____ No

(11) Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

_____ Yes _____ Yes If Contingencies Met _____ No

(12) Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies participants would receive even if not participating in the research). The IRB should 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 purview of its responsibility.

A. The research is likely to achieve its proposed aims.

AND

B. The importance of the knowledge expected to result is clear.

_____ Yes _____ Yes If Contingencies Met _____ No

(13) Selection of participants imposes fair and equitable burdens and benefits, taking into account ALL of the following:

A. The purposes of the research.

B. The setting in which the research will be conducted.

C. Recruitment methods.

D. If applicable, the special problems of research involving vulnerable populations, including those defined by the regulations (see associated checklists as indicated) as well as others (i.e., economically or educationally disadvantaged, students, employees, etc.).

_____ Yes _____ Yes If Contingencies Met _____ No

(14) One of the following is true:

Informed consent will be sought from each prospective participant or the participant's representative (Choose the appropriate mechanism below).

The requirement for written documentation will be waived.

Informed consent will be documented in writing.

The informed consent process will be waived and the PI has provided adequate justification.

_____ Yes _____ Yes If Contingencies Met _____ No

(15) Does the research plan make adequate provision for monitoring the data collected to ensure the safety of participants (i.e., the DSMP is appropriate for the level of risk?).

_____ Yes _____ Yes If Contingencies Met _____ No

(16) When appropriate, there are adequate provisions to protect the privacy of participants.

_____ Yes _____ Yes If Contingencies Met _____ No

(17) When appropriate, there are adequate provisions to maintain the confidentiality of data.

_____ Yes _____ Yes If Contingencies Met _____ No

(18) One of the following is true:

None of the participants are likely to be vulnerable to coercion or undue influence.

Additional safeguards are 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

(19) The IRB considered the review interval and one of the following is true:

- Continuing review is designated at one year.
- After protocol review, the Committee designated continuing review at an interval less than one year because there was increased concern(s) related to**:
 - A. First use of investigational device or agent in humans
 - B. Increased risk related to the enrollment of vulnerable populations
 - C. Involvement of recombinant DNA or other types of gene transfer protocols
 - D. Classified research
 - E. Research for which participants would be exposed to additional risks (e.g. breach of confidentiality, Phase I studies, disproportionate number or severity of adverse events)
 - F. Previous Suspensions of the research due to non-compliance, record-keeping or other concerns
 - G. Recommendations from other Institutional committees (e.g., RSC, GCRC)
 - H. Any other concern designated by the IRB (Indicate rationale here):

_____ Yes _____ Yes If Contingencies Met _____ No

** Items listed here do not REQUIRE that the review interval be less than one year and are simply examples of types of studies to be considered under this criteria.

ONLY Complete the Below Section if the Study Under Review Involves VAHMCS Research

(20) 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

(21) Does this study involve Exception from Informed Consent Requirements for Planned Emergency Research? _____ No or _____ Yes → STOP, VAHMCS prohibits this type of research

(22) 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.

(23) One of the following is true:

- Approval without modification
- Approvable with *minor modifications to the protocol*/Approvable with *minor contingencies to the research application*
- Additional issues need to be addressed and CONTINGENCIES CANNOT BE DEVELOPED → The protocol MUST BE DEFERRED
- The protocol is without scientific merit or the risks are unacceptable → The protocol MUST BE DISAPPROVED

_____ Yes _____ No

The research is:

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

The review period is:

- One year
- Less than one year, the recommended interval is (specify):
- Following the enrollment of a specified # of subjects (specify #):
- Other

_____ see item 20 A-I

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