NOTE: This form covers all types (levels) of review for projects using human subjects and is intended to guide IRB review and discussion and to guide application development by investigators (see also IRB Application Guide). Its use may help investigators to develop more complete applications and move through IRB faster. Not all items are relevant to every proposal.

USE OF THIS CHECKLIST for review of assigned applications, other than as a guide, is optional. New IRB members are encouraged to use it to become familiar with the scope of reviews. The FORM: Reviewer Response Sheet which summarizes the criteria and is shorter is available, is preferred for expedited reviews. Reviewers of full board applications may complete this checklist or the shorter Reviewer Response Sheet. Regardless of which form is used, comment on missing or inadequately explained items in reference to the relevant criteria.

Both forms can be used for initial or continuing review or reviews of modified proposals.

IF YOU USE THIS LONG FORM FOR REVIEWS: please assess the presence of CONFLICT OF INTEREST of interest with each application assigned to you, whether for expedited or full board review, and sign the COI statement below for each. If you have a conflict, return the first page of this checklist to the Research Compliance Specialist (FAX 348-7189) as soon as possible so that the application can be reassigned.

If you have no conflict, review the application and return the first page of this checklist with your completed review or to the meeting of the full board at which the application is reviewed and give it to the Research Compliance Specialist.

REVIEWER COI STATEMENT:

I ______ DO ______ DO NOT have a conflict of interest with this application.

SIGNATURE____________________________________________________

DATE________________________
Investigator: ____________________________________________________________

Study Title: ____________________________________________________________

Type of Application: Initial _____ Continuing _____ Modification _______ Expedited _____

IRB #: __________________________ Date: ___________________

Criteria for Approval

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Physical, psychological, social, legal, and economic risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.</td>
<td></td>
</tr>
<tr>
<td>Would an alternative scientific design reduce the likelihood or magnitude of harm, but still answer the scientific question?</td>
<td></td>
</tr>
<tr>
<td>Would alternative procedures reduce the likelihood or magnitude of harm, but still answer the scientific question?</td>
<td></td>
</tr>
<tr>
<td>Would an alternative participant population reduce the likelihood or magnitude of harm, but still answer the scientific question?</td>
<td></td>
</tr>
<tr>
<td>Would fewer procedures answer the scientific question?</td>
<td></td>
</tr>
<tr>
<td>Would fewer participants answer the scientific question?</td>
<td></td>
</tr>
<tr>
<td>Are the research staff members qualified to conduct the procedures?</td>
<td></td>
</tr>
<tr>
<td>Does the investigator have adequate numbers of qualified staff?</td>
<td></td>
</tr>
<tr>
<td>Does the investigator have adequate facilities to conduct the research?</td>
<td></td>
</tr>
<tr>
<td>Does the investigator have a process to ensure that persons assisting with the research are adequately informed about the protocol and their research-related duties and functions?</td>
<td></td>
</tr>
<tr>
<td>Are medical or psychological resources available that participants might require as a consequence of the research?</td>
<td></td>
</tr>
<tr>
<td>For community-based research, is evidence present of community collaboration, support, service, or investigator feedback to community?</td>
<td></td>
</tr>
<tr>
<td>(2) Physical, psychological, social, legal, and economic risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.</td>
<td></td>
</tr>
<tr>
<td>Are procedures that will answer the scientific question being done anyway?</td>
<td></td>
</tr>
<tr>
<td>If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm?</td>
<td></td>
</tr>
<tr>
<td>(3) Physical, psychological, social, legal, and economic 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.</td>
<td></td>
</tr>
<tr>
<td>Is it clear what this study hopes to learn? (Research questions or hypotheses are present and clearly stated.)</td>
<td></td>
</tr>
<tr>
<td>Does the investigator have access to a population that will allow recruitment of the necessary number of participants?</td>
<td></td>
</tr>
<tr>
<td>Does the investigator have sufficient time to conduct and complete the research?</td>
<td></td>
</tr>
<tr>
<td>Is the research feasible?</td>
<td></td>
</tr>
<tr>
<td>Is the research likely to answer its proposed question?</td>
<td></td>
</tr>
<tr>
<td>Does the knowledge expected to result have importance?</td>
<td></td>
</tr>
</tbody>
</table>
| 4 | Selection of participants is equitable.  
Consider the purpose of the research.  
Consider the setting in which the research will be conducted.  
Consider the involvement of populations vulnerable to coercion or undue influence.  
Consider inclusion and exclusion criteria.  
Consider recruitment and payment methods. |
| 5 | The informed consent process will be waived or altered. (See Criteria to Waive or Alter Requirement to Obtain Informed Consent)  
OR  
Informed consent will be sought from each prospective participant or the participant’s representative in accordance with the regulations as follows: |

| 5a | The investigator will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative (LAR).  
Has the investigator indicated whether consent will be obtained from the participant, from a legally authorized representative, or both?  
If a legally authorized representative will be used, do the individuals to be used meet the regulatory definition?  
Are there impediments to participants’ or representatives’ understanding of the facts?  
Will the participants or representatives appreciate the implications of decision?  
Will the participants or representatives be able to decide?  
Are participants provided an opportunity to ask questions?  
Is contact information for investigator and Office of Research Compliance present for later questions, concerns, or complaints? |
| 5b | The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.  
How much time will be devoted to the consent discussion?  
How much time will be allowed for a decision? |
| 5c | The circumstances of consent minimize the possibility of coercion or undue influence.  
Is there a power differential?  
Are there communication issues?  
Are there issues regarding the capacity to make a decision?  
IF YES, will the capacity of prospects be assessed?  
Are there excessive motivating factors?  
Is the recruitment process acceptable (not coercive or stigmatizing?)  
Are advertisements acceptable?  
Do payment arrangements conform to IRB policy? |
(5d) The information that will be given to the participant or the representative will be in language understandable to the participant or the representative.

What language do the participants or representatives speak?
Will written information be in the language understandable to the participants or representatives?
Can the research team communicate in understandable language to the participants or representatives?
Is the reading level of the explanation or consent document at grade 8 or lower or otherwise justified?

(5e) No information will be provided to the participant or the representative that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Is the information factual? (E.g., the policy, plan, expectation, or law)
Does the information avoid stating an outcome? (E.g., something will or will not happen)

(5f) All required and appropriate additional disclosures will be provided to the participant or the participant's representative. (See Elements of Informed Consent Disclosure)

(6)

- The informed consent process will be waived. (See Criteria to Waive or Alter Requirement to Obtain Informed Consent)

  OR

- The requirement for written documentation will be waived. (See Criteria to Waive Requirement for Written Documentation of Informed Consent)

  OR

- Informed consent will be documented in writing in accordance with the appropriate regulations. All consent documents for FDA-regulated research must be signed and dated. All UA consent documents, including re-assessment and verification of continued consent, will be signed and dated

<table>
<thead>
<tr>
<th>Long form</th>
</tr>
</thead>
<tbody>
<tr>
<td>The consent document embodies the basic and appropriate additional elements of disclosure. (See Elements of Informed Consent Disclosure at end of form).</td>
</tr>
<tr>
<td>The participant or the participant’s legally authorized representative will sign and date the consent document. (ALL UA written consent documents are to be signed and dated.)</td>
</tr>
<tr>
<td>For FDA-regulated research, the participant or the participant’s legally authorized representative will sign and date the consent document.</td>
</tr>
<tr>
<td>A copy of the consent document will be given to the person signing the consent document or the legally authorized representative.</td>
</tr>
<tr>
<td>The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Short form</th>
</tr>
</thead>
<tbody>
<tr>
<td>The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant’s legally authorized representative.</td>
</tr>
<tr>
<td>A written summary (Information Sheet) embodies the basic and appropriate additional elements of disclosure.</td>
</tr>
<tr>
<td>There will be a witness to the oral presentation.</td>
</tr>
</tbody>
</table>
For participants who do not speak English, the witness is conversant in both English and the language of the participant.
The participant or the participant’s legally authorized representative will sign the consent document.
For FDA-regulated research, the participant or the participant’s legally authorized representative will sign and date the consent document.
The witness will sign both the short form and a copy of the summary.
The person actually obtaining consent will sign a copy of the summary.
A copy of the short form will be given to the participant or the representative.
A copy of the summary will be given to the participant or the representative.
For VA research:
The participant or the participant’s legally authorized representative will sign and date the consent document.
The witness will sign and date both the short form and a copy of the summary.
The person actually obtaining consent will sign and date a copy of the summary.
A copy of the signed and dated short form will be given to the participant or the representative.

1. **(7)** The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. *(Not applicable if the research involves no more than minimal risk.)*

   - Does proposal state who will monitor the data?
   - What data will be monitored?
   - How frequently will data be monitored?
   - What analyses will be performed on the data?
   - What decision rules (e.g., stopping rules) will be considered?
   - Will unexpected harms be detected promptly?
   - Will an increased frequency or severity of unexpected harms be detected promptly?
   - Will the protocol be stopped once benefits are proven to outweigh harms?
   - Will the protocol be stopped once harms are proven to outweigh benefits?

2. **(8)** There are adequate provisions to protect the privacy of participants.

   - Will participants have an expectation of privacy?
   - Will participants think that the information sought is any of the researcher’s business—that researcher has a reasonable right to know this for research?
   - Will participants be comfortable in the research setting?
   - Are prospects informed of observations that must be reported to legal or other authorities (e.g., child, elder, or spouse abuse)?
   - Will participants be comfortable with the research procedures?

3. **(9)** There are adequate provisions to maintain the confidentiality of the data.

   - If Protected Health Information (PHI) is to be used, have the investigator and staff completed HIPAA training?
   - Will confidentiality be pledged?
   - Are there legal/ethical requirements?
   - Will data release cause risk of harm?
   - Are appropriate techniques being used to protect confidentiality?
     - Inter-file linkage
     - Error inoculation
     - Statistical strategies
     - Top coding
Restricted public use data
Restricted access, enclaves, archives
Certificates of Confidentiality
Ethical editing of qualitative descriptions
Data brokering

- (10) 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.
- If children/minors are to be enrolled, will appropriate assent be obtained?

### Considerations For All Reviews

- Does the IRB have the scientific or scholarly expertise, the representational experience, knowledge of the local context, and other expertise needed to review this research? *(If not, obtain consultation or review by another IRB.)*

- Is there a potential conflict of interest (COI) for the investigator or staff that may adversely affect the protection of participants in terms of criteria for IRB approval or the integrity of the research?

- Should review be performed more often than annually? *(If YES, justify and suggest review period.)*

- Are necessary letters of agreement or other evidence of support from collaborating units or institutions (e.g., nursing units, community agencies, public schools) present and adequate for the details of the research?

- UA Policy: Are all consent documents (including re-consenting or verification of ongoing consent) signed and dated?

- Is this a multi-site study in which the UA investigator is the lead site? If YES, is the investigator’s management of information obtained in multi-site research that might be relevant to the protection of human subjects adequate?

- Has the PI demonstrated awareness of and responsiveness to relevant regulations and legislation (PPRA, FERPA, HIPAA, DoD, DOE requirements, etc.)?

### Considerations For Continuing Review

- Should review be performed more often than annually?
- Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review?
- Has new information about COI become available? If so, does it affect participant risk or research integrity?
- Is the consent document accurate and complete?
- Has information arisen that might affect the willingness of participants to continue to take part in the research? *IF YES, will it be provided to those participants?*

### Considerations For Review Of Modifications To Previously Approved Research

- Has information arisen that might affect the willingness of participants to continue to take part in the research? *IF YES, will it be provided to those participants?*
### Criteria for Approval (Brief)

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Physical, psychological, social, legal, and economic risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.</td>
<td></td>
</tr>
<tr>
<td>(2) Physical, psychological, social, legal, and economic risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.</td>
<td></td>
</tr>
<tr>
<td>(3) Physical, psychological, social, legal, and economic 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.</td>
<td></td>
</tr>
<tr>
<td>(4) Selection of participants is equitable.</td>
<td></td>
</tr>
<tr>
<td>(5) The informed consent process will be waived or altered. (See Criteria to Waive or Alter Requirement to Obtain Informed Consent)</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Informed consent will be sought from each prospective participant or the participant’s representative in accordance with the regulations as follows:</td>
<td></td>
</tr>
<tr>
<td>(5a) The investigator will obtain the legally effective informed consent of the participant or the participant’s legally authorized representative.</td>
<td></td>
</tr>
<tr>
<td>(5b) The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.</td>
<td></td>
</tr>
<tr>
<td>(5c) The circumstances of consent minimize the possibility of coercion or undue influence.</td>
<td></td>
</tr>
<tr>
<td>(5d) The information that will be given to the participant or the representative will be in language understandable to the participant or the representative.</td>
<td></td>
</tr>
<tr>
<td>(5e) No information will be provided to the participant or the representative that waives or appears to waive any of the participant’s legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.</td>
<td></td>
</tr>
<tr>
<td>(5f) All required and appropriate additional disclosures will be provided to the participant or the participant’s representative. (See Elements of Informed Consent Disclosure)</td>
<td></td>
</tr>
<tr>
<td>(6) The informed consent process will be waived. (See Criteria to Waive or Alter Requirement to Obtain Informed Consent)</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>The requirement for written documentation will be waived. (See Criteria to Waive Requirement for Written Documentation of Informed Consent)</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td></td>
</tr>
<tr>
<td>Informed consent will be documented in writing in accordance with the regulations.</td>
<td></td>
</tr>
<tr>
<td>Long form</td>
<td></td>
</tr>
<tr>
<td>The consent document embodies the basic and appropriate additional elements of disclosure. (See Elements of Informed Consent Disclosure)</td>
<td></td>
</tr>
<tr>
<td>The participant or the participant’s legally authorized representative will sign and date the consent document.</td>
<td></td>
</tr>
<tr>
<td>If the research is FDA-regulated, the participant or the participant’s legally authorized representative will sign and date the consent document.</td>
<td></td>
</tr>
<tr>
<td>A copy of the signed and dated consent document will be given to the person signing the consent document.</td>
<td></td>
</tr>
<tr>
<td>The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed and dated.</td>
<td></td>
</tr>
</tbody>
</table>
Short form

The consent document states that the elements of disclosure required by regulations have been presented orally to the participant or the participant’s legally authorized representative.

A written summary embodies the basic and appropriate additional elements of disclosure. There will be a witness to the oral presentation.

For participants who do not speak English, the witness is conversant in both English and the language of the participant.

The participant or the participant’s legally authorized representative will sign and date the consent document.

The witness will sign and date both the short form and a copy of the summary.

The person actually obtaining consent will sign and date a copy of the summary.

A copy of the signed and dated short form will be given to the participant or the representative.

A copy of the signed and dated summary will be given to the participant or the representative.

(7) The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants. (Not applicable if the research involves no more than minimal risk.)

(8) There are adequate provisions to protect the privacy of participants.

(9) There are adequate provisions to maintain the confidentiality of the data.

(10) 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.

Considerations For All Reviews

Does the IRB have the scientific or scholarly expertise, the representational experience, knowledge of the local context, and other expertise needed to review this research? (If not, obtain consultation or review by another IRB.)

Has the PI addressed all regulations and legislation

Considerations For Initial Review

Should review be obtained more often than annually?

Considerations For Continuing Review

Should review be obtained more often than annually?

Should verification be obtained from sources other than the investigator that no material changes have taken place since prior IRB review?

Has new information about COI become available? If so, does it affect participant risk or research integrity?

Is the consent document is accurate and complete?

If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?

Considerations For Review Of Modifications To Previously Approved Research

If information has arisen that might affect the willingness of participants to continue to take part in the research, will it be provided to those participants?
### Elements of Informed Consent Disclosure (5f)

**Required**

- 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 that are experimental. *(May be omitted if there are none.)*
- A description of any reasonably foreseeable risks or discomforts to the participant. *(May be omitted if there are none.)*
- A description of any benefits to the participant or to others, which may reasonably be expected from the research. *(May be omitted if there are none.)*
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant. *(May be omitted if there are none.)*
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. *(May be omitted if confidentiality will not be maintained.)*
- A statement that notes the possibility that the Food and Drug Administration may inspect the records. *(May be omitted for research that is not subject to FDA regulations.)*
- An explanation as to whether compensation is available if injury occurs. *(May be omitted if the research involves no more than minimal risk.)*
- If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- An explanation as to whether any medical treatments are available if injury occurs. *(May be omitted if the research involves no more than minimal risk.)*
- If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained. *(May be omitted if the research involves no more than minimal risk.)*
- An explanation of whom to contact for answers to pertinent questions about the research.
- An explanation of whom to contact for answers to pertinent questions about the research participants’ rights.
- An explanation of whom to contact in the event of a research-related injury to the participant. *(Note: May not be omitted just because the research involves no more than minimal risk.)*
- 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 can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

- A description of the amount and schedule of any payments.

### CRITERIA TO WAIVE/ALTER INFORMED CONSENT (Non-FDA-Regulated Research Only)

- The research involves no more than minimal risk to subjects.
- The waive or alteration will not adversely affect the rights and welfare of the subjects.
- The research could not practicably be carried out without the waiver or alteration of informed consent.
- In research using deception or concealment subjects should be provided with additional pertinent information (debriefing) at the end of the study if their identity is known and data were collected with identifiers.

### CRITERIA FOR WAIVER OF WRITTEN DOCUMENTATION OF INFORMED CONSENT

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality; each subject must be asked whether s/he wants documentation; or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

*NOTE: The first criterion is not included in FDA 21 CFR 56.109 (c). The second is in both FDA 21 CFR 56.109 (c). and HHS regulations 45 CFR 46.116(a)-(b).*

### Required for VA Research

- A statement that in the event of a research-related injury the VA had to provide necessary medical treatment to a participant injured by participation.
- A statement that a veteran-participant would not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans were required to pay co-payments for medical care and services provided by VA.

### Additional

- A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. *(Look for when research involves investigational drugs/devices, novel procedures involving risk, or where a goal of the research is to define safety.)*
- A statement that if the participant is or becomes pregnant, the
particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)

- **Anticipated circumstances under which the participant’s participation may be terminated by the investigator without regard to the participant’s consent.** (Look for when the protocol mentions this as a possibility.)

- **Any additional costs to the participant that may result from participation in the research.** (Look for when additional costs are expected.)

- **The consequences of a participant’s decision to withdraw from the research.** (Look for when withdrawal from the research will have adverse consequence.)

- **Procedures for orderly termination of participation by the participant.** (Look for when such procedures are part of the protocol.)

- **A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.** (Look for on long-term clinical trials.)

- **The approximate number of participants involved in the study.**

  **Other**

- **No statements similar to “Compensation will not be provided.”**

- **No signature line for legally authorized representative or parent, when the research is not approved for cognitively impaired adults or children.**