### Research Protocol #:

### Investigator Full Name:

### Research Protocol Title:

**Instructions:**

- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.

For example, if modifications are needed to meet an approval criterion, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.

- If a 45 CFR 46.111 approval criteria is "Not Relevant" based on the type of research, explain why.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

#### Review Type. (Check applicable boxes.) If the answer to one of the first two questions is "No," then modifications must be requested.

- [ ] Initial Review
- [ ] Continuing Review
- [ ] Expedited review *(attach Expedited Addendum)*
- [ ] Convened

**YN**

For initial review, does the investigator have the resources necessary to protect subjects?

- Resources might include: availability, number, expertise, and experience of investigator and staff
- Time to conduct and complete the research
- Facilities and equipment to conduct, monitor, and protect subjects
- Access to a population that will allow recruiting the necessary number of subjects
- Availability of medical or psychological resources that subjects may need as a consequence of the research
- Resources for subject communication, e.g., translation services

**YN**

On continuing review, does the investigator continue to have the resources necessary to protect subjects?

- Resources might include personnel, time, and access to a study population
- Sufficient time to conduct and complete the research
- Researchers should stop a study if resources become unavailable

**YN**

On continuing review, is verification needed from sources other than the investigator that no material changes have occurred since the previous IRB review? *If not applicable, skip question.*

- Does information contained in the continuing review report raise concerns about possible material changes in the study occurring without IRB approval?
- Has the investigator previously failed to comply with the requirements of the HHS regulations at 45 CFR part 46 or the requirements or determinations of the IRB?
- Does the protocol involve a complex design or unusual levels or types of risk?
On continuing review, do any new significant findings that arise from the review process and that may relate to the subjects’ willingness to continue participation need to be provided to subjects?

Explain if YES.

Is this a multi-site study in which the investigator is the lead site?

Answer only if above is YES. Is the investigator’s management of information relevant to the protection of subjects adequate in this role as the lead site?

Explain if YES.

1 Study Population.

<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

Is subject selection equitable? [45 CFR 46.111(a)(3)]

- Justification for the inclusion of any vulnerable population
- Inclusion/Exclusion criteria are appropriate
- A certain group is not targeted or excluded without justification
- Subject recruitment and enrollment procedures do not cause inequitable selection
- The amount and timing of payments to subjects does not cause inequitable selection

Comments:

2 Drugs, Biologics and Devices Used in the Research.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Drugs or Biologics.</th>
</tr>
</thead>
</table>

(Check applicable boxes, if more than one drug indicate your determination for each one.)

Reference:

- Tip Sheet #9

- IND is not required for this study. Indicate category for IND exemption.
  - Category 1: FDA Determination of Exemption
  - Category 2: FDA-approved drug
  - Category 3: in vitro diagnostic biological product
  - Category 4: in vitro or animal use
  - Category 5: Bioavailability or bioequivalence study
  - Category 6: Clinical bioavailability or bioequivalence study for approval of abbreviated or supplemental NDA

- IND is required for this study and has been provided and verified.
  - External Sponsor holds IND
  - UIC Investigator holds IND - management plan for sponsor and investigator roles
  - Non-UIC Investigator holds IND

- IND is required for this study, but has not been provided.
### Reference:
- Tip Sheet #9

<table>
<thead>
<tr>
<th>Reference:</th>
<th>IDE is not required for this study. Indicate category for IDE exemption.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1: FDA Determination of Exemption</td>
<td></td>
</tr>
<tr>
<td>Category 2: FDA-approved (PMA or 510(k) application) device</td>
<td></td>
</tr>
<tr>
<td>Category 3: <em>In vitro</em> diagnostic device</td>
<td></td>
</tr>
<tr>
<td>Category 4: Consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution</td>
<td></td>
</tr>
<tr>
<td>Category 5: Custom Devices</td>
<td></td>
</tr>
<tr>
<td>Category 6: Devices in commercial distribution immediately before May 28, 1976</td>
<td></td>
</tr>
</tbody>
</table>

- Device represents a non-significant risk device and the sponsor may conduct the study in accordance with the abbreviated IDE regulations
- Non-significant risk determination was made by the FDA and documentation provided.
- Non-significant risk determination is being made by IRB.
  **Provide rationale for determination:**

- Device represents a significant risk device and an IDE is required
  **Provide rationale for determination:**

- IDE is required for this study and has been provided and verified.
  - External Sponsor holds IDE
  - UIC Investigator holds IDE - management plan for sponsor and investigator roles
  - Non-UIC Investigator holds IDE

- IDE is required for this study, but has not been provided.

### Handling of Drugs, Biologic or Devices

- IDS at UIC will be responsible for handling test article.
- Investigator will be responsible for handling test article at UIC or other non-VA site
  **Provide rationale for determination:**

<table>
<thead>
<tr>
<th>Comment:</th>
<th>Plan for handling test article is acceptable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Plan for handling test article is <strong>not</strong> acceptable</td>
</tr>
</tbody>
</table>
### 3 Vulnerable Populations.

<table>
<thead>
<tr>
<th>Reference:</th>
<th>Tip Sheet #1</th>
</tr>
</thead>
</table>

- Consider whether appropriate additional safeguards are in place to protect vulnerable populations from coercion.
- Vulnerable populations include: pregnant women, fetuses, neonates, prisoners, children, cognitively impaired, decisionally impaired, and economically disadvantaged.
- Vulnerable populations may include any other group vulnerable to coercion that may need additional protections to prevent coercion, including but not limited to, the terminally ill and students.
- Attach and complete applicable review guide.
- Additional criteria required by other agencies met (DOE, DOD, DOJ) (speak with AD or coordinator if funding source is one of these sources and vulnerable populations are involved).

### 4 Privacy.

<table>
<thead>
<tr>
<th>Reference:</th>
<th>Tip Sheet #1</th>
</tr>
</thead>
</table>

Privacy is about people and refers to their interest in controlling access of others to themselves.

### 5 Confidentiality.

<table>
<thead>
<tr>
<th>Reference:</th>
<th>Tip Sheet #1</th>
</tr>
</thead>
</table>

Confidentiality is about data, and about agreements and procedures for limiting access of others to data.

Are you recommending that the investigator obtain a Certificate of Confidentiality?

- [ ] Yes
- [ ] No

Comments:
6 Risks to subjects are minimized by using procedures consistent with sound research design and that do not unnecessarily expose subjects to risk. [45 CFR 46.111(a)(1)(i)]

- Criterion Met
- Continues to be Met
- Criterion Not Met

Reference:
- Tip Sheet #1

Comments:

7 Risks to subjects are minimized, when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. [45 CFR 46.111(a)(1)(ii)]

- Not Applicable
- Criterion Met
- Continues to be Met
- Criterion Not Met

If such procedures are not relevant to the research context, this strategy for minimizing risks should be marked Not Applicable.

Reference:
- Tip Sheet #1
- Use of standard of care procedures when possible
- Consider whether the investigator's description of new literature changes this criterion

Comments:

8 Risks to subjects are reasonable in relationship to the potential benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. [45 CFR 46.111(a)(2)]

- Criterion Met
- Continues to be Met
- Criterion Not Met

Reference:
- Tip Sheet #1
- Consider whether the investigator's description of new literature changes this criterion

Comments:
### Data Safety Monitoring Plan

<table>
<thead>
<tr>
<th>Reference</th>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

When appropriate, does the research plan make adequate provisions for monitoring the data collected to ensure the safety of subjects? [45 CFR 46.111(a)(6)]

Not Applicable when research is minimal risk, is not required by sponsor or IRB to have DSMP and is not being performed at JBVAMC

Reference:
- Tip Sheets #1-2

**Comments:**
Changes to provisions of DSMP and/or recommend DSMB/DMC:

---

### Recruitment

<table>
<thead>
<tr>
<th>Reference</th>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

Are recruitment procedures and materials fair and appropriate?

Reference:
- Tip Sheet #3

**Comments:**

---

### Incentives or Reimbursements

<table>
<thead>
<tr>
<th>Reference</th>
<th>Not Relevant</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

Are compensation amounts and disbursement methods coercive or might they present undue influence? (45 CFR 46.111(b)(6))

Reference:
- Tip Sheet #4

**Comments:**

---

### Informed Consent Document

<table>
<thead>
<tr>
<th>Reference</th>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

Eight basic elements of informed consent, as appropriate, prohibition against exculpatory language, and signature line; additional elements as appropriate; FDA requirements; UIC requirements

Reference:
- Tip Sheet #5, 6

**Comments:**
- Are additional disclosures needed for inclusion in the consent process?
### Informed Consent Process

**Box 1:** Informed consent will be/will continue to be obtained from the subject or the subject's legally authorized representative. [45 CFR 46.111(a)(4); 46.116(a), (b)]

<table>
<thead>
<tr>
<th>Reference:</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Tip Sheets #5, 6</td>
</tr>
</tbody>
</table>

- Researcher or appropriately delegated and trained research personnel will obtain legally effective consent from subject or LAR
- The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence
- No information will be provided to the subject or the representative that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence
- Individuals communicating information to the subject or LAR during the consent process will convey that information in language understandable to the subject or representative
- All required and appropriate disclosures will be provided either to the subject or to the subject's representative

**Box 1a:** Research involves subjects whose decision-making capacity may be diminished and the study provides safeguards to ensure an appropriate consent process.

<table>
<thead>
<tr>
<th>Not Applicable, research does not involve subjects with diminished decision-making capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
</tbody>
</table>

- Even when subjects are judged capable of providing informed consent, the possibility exists that environmental, medical, mental or social circumstances may diminish their understanding of the consent process and decision-making ability. Examples may include participants who are educationally or economically disadvantaged, terminally ill, alcohol or substance abusers, or pre- or post an invasive medical procedure
- Extent of safeguards should be guided by the complexity of the study, risks, and potential for subjects to be recruited who may be capable of providing informed consent but due to circumstances have a diminished decision-making ability

Most frequently utilized approach is to have researcher assess participants understanding and decision-making ability by asking questions concerning the nature of the research and their participation; consequences of their participation, particularly risks, benefits or impact on their health; and alternatives to participation. Depending on the study and population, the IRB may require additional safeguards, including a witness, formal assessment of capacity to consent or use of a subject advocate/ombudsperson.

**If criterion is not met, describe why and recommend appropriate safeguards:**
### Informed Consent Process. (continued)

**Box 2: The consent procedure will be waived or altered.**  
[45 CFR 46.116 (c) (d)]

*If deception is used, the elements of alteration of consent must be met.*

<table>
<thead>
<tr>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved for all of the research</td>
</tr>
<tr>
<td>Approved only for the following research components (specify):</td>
</tr>
<tr>
<td>Criterion for waiver or alteration not met</td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheets #7, 9

- **a). Is this research FDA-regulated?**
  - [ ] Yes
  - [ ] No

  Alterations or waivers are NOT permitted unless the research involves *exceptions discussed in tip sheet 9*, *in vitro* diagnostic device investigations with specimens that are not individually identifiable OR is being requested only for reviewing medical records for identifying potential subjects for recruitment.  

  Address b). or c). if waiver or alteration is being requested.

- **b).**
  1. Protocol specific findings justifying the determination that the research (or portion where consent is waived or altered) involves no more than minimal risk
     - Document reasoning (required):

- **c).**
  1. Protocol specific findings justifying the determination that the waiver will not adversely affect the rights and welfare of subjects
     - Document reasoning (required):

  OR

  1. Protocol specific findings regarding whether it is appropriate to provide subjects with additional pertinent information after participation
     - Document reasoning (required):

  1. Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration
     - Document reasoning (required):

**For Department of Defense sponsored non-exempt research, refer to the DOD review guide for guidance.**
### Box 1: Informed consent will be documented using the long form consent document. 45 CFR 46.117(b)(1)

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The consent form includes the required elements and appropriate additional disclosures</td>
</tr>
<tr>
<td></td>
<td>The investigator will give either the subject or the LAR adequate opportunity to read the consent document before it is signed</td>
</tr>
<tr>
<td></td>
<td>The subject or the LAR will sign and date the written consent form</td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #6

- A copy of the consent form will be given to the person signing the consent (subject or LAR)
- When appropriate, a witness will sign and date the written form
- When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness’ signature line
- Investigator must give either the subject or the representative adequate opportunity to read it before it is signed

### Box 2: Informed consent will be documented using the short form consent document. 45 CFR 46.117(b)(2)

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consent document states that the elements of informed consent required by 46.116 and 50.25 have been presented orally to the subject or the subject's LAR</td>
</tr>
<tr>
<td></td>
<td>A written summary of what is to be said to the subject or the representative and includes the basic and required additional elements of disclosure is provided</td>
</tr>
</tbody>
</table>

- Witness will be present at the oral presentation
- When the subject and/or subject’s LAR do not speak English as their primary language, the witness must be conversant in both English and the language of the subject and/or subject's LAR

- Review documents and description of process to ensure 1. subject or LAR will sign short form consent, 2. witness will sign short form consent and written summary and 3. person obtaining consent will sign written summary

- Witness should not be the individual obtaining consent
- Subject or LAR should receive signed copies of short form consent and written summary

### Box 3: The requirement to obtain a signed consent form will be waived.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>46 CFR 45.117 (c)(1)(2)</td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheets #5,6,8

- An oral or written consent script was submitted
- The oral or written consent script includes the required and appropriate additional elements of disclosure

**Check applicable category of waiver of documentation below:**

- (i) The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context.
- OR

- (ii) The only record linking the subject and the research is the consent document and the principal risk is loss of confidentiality. The research is not FDA-regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
Check if written statement is required.  

The PI is required to provide subjects with a written statement about the research.

## 15 HIPAA Authorization and/or Waivers. (If granting a HIPAA waiver, please make a consistent determination in the Informed Consent Sections.)

<table>
<thead>
<tr>
<th>Description</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable - No PHI accessed in this research</td>
<td></td>
</tr>
<tr>
<td>HIPAA Authorization document approved with NO Waivers</td>
<td></td>
</tr>
<tr>
<td>Waiver and/or Alteration of HIPAA Approved - for ALL of the research</td>
<td></td>
</tr>
<tr>
<td>Waiver and/or Alteration of HIPAA Approved - for SOME of the research</td>
<td></td>
</tr>
<tr>
<td>Waiver(s) and/or alteration(s) fulfill ALL requirements for waiver under 45 CFR 164.512</td>
<td></td>
</tr>
<tr>
<td>Use or disclosure of PHI involves no more than minimal risk</td>
<td></td>
</tr>
<tr>
<td>Waiver will not adversely affect the privacy rights and welfare of subjects</td>
<td></td>
</tr>
<tr>
<td>Research would be so difficult as to be nearly impossible without access to and use of PHI</td>
<td></td>
</tr>
<tr>
<td>Risks are reasonable in relation to anticipated benefits to subjects and importance of knowledge gained</td>
<td></td>
</tr>
<tr>
<td>Adequate plans and procedures in place to protect against improper use and disclosure of PHI</td>
<td></td>
</tr>
<tr>
<td>Identifiers will be destroyed at the earliest opportunity (unless retention required by law)</td>
<td></td>
</tr>
<tr>
<td>Written assurances that PHI will not be reused or shared unless required by law or this regulation</td>
<td></td>
</tr>
</tbody>
</table>

Specify the purposes for which a waiver or alteration of HIPAA is approved:

## 16 Additional Review Guide Checklists. (Complete only if not pre-reviewed; attach additional applicable review guides)

<table>
<thead>
<tr>
<th>Description</th>
<th>Approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Expedited Addendum</td>
<td>DoD Research</td>
</tr>
<tr>
<td>Review of Modifications</td>
<td>Prisoners</td>
</tr>
<tr>
<td>Amendment</td>
<td>Wards</td>
</tr>
<tr>
<td>Adults Unable to Consent</td>
<td>Prompt Reporting (circle: convened or expedited)</td>
</tr>
<tr>
<td>Children</td>
<td>Protocol Exception to Previously Approved Research</td>
</tr>
<tr>
<td>Pregnant Women/Neonates/Fetuses</td>
<td>Lapse of Approval (circle: convened or expedited)</td>
</tr>
</tbody>
</table>
17 Review Frequency.

<table>
<thead>
<tr>
<th>Yes</th>
<th>Does this protocol meet criteria (listed below) for protocols that will generally be reviewed more often than annually?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Novel high-risk study involving new therapeutic modality</td>
</tr>
<tr>
<td></td>
<td>Phase I study of a new drug or biologic that has never been tested in humans</td>
</tr>
<tr>
<td></td>
<td>Study involving a novel significant risk medical device which has never been tested in humans</td>
</tr>
<tr>
<td></td>
<td>High-risk study as IRB members deem appropriate (includes research for which IRB determines that reports to the IRB</td>
</tr>
<tr>
<td></td>
<td>of monitoring data should be more than annually)</td>
</tr>
</tbody>
</table>

Select Review Frequency:

- 12 Months
- 6 Months
- Other: ____________

18 Approval Recommendation.

- Approved
- Risk level: Greater than Minimal Risk
- Risk level: Minimal Risk, keep at convened review
- Risk level: Minimal Risk, eligible for expedited review (attach Expedited Addendum)

- Modifications required (list in comments section below)
- Refer to Convened Review - Further review required by full IRB
  - With modifications noted below or on attached page
  - Copies Only

- Deferred (only if being reviewed at convened meeting)
- Disapproved (only if being reviewed at convened meeting)
- Suspension
<table>
<thead>
<tr>
<th>Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Accept pre-review comments</td>
</tr>
<tr>
<td>[ ] Accept pre-review comments with modifications</td>
</tr>
<tr>
<td>[ ] Do not accept pre-review comments</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Printed Name

______________________________________________
## Social and Behavioral

**Initial and Continuing Review**  ●  **Review Guide Checklist**  
University of Illinois at Chicago  ●  Office for the Protection of Research Subjects  ●  Version 1.2, dated April 30, 2012

**Research Protocol #:**

Investigator Full Name: 

Research Protocol Title: 

### Instructions:
- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.  
  *For example, if modifications are needed to meet an approval criterion, please explain what is lacking and what the investigator would need to change or provide to meet this criterion.*
- **If a 45 CFR 46.111 approval criterion is "Not Relevant" based on the type of research, explain why**
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

### Review Type.  *(Check applicable boxes.)*  If the answer to the first two questions is "No," then modifications must be requested.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review</td>
<td></td>
</tr>
<tr>
<td>Continuing Review</td>
<td></td>
</tr>
<tr>
<td>Expedited review <em>(attach Expedited Addendum)</em></td>
<td></td>
</tr>
<tr>
<td>Convened</td>
<td></td>
</tr>
</tbody>
</table>

### Y N  
**For initial review, does the investigator have the resources necessary to protect subject?**
- Resources might include: availability, number, expertise, and experience of investigator and staff
  - time to conduct and complete the research
  - facilities and equipment to conduct, monitor and protect subjects
  - access to a population that will allow recruitment of the necessary number of subjects
  - availability of medical or psychological resources that subjects may need as a consequence of the research
  - resources for subject communication, e.g., translation services

### Y N  
**On continuing review, does the investigator continue to have the resources necessary to protect subjects?**
- Resources might include personnel, time, and access to a study population
  - Sufficient time to conduct and complete the research
  - Researchers should stop a study if resources become unavailable

### Y N  
**On continuing review, is verification needed from sources other than the investigator that no material changes have occurred since the previous IRB review?**  *If not applicable, skip question.*
- Does information contained in the continuing review report raise concerns about possible material changes in the study occurring without IRB approval?
  - Has the investigator previously failed to comply with the requirements of the HHS regulations at 45 CFR part 46 or the requirements or determinations of the IRB?
  - Does the protocol involve a complex design or unusual levels or types of risk?


<table>
<thead>
<tr>
<th>Study Population.</th>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is subject selection equitable? [45 CFR 46.111(a)(3)]</td>
<td>● Justification for the inclusion of any vulnerable population</td>
<td>● Inclusion/Exclusion criteria are appropriate</td>
<td>● A certain group is not targeted or excluded without justification</td>
<td>● Subject recruitment and enrollment procedures do not cause inequitable selection</td>
</tr>
</tbody>
</table>

Comments:

2 Vulnerable Populations.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>If applicable, are additional safeguards provided for populations vulnerable to coercion and undue influence? [45 CFR 46.111(b)]</td>
<td>● Consider whether appropriate additional safeguards are in place to protect vulnerable populations from coercion</td>
<td>● Vulnerable populations include: pregnant women, fetuses, neonates, prisoners, children, cognitively impaired, decisionally impaired, and economically disadvantaged</td>
<td>● Vulnerable populations may include any other group vulnerable to coercion that may need additional protections to prevent coercion, including but not limited to, the terminally ill and students</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #1
### 3 Privacy.
<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>If appropriate, are there adequate provisions to protect the privacy of subjects? [45 CFR 46.111(a)(7)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

**Comments:**
- Privacy protections adequate

### 4 Confidentiality.
<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>If appropriate, are there adequate provisions to maintain the confidentiality of the data? [45 CFR 46.111(a)(7)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

**Comments:**
- Plan to protect confidentiality of data adequate

**Are you recommending that the investigator obtain a Certificate of Confidentiality?**
- Yes
- No

**Comments:**

### 5 Risks to subjects are minimized by using procedures consistent with sound research design and that do not unnecessarily expose subjects to risk. [45 CFR 46.111(a)(1)(i)]
| Criterion Met          |                                                                                                  |
| Continues to be Met    |                                                                                                  |
| Criterion Not Met      |                                                                                                  |

**Reference:**
- Tip Sheet #1

**Comments:**

### 6 Risks to subjects are minimized, when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. [45 CFR 46.111(a)(1)(iii)]
<table>
<thead>
<tr>
<th>Not Relevant</th>
<th>If such procedures are not relevant to the research context, this strategy for minimizing risks should be marked Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

**Comments:**
- Use of standard of care procedures when possible
- Consider whether the investigator's description of new literature changes this criterion
7 Risks to subjects are reasonable in relationship to the potential benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. [45 CFR 46.111(a)(2)]

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference: 
- Tip Sheet #1

Consider whether the investigator’s description of new literature changes this criterion.

8 Data Safety Monitoring Plan / Data Safety Monitoring Board.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>When appropriate, does the research plan make adequate provisions for monitoring the data collected to ensure the safety of subjects? [45 CFR 46.111(a)(6)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td>Not Applicable when research is minimal risk, is not required by sponsor or IRB to have DSMP and is not being performed at JBVAMC</td>
</tr>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference: 
- Tip Sheets #1-2

Comments: Changes to provisions of DSMP and/or recommend DSMB/DMC:

9 Recruitment.

<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>Are recruitment procedures and materials fair and appropriate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference: 
- Tip Sheet #3

Comments:

10 Incentives or Reimbursements.

<table>
<thead>
<tr>
<th>Not Relevant</th>
<th>Are compensation amounts and disbursement methods coercive or might they present undue influence? (45 CFR 46.116)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference: 
- Tip Sheet #4

Comments:
Informed consent document contains required basic and additional elements. Also, at continuing review, the current consent provided by the investigator remains accurate and complete.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Eight basic elements of informed consent, as appropriate, prohibition against exculpatory language, and signature line; additional elements as appropriate; UIC requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #6

**Comments:**
- Are additional disclosures needed for inclusion in the consent process?

Informed Consent Process. (Select either Box 1 or Box 2 and confirm whether criteria have been met / continue to be met)

**Box 1:** Informed consent will be/ will continue to be obtained from the subject or the subject's legally authorized representative. [45 CFR 46.111(a)(4); 46.116(a), (b)]

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Researcher or appropriately delegated and trained research personnel will obtain legally effective consent from subject or LAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td>The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence</td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td>No information will be provided to the subject or the representative that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence</td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheets #5, 6

**Box 1a:** Research involves subjects whose decision-making capacity may be diminished and the study provides safeguards to ensure an appropriate consent process.

<table>
<thead>
<tr>
<th>Not Applicable, research does not involve subjects with diminished decision-making capacity</th>
<th>Even when subjects are judged capable of providing informed consent, the possibility exists that environmental, medical, mental or social circumstances may diminish their understanding of the consent process and decision-making ability. Examples may include participants who are educationally or economically disadvantaged, terminally ill, alcohol or substance abusers, or pre- or post an invasive medical procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td>Extent of safeguards should be guided by the complexity of the study, risks, and potential for subjects to be recruited who may be capable of providing informed consent but due to circumstances have a diminished decision-making ability</td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td>Most frequently utilized approach is to have researcher assess participants understanding and decision-making ability by asking questions concerning the nature of the research and their participation; consequences of their participation, particularly risks, benefits or impact on their health; and alternatives to participation. Depending on the study and population, the IRB may require additional safeguards, including a witness, formal assessment of capacity to consent or use of a subject advocate/ombudsperson.</td>
</tr>
</tbody>
</table>

If criterion is not met, describe why and recommend appropriate safeguards:
### 12 Informed Consent Process. (Continued)

**Box 2: The consent procedure will be waived or altered.** [45 CFR 46.116 (c) (d)]

*(If deception is used, the elements of alteration of consent must be met.)*

<table>
<thead>
<tr>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved for all of the research</td>
</tr>
<tr>
<td>Approved only for the following research components (specify):</td>
</tr>
<tr>
<td>Criterion for waiver or alteration not met</td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheets #7

**If a waiver or alteration is approved for all or some of the research, complete either a). or b). Below**

**a).**

45 CFR 46.116(d)

1. Protocol specific findings justifying the determination that the research (or portion where consent is waived or altered) involves no more than minimal risk
   - **Document reasoning (required):**

2. Protocol specific findings justifying the determination that the waiver will not adversely affect the rights and welfare of subjects
   - **Document reasoning (required):**

3. Protocol specific findings regarding whether it is appropriate to provide subjects with additional pertinent information after participation
   - **Document reasoning (required):**

4. Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration
   - **Document reasoning (required):**

**OR**

**b).**

45 CFR 46.116(c)

1. Research is conducted under the direction of state or local government officials AND is designated to study public benefit/service programs, procedures for obtaining public benefits/services, changes or alternatives to public benefit/service programs, or levels of payment for public benefits/services AND
   - **Document reasoning (required):**

2. Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration
   - **Document reasoning (required):**
Disclosure of directory information.

Studies for, or on behalf, of the institution to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction

Removal of all personally identifiable information

Criterion not met

Not Applicable

Criterion met

Reference:

Tip Sheet #7

If the researcher is requesting to access education records for students over 18 years of age or attending postsecondary institution, the following must be completed and the criterion met along with the 116 or 408 criteria for approval of waiver.

Box 2a: One or more of the following criteria must be met to allow access to student education records without student consent.

Criterion Not Met

Criterion Met

Criterion not met

Reference:

Tip Sheet #7

For Department of Defense sponsored non-exempt research, refer to the DOD review guide for guidance.

Consent Documentation. (Select Box 1, 2, or 3 below and confirm whether criteria have been met. If a long form consent will be used for English-speaking subjects and a short form will be used for non-English speaking subjects, select Boxes 1 and 2.) 45 CFR 46.117(b)(1)

Box 2b: If research is funded by the Department of Education, it does not involve surveys, analyses, or evaluations that reveal information concerning one or more of the 8 PPRA protected areas (Tip Sheet #7).

Criterion Met

Criterion not met

Reference:

Tip Sheet #7

If the researcher is funded by the Department of Education and is requesting to conduct surveys, analyses or evaluations of adult or emancipated students, the following must be completed and the criterion met along with the 116 or 408 criteria for approval of waiver.

For surveys administered to students that are not funded by the Department of Education and reveal information concerning one or more of the 8 PPRA protected areas, refer to the local school's PPRA policy and determine whether their policy is being followed.

Consent Documentation. (Select Box 1, 2, or 3 below and confirm whether criteria have been met. If a long form consent will be used for English-speaking subjects and a short form will be used for non-English speaking subjects, select Boxes 1 and 2.) 45 CFR 46.117(b)(1)

Box 1: Informed consent will be documented using the long form consent document.

Criterion Met

Criterion Not Met

Not Applicable

Reference:

Tip Sheets #5,6

The consent form includes the required elements and appropriate additional disclosures

The investigator will give either the subject or the LAR adequate opportunity to read the consent document before it is signed

The subject or the LAR will sign and date the written consent form

A copy of the consent form will be given to the person signing the consent (subject or LAR)

When appropriate, a witness will sign and date the written form

When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness' signature line

Investigator must give either the subject or the representative adequate opportunity to read it before it is signed

The investigator will give either the subject or the LAR adequate opportunity to read the consent document before it is signed

When appropriate, a witness will sign and date the written form

When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness' signature line

Investigator must give either the subject or the representative adequate opportunity to read it before it is signed

When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness' signature line

For Department of Defense sponsored non-exempt research, refer to the DOD review guide for guidance.
Continues to be Met

Witness should not be the individual obtaining consent

Subject or LAR should receive signed copies of short form consent and written summary

<table>
<thead>
<tr>
<th>Box 2: Informed consent will be documented using the short form consent document. 45 CFR 46.117(b)(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Continues to be Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Box 3: The requirement to obtain a signed consent form will be waived. 45 CFR 46.117(c)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Continues to be Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
</tbody>
</table>

Reference: Tip Sheets #5,6, 8

Check if applicable:

- Check if written statement is required.
  - The PI is required to provide subjects with a written statement about the research.

Check applicable category of waiver of documentation below:

(i) The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context.

OR

(ii) The only record linking the subject and the research is the consent document and the principal risk is loss of confidentiality. The research is not FDA-regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.

Justify:
14 Complete only if research is funded by the National Institute of Justice

Are the following conditions found in the consent document?
- Statement under what circumstances confidentiality can be broken (required; subject reports immediate harm to themselves or others or if relevant: certain communicable diseases)
- Child (domestic or elder) abuse is only reported, if subject signs a separate consent allowing this

Yes
No (not approvable)

15 HIPAA Authorization and/or Waivers. (If granting a HIPAA waiver, please make a consistent determination in the Informed Consent Sections.)

- Not Applicable - No PHI accessed in this research
- HIPAA Authorization document approved with NO Waivers
- Waiver and/or Alteration of HIPAA Approved - for ALL of the research
- Waiver and/or Alteration of HIPAA Approved - for SOME of the research
- Waiver(s) and/or alteration(s) fulfill ALL requirements for waiver under 45 CFR 164.512
  - Use or disclosure of PHI involves no more than minimal risk
  - Waiver will not adversely affect the privacy rights and welfare of subjects
  - Research would be so difficult as to be nearly impossible without access to and use of PHI
  - Risks are reasonable in relation to anticipated benefits to subjects and importance of knowledge gained
  - Adequate plans and procedures in place to protect against improper use and disclosure of PHI
  - Identifiers will be destroyed at the earliest opportunity (unless retention required by law)
  - Written assurances that PHI will not be reused or shared unless required by law or this regulation

Specify the purposes for which a waiver or alteration of HIPAA is approved:

16 Additional Review Guide Checklists. (Complete only if not pre-reviewed; attach applicable review guides)

- Not Applicable
- Expedited Addendum
- Review of Modifications
- Amendment
- Adults Unable to Consent
- DoD Research
- Pregnant Women/Neonates/Fetuses
- Prisoners
- Children
- Wards
- Lapse of Approval (circle: convened or expedited)
- Prompt Reporting (circle: convened or expedited)
- Protocol Exception to Previously Approved Research

17 Review Frequency.

Select Review Frequency:
- 12 Months
- 6 Months
- Other: [ ]
18 Approval Recommendation.

- Approved
  - Risk level: Greater than Minimal Risk
  - Risk level: Minimal Risk, keep at convened review
  - Risk level: Minimal Risk, eligible for expedited review (attach Expedited Addendum)

- Modifications required (list all, including informed consent document and HIPAA authorization matters, in comments section below)
- Refer to Convened Review - Further review required by full IRB
  - With modifications noted below or on attached page
  - Copies Only
- Deferred (only if being reviewed at convened meeting)
- Disapproved (only if being reviewed at convened meeting)
- Suspension

Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

- Accept pre-review comments
- Accept pre-review comments with modifications
- Do not accept pre-review comments

Signature

Date

Printed Name
Initial and Continuing Review • Review Guide Checklist

University of Illinois at Chicago • Office for the Protection of Research Subjects • Version 2.1, April 29, 2012

Review Guide: JBVAMC IR/CR Bio

IRB Number: 4

Research Protocol #: _____________________________
Investigator Full Name: ___________________________
Research Protocol Title: ___________________________

Instructions:
- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.
- For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.
- If a 45 CFR 46.111 approval criteria is "not relevant" based on the type of research, explain why.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

Review Type. Check applicable boxes.

<table>
<thead>
<tr>
<th>Initial Review</th>
<th>Expedited Review (attach Expedited Addendum)</th>
<th>Continuing Review</th>
<th>Convened</th>
<th>Amendment adding the JBVAMC as a performance site (treat as an Initial Review)</th>
</tr>
</thead>
</table>

Investigator Resources

Criterion Met

Continues to be Met

Criterion Not Met

The investigator has the resources necessary to protect subjects.

- Resources might include: availability, number, expertise, and experience of investigator and staff
- time to conduct and complete the research
- facilities and equipment to conduct, monitor and protect subjects
- access to a population that will allow recruitment of the necessary number of subjects
- availability of medical or psychological resources that subjects may need as a consequence of the research
- resources for subject communication, e.g., translation services

Y N

Is this a multi-site study in which the investigator is the lead site?

Y N

Answer only if above is YES. Is the investigator's management of information relevant to the protection of subjects adequate in this role as the lead site?

Explain if YES.

1. Is the subject of the research a fetus, in-utero or ex-utero (including human fetal tissue), or does the research involved in vitro fertilization?

   Yes
   No

If yes, please stop and speak with the IRB #4 Assistant Director

2. Study Population.

   Not Relevant (explain)
   Criterion Met
   Continues to be Met
   Criterion Not Met

   Subject selection is equitable.

   Reference:
   - Tip Sheet #1
   - Justification for the inclusion of any vulnerable population
   - Inclusion/Exclusion criteria are appropriate
   - A certain group is not targeted or excluded without justification
   - Subject recruitment and enrollment procedures do not cause inequitable selection
   - The amount and timing of payments to subjects does not cause inequitable selection
   - The target number of enrollees appears appropriate given the research objective/s

   Comments:

3. Privacy.

   Not Relevant (explain)
   Criterion Met
   Continues to be Met
   Criterion Not Met

   There are adequate provisions to protect the privacy of subjects.

   Reference:
   - Tip Sheet #1
   - Privacy is about people and refers to their interest in controlling access of others to themselves

   Comments:
4 Confidentiality.

<table>
<thead>
<tr>
<th>Not Relevant [explain]</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

There are adequate provisions to maintain the confidentiality of the data.

Reference:
- Confidentiality is about data, and about agreements and procedures for limiting access of others to the data.

Are you recommending that the investigator obtain a Certificate of Confidentiality?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Comments:

5 Does this submission include any recruitment materials?

<table>
<thead>
<tr>
<th>Yes - recruitment materials are included</th>
<th>No - no recruitment materials are being utilized</th>
</tr>
</thead>
</table>

5a Recruitment.

<table>
<thead>
<tr>
<th>Not Relevant [explain]</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The recruitment process and recruitment materials are fair and appropriate.

Reference:
- Tip Sheet #3

Comments:

5b Do the research procedures meet the following VA requirements for contacting Veterans?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If NO, modifications must be requested</td>
</tr>
</tbody>
</table>

- During the recruitment process, researchers must make initial contact with the patient in person and/or through a letter prior to any phone contact and provide a telephone number or other means that veterans can use to verify the validity of the study;
- Phone and other contacts with veterans are restricted to only those procedures and data elements outlined in the IRB approved protocol application, and, in these contacts, research staff must not request social security numbers; and
- The informed consent document includes information about where and how a veteran can verify the validity of a study and authorized contacts.

5c Do the investigators propose to use to protected health information from data repositories or medical records to identify potential participants (including their own patients) to recruit for the research?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- If YES, has the investigator requested, or hold, a Waiver of Informed Consent for Recruitment and a Waiver of Authorization for Recruitment?
- Yes - Criteria met
- No - Modifications must be requested
5d | Does the investigator propose enrolling non-veterans in the VA protocol or at the VA site?  
---|---
Yes | , answer 5.e.
No | , proceed to 6

5e | Are the following criteria for allowing enrollment of non-veterans met:  
---|---|---
Yes | 1 Research is relevant to the care of veterans or active duty military personnel, AND Researcher has made a compelling argument for the inclusion of non-veterans (e.g., insufficient veterans available to complete the study, survey of VA employees, study of active duty military, study involving veterans' family members)
No | 2

6 | Incentives or reimbursements.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Compensation amounts and disbursement methods are not coercive or they do not present undue influence.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continues to be Met</td>
<td></td>
</tr>
<tr>
<td>Criteria Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference:  
- Tip Sheet #3

7 | Are any vulnerable populations to be recruited for this research?  
---|---
Yes | If YES, specify which populations:
No | (Skip to #8)

Reference:  
- Tip Sheet #1
- Pregnant Women (complete #7a, b)
- Decisionally or Cognitively Impaired (complete #7a, c, d)
- Other (specify on line below and complete 7a and other section 7 questions that apply to the population)

Explain why this population is considered vulnerable:
### 7a Vulnerable Populations

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #1

> If applicable, additional safeguards are provided for populations vulnerable to coercion and undue influence.

### 7b If pregnant women are to be recruited for the research, have all the VA requirements for approval and inclusion of this vulnerable population been met?

- Yes [ ]
- No [ ]

*Please also complete the review guide for pregnant women, neonates and fetuses*

- The proposed research meets the requirements of 45 CFR 46.204
- Provisions for consent are consistent with those listed at 45 CFR 46.204(d)

### 7c If decisionally or cognitively impaired persons will be recruited for the research, are the requirements in VHA handbook 1200.05, paragraphs 36 and 49 met?

- Yes [ ]
- No [ ]

*Please also complete the review guide for decisionally impaired adults*

- Criteria for determining and documenting a lack of decision-making capacity are met
- Informed consent from LARs as defined in paragraph 36 will be obtained
- Procedures for respecting dissent are appropriate
- Need for obtaining assent has been ascertained and, if required, plan is adequate
- Need for additional safeguards has been ascertained
- Inclusion of individuals lacking decision-making capacity meets one or more of the criteria in Handbook 1200.05, paragraph 49.d.

If no, explain:

### 7d If decisionally or cognitively impaired individuals will be recruited, additional safeguards included in protocol are adequate?

- Yes [ ]
- No [ ]

If no, explain:

### 7e If the research includes children, are the following requirements met?

- Yes [ ]
- No [ ]

*Please also complete the review guide for children*

- A waiver from the Chief Research and Development Officer (CRADO) been submitted and
- The research poses no more than minimal risk
Drugs, Biologics and Devices Used in the Research.

| Category 1: FDA Determination of Exemption |
| Category 2: FDA-approved drug |
| Category 3: in vitro diagnostic biological product |
| Category 4: in vitro or animal use |
| Category 5: Bioavailability or bioequivalence study |
| Category 6: Clinical bioavailability or bioequivalence study for approval of abbreviated or supplemental NDA |

- External Sponsor holds IND
- JB/NU/UIC Investigator holds IND - Management plan for sponsor and investigator roles
- Non-JB/NU/UIC Investigator holds IND

- IND is required for this study and has been provided and verified.
- IND is required for this study, but has not been provided.

Provide rationale for determination:

- Device represents a non-significant risk device and the sponsor may conduct the study in accordance with the abbreviated IDE regulations
- Non-significant risk determination was made by the FDA and documentation provided.
- Non-significant risk determination is being made by IRB.

Provide rationale for determination:

- Device represents a significant risk device and an IDE is required
- Significant risk determination was made by the FDA and documentation provided.
- Significant risk determination is being made by IRB.

Provide rationale for determination:
### 8 Drugs, Biologics and Devices Used in the Research. (Continued)

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDE is required for this study and has been provided and verified.</td>
<td></td>
</tr>
<tr>
<td>External Sponsor holds IDE</td>
<td></td>
</tr>
<tr>
<td>JB/NJ/UIC Investigator holds IDE - management plan for sponsor and</td>
<td></td>
</tr>
<tr>
<td>investigator roles</td>
<td></td>
</tr>
<tr>
<td>Non-JB/NJ/UIC Investigator holds IDE</td>
<td></td>
</tr>
<tr>
<td>IDE is required for this study, but has not been provided.</td>
<td></td>
</tr>
</tbody>
</table>

**Handling of Drugs, Biologic or Devices**

- IDS at UIC, NU, or JBVAMC will be responsible for handling test article.
- Investigator will be responsible for handling test article at UIC, NU, or JBVAMC

Plan for handling test article is acceptable

Plan for handling test article is not acceptable

**Comment:**

### 9 Evaluation of Risks

#### 9a

Risks to subjects are minimized by using procedures consistent with sound research design and that do not unnecessarily expose subjects to risk.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Met</td>
<td></td>
</tr>
<tr>
<td>Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

**Comments:**

#### 9b

Risks to subjects are minimized, when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Relevant</td>
<td>If such procedures are not relevant to the research context, this strategy for minimizing risks should be marked NOT Applicable.</td>
</tr>
<tr>
<td>Met</td>
<td></td>
</tr>
<tr>
<td>Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Use of standard of care procedures when possible
- Consider whether the investigator's description of new literature changes this criterion

**Comments:**

#### 9c

Risks to subjects are reasonable in relationship to the potential benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Met</td>
<td></td>
</tr>
<tr>
<td>Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

**Comments:**
- Consider whether the investigator's description of new literature changes this criterion
10 Data Monitoring Plan (DSMP) / Data Safety Monitoring Board (DSMB).

<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheets #1-2

Comments:
Changes to provisions of DSMP and/or recommend DSMB/DMC:

11 Does the research involve (or propose changes in the exposure to) ionizing radiation or recombinant DNA, infectious agents and/or toxins?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(modifications may be required)</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheets #1-2

12a Does the research involve the banking of tissues?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No (skip to #13)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference: Tip Sheets #19-21</td>
</tr>
</tbody>
</table>

12b If yes to above (12a), Are the tissues being banked at a VA-sponsored (i.e., typically a VA facility) or VA-approved (see approved list) banking facility?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reference: Tip Sheet #20</td>
</tr>
</tbody>
</table>

13 Does the research involve recording of voice or video or taking pictures of the subject?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If YES, are the following true?</td>
</tr>
</tbody>
</table>

- consent document discusses why recordings or pictures are being taken, who will access them, and what their disposition will be after the study (unless IRB waives documentation)
- subjects will sign and date VA form 10-3203

| Yes | No (modifications may be required) |

Reference:
- Tip Sheets #5, 6, 22

14 Informed Consent Process. (Select either Box 1 or Box 2 and confirm whether criteria have been met / continue to be met)

**Box 1: Informed consent will be will continue to be obtained from the subject or the subject's legally authorized representative. (38 CFR 46.111(a)(4); 38.116(a), (b))**

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Researcher or appropriately delegated and trained research personnel will obtain legally effective consent from subject or LAR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No information will be provided to the subject or the representative that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individuals communicating information to the subject or LAR during the consent process will convey that information in language understandable to the subject or representative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>All required and appropriate disclosures will be provided either to the subject or to the subject's representative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheets #5, 6, 22
14 Informed Consent Process. (Continued)

Box 1a: Research involves subjects whose decision-making capacity may be diminished and the study provides safeguards to ensure an appropriate consent process.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Even when subjects are judged capable of providing informed consent, the possibility exists that environmental, medical, mental or social circumstances may diminish their understanding of the consent process and decision-making ability. Examples may include participants who are educationally or economically disadvantaged, terminally ill, alcohol or substance abusers, or pre- or post an invasive medical procedure</td>
<td></td>
</tr>
<tr>
<td>● Extent of safeguards should be guided by the complexity of the study, risks, and potential for subjects to be recruited who may be capable of providing informed consent but due to circumstances have a diminished decision-making ability</td>
<td></td>
</tr>
</tbody>
</table>

Most frequently utilized approach is to have researcher assess participants understanding and decision-making ability by asking questions concerning the nature of the research and their participation; consequences of their participation, particularly risks, benefits or impact on their health; and alternatives to participation. Depending on the study and population, the IRB may require additional safeguards, including a witness, formal assessment of capacity to consent or use of a subject advocate/ombudsperson.

If criterion is not met, describe why and recommend appropriate safeguards:

Box 2: The consent procedure will be waived or altered.

(If deception is used, the elements of alteration of consent must be met.)

<table>
<thead>
<tr>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved for all of the research</td>
</tr>
<tr>
<td>Approved only for the following research components (specify):</td>
</tr>
<tr>
<td>Criterion for waiver or alteration not met</td>
</tr>
</tbody>
</table>

Reference:

● Tip Sheets #7, 9

a). Is this research FDA-regulated?

[ ] Yes Alterations or waivers are NOT permitted unless the research involves in vitro diagnostic device investigations with specimens that are not individually identifiable OR is being requested only for reviewing medical records for identifying potential subjects for recruitment.

[ ] No address b). or c). if waiver or alteration is being requested

If a waiver or alteration is requested for all or some of the research, complete either b). or c). Below.

b).

i) Protocol specific findings justifying the determination that the research (or portion where consent is waived or altered) involves no more than minimal risk

Document reasoning (required):
ii) Protocol specific findings justifying the determination that the waiver will not adversely affect the rights and welfare of subjects

Document reasoning (required):

iii) Protocol specific findings regarding whether it is appropriate to provide subjects with additional pertinent information after participation

Document reasoning (required):

iv) Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration

Document reasoning (required):

OR

c).

i. Research is conducted under the direction of state or local government officials AND is designated to study public benefit/service programs, procedures for obtaining public benefits/services, changes or alternatives to public benefit/service programs, or levels of payment for public benefits/services AND

ii. Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration

Document reasoning (required):

14a Are the VA consent form(s) written on the appropriate VA Form (10-1086)?

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

14b Informed consent document contains required basic and additional elements. Also, at continuing review, the current consent provided by the investigator remains accurate and complete.

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference:</td>
<td></td>
<td>Eight basic elements of informed consent, as appropriate, prohibition against exculpatory language, and signature line; additional elements as appropriate; JBVAMC requirements; FDA requirements; UIC/NIC requirements</td>
<td></td>
</tr>
</tbody>
</table>

14c If the research involves subjects with fluctuating decision making capacity or with decreasing capacity to give consent, is a re-consenting process with surrogate consent necessary?

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>
14d Is a witness required to sign the consent document? (e.g., IRB may require this when study involves an invasive intervention or an investigational drug or device). This is always required when a short form consent is used.

<table>
<thead>
<tr>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
</table>

If yes, should the witness observe only the subject's or LAR signature (only requirement) or witness the consent process (discretion of IRB or sponsor)

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Explain:

15 Consent Documentation. (Select Box 1, 2, or 3 below and confirm whether criteria have been met. If a long form consent will be used for English-speaking subjects and a short form will be used for non-English speaking subjects, select Boxes 1 and 2.)

**Box 1: Informed consent will be documented using the long form consent document.**

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● The consent form includes the required elements and appropriate disclosures</td>
<td>● The investigator will give either the subject or the LAR adequate opportunity to read the consent document before it is signed</td>
<td>● The subject or the LAR will sign and date the written consent form</td>
</tr>
<tr>
<td></td>
<td>● A copy of the consent form will be given to the person signing the consent (subject or LAR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● When appropriate, a witness will sign and date the written form</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness’ signature line</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● VA Form 10-1086 must be used at JBVAMC</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Investigator must give either the subject or the representative adequate opportunity to read it before it is signed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #5, 6

**Box 2: Informed consent will be documented using the short form consent document.**

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● Consent document states that the elements of informed consent required by 46.116 and 50.25 have been presented orally to the subject or the subject’s LAR</td>
<td>● a written summary of what is to be said to the subject or the representative and includes the basic and required additional elements of disclosure is provided</td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Witness will be present at the oral presentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● When the subject and/or subject’s LAR do not speak English as their primary language, the witness must be conversant in both English and the language of the subject and/or subject’s LAR</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Review documents and description of process to ensure 1. subject or LAR will sign short form consent, 2. witness will sign short form consent and written summary and 3. person obtaining consent will sign written summary</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Witness should not be the individual obtaining consent</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>● Subject or LAR should receive signed copies of short form consent and written summary</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Box 3: The requirement to obtain a signed consent form will be waived.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td>- No PHI used/disclosed in this research (skip to 17)</td>
</tr>
<tr>
<td>Criterion Met</td>
<td>- HIPAA Authorization document submitted/approved with NO Waivers</td>
</tr>
<tr>
<td>Continues to be Met</td>
<td>- Waiver and/or Alteration of HIPAA requested/approved - for ALL of the research</td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td>- Waiver(s) and/or alteration(s) fulfill ALL requirements for waiver under 45 CFR 164.512</td>
</tr>
</tbody>
</table>

**Check if applicable:**
- Use or disclosure of PHI involves no more than minimal risk
- Waiver will not adversely affect the privacy rights and welfare of subjects
- Research would be so difficult as to be nearly impossible without access to and use of PHI
- Risks are reasonable in relation to anticipated benefits to subjects and importance of knowledge gained
- Adequate plans and procedures in place to protect against improper use and disclosure of PHI
- Identifiers will be destroyed at the earliest opportunity (unless retention required by law)
- Written assurances that PHI will not be reused or shared unless required by law or this regulation

Specify the purposes for which a waiver or alteration of HIPAA is approved:
<table>
<thead>
<tr>
<th>16a. Is the authorization form written on the template form?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>16b. Does the authorization form contain the required template language?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17. Does the research involve, or make changes to, the use and disclosure of protected health information related to the treatment of alcoholism, drug abuse, sickle cell anemia, or infection with Human Immunodeficiency Virus (HIV)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>If YES, use and disclosure of this information requires EITHER:</td>
</tr>
<tr>
<td>A written authorization signed by the research subject that describes the information to be disclosed in a specific and meaningful fashion and specifically identifies that the information to be released concerns alcoholism, drug abuse, sickle cell anemia, or testing for or infection with Human Immunodeficiency Virus (HIV); OR</td>
</tr>
<tr>
<td>If the investigator is requesting a waiver of authorization and informed consent, assurance in writing (i.e., within protocol) from the VA researcher that the purpose of the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>18. Is the protocol document, informed consent document, and HIPAA authorization form consistent?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable - Explain:</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No - Modifications must be requested. (Explain which documents are incorrect either here or at the end of the review guide.)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>19. Initial Reviews (or amendments adding the VA as a performance site) Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>19a. Does the submission contain a complete R&amp;D Packet?</td>
</tr>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>19b. Does the research need to be flagged in CPRS?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes - the research is to be flagged, as it meets one of the criterion listed below</td>
</tr>
<tr>
<td>No - the research does not meet the following criteria:</td>
</tr>
<tr>
<td>Any invasive research procedure (e.g., muscle biopsy or bronchoscopy);</td>
</tr>
<tr>
<td>Interventions that will be used in the medical care of the subject, or that could interfere with other care the subject is receiving or may receive (e.g., administration of a medication, treatment, or use of an investigational device);</td>
</tr>
<tr>
<td>Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as a part of the study), or that could interfere with other care the subject is receiving or may receive;</td>
</tr>
<tr>
<td>The use of a survey or questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interests of the subject (e.g., an interview study of victims of sexual assault).</td>
</tr>
<tr>
<td>In other situations, the IRB determines if flagging is necessary.</td>
</tr>
</tbody>
</table>

Explain:
19c Does the investigator need to maintain a master list of subjects?

- N/A - the investigator is not required to obtain informed consent for the purposes of the research.
- Yes - the investigator must maintain a master list of all subjects from whom informed consent was obtained
- No - the investigator is not required to maintain a master list of subjects as the research meets the following criteria:

  - There is a waiver of documentation of informed consent, AND
  - The inclusion of subjects on the master list poses a potential risk to the subjects from a breach of confidentiality.

Justify *(Written documentation justifying the master list is required in the minutes)*

20 Continuing Reviews Only

20a For continuing review, are all of the items below included?

- Not Applicable
- Yes
- No

- Brief summary of the research methodology and the research procedures;
- Number of subjects entered and withdrawn (reasons for withdrawals) since the last review and study inception;
- A summary of complaints regarding the research since the last IRB review;
- Gender and minority status of subjects enrolled in the protocol;
- Number of subjects considered as members of specific vulnerable populations;
- A copy of the current informed consent form(s) and any new proposed informed consent form along with a description of changes in the new form;
- A copy of the current HIPAA authorization document;
- A list of all amendments to the protocol since the last IRB initial or continuing review and approval;
- Information that may impact on the risk benefit ratio, such as SAEs and complaints regarding the research;
- Summaries, recommendations, or minutes of the DMC meetings (if applicable) or findings based on information collected by the data and safety monitoring plan submitted in the initial proposal;
- An assurance that all identified unanticipated internal or local SAEs, whether related or unrelated to the research, have been reported as required to the IRB of record;
- A summary of all unanticipated problems involving risks to subjects or others, and all internal or local SAEs;
- Research findings to date, if available;
- Any relevant multi-center trial reports;
- New scientific findings in the literature, or other relevant findings, that may impact on the research;
- A statement signed by the PI certifying that all subjects entered onto the master list of subjects for the study signed an informed consent form prior to undergoing any study interactions or interventions, unless the IRB has granted a waiver of informed consent, or a waiver of the signed informed consent form.
20b Y On continuing review, is verification needed from sources other than the investigator that no material changes have occurred since the previous IRB review? If not applicable, skip question.
- Does information contained in the continuing review report raise concerns about possible material changes in the study occurring without IRB approval?
- Has the investigator previously failed to comply with the requirements of the HHS regulations at 45 CFR part 46 or the requirements or determinations of the IRB?
- Does the protocol involve a complex design or unusual levels or types of risk?

20c Y On continuing review, do any new significant findings that arise from the review process and that may relate to the subjects' willingness to continue participation need to be provided to subjects?
Explain if YES.

20d On continuing review, has the investigator provided confirmation that he/she has maintained a master list of subjects?

<table>
<thead>
<tr>
<th></th>
<th>N/A - the investigator is not required to maintain a master list of subjects based on the IRB's previous determination.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes - the investigator has maintained a master list of all subjects from whom informed consent was obtained</td>
</tr>
<tr>
<td></td>
<td>No - the investigator has not maintained a master list of all subjects from whom informed consent was obtained</td>
</tr>
</tbody>
</table>

Explain:

21 Review frequency.

<table>
<thead>
<tr>
<th></th>
<th>Does this protocol meet criteria (listed below) for protocols that will generally be reviewed more often than annually?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Novel high-risk study involving new therapeutic modality</td>
</tr>
<tr>
<td></td>
<td>Phase I study of a new drug or biologic that has never been tested in humans</td>
</tr>
<tr>
<td></td>
<td>Study involving a novel significant risk medical device which has never been tested in humans</td>
</tr>
<tr>
<td></td>
<td>High-risk study as IRB members deem appropriate (includes research for which IRB determines that reports to the IRB of monitoring data should be more than annually)</td>
</tr>
</tbody>
</table>

Select Review Frequency:

<table>
<thead>
<tr>
<th></th>
<th>12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 Months</td>
</tr>
<tr>
<td></td>
<td>Other:</td>
</tr>
</tbody>
</table>
Approval Recommendation.

☐ Approved
☐ Risk level: Greater than Minimal Risk
☐ Risk level: Minimal Risk, keep at convened review
☐ Risk level: Minimal Risk, eligible for expedited review (attach Expedited Addendum)

☐ Modifications required (list all, including informed consent document and HIPAA authorization matters, in comments section below)

☐ Refer to Convened Review - Further review required by full IRB With modifications noted below or on attached page
☐ Copies Only

☐ Deferred (only if being reviewed at convened meeting)
☐ Disapproved (only if being reviewed at convened meeting)
☐ Suspension

Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

☐ Accept pre-review comments
☐ Accept pre-review comments with modifications
☐ Do not accept pre-review comments

Signature ___________________________ Date ________________

Printed Name ___________________________
### Review Guide: JBVAMC IR/CR SBR

**Initial and Continuing Review ● Review Guide Checklist**

**University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 2.1, April 29, 2012**

---

**Research Protocol #:**

**Investigator Full Name:**

**Research Protocol Title:**

---

**Instructions:**

- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.

*For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.*

- If a 45 CFR 46.111 approval criteria is "not relevant" based on the type of research, explain why.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

---

**Review Type. Check applicable boxes.**

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Review</td>
<td>Expeditd review (attach Expedited Addendum)</td>
</tr>
<tr>
<td>Continuing Review</td>
<td>Convended</td>
</tr>
<tr>
<td>Amendment adding the JBVAMC as a performance site (treat as an Initial Review)</td>
<td></td>
</tr>
</tbody>
</table>

---

**Investigator Resources**

- **Criterion Met**
  - The investigator has the resources necessary to protect subjects
  - Resources might include: availability, number, expertise, and experience of investigator and staff
  - time to conduct and complete the research
  - facilities and equipment to conduct, monitor and protect subjects
  - access to a population that will allow recruitment of the necessary number of subjects
  - availability of medical or psychological resources that subjects may need as a consequence of the research
  - resources for subject communication, e.g., translation services

- **Criterion Not Met**

---

**Y N** Is this a multi-site study in which the investigator is the lead site?

**Y N** Answer only if above is YES. Is the investigator’s management of information relevant to the protection of subjects adequate in this role as the lead site?

*If YES.*

---

**1. Is the subject of the research a fetus, in-utero or ex-utero (including human fetal tissue), or does the research involved in vitro fertilization?**

| Yes |
| No |

*If yes, please stop and speak with the IRB #4 Assistant Director*

---

---
**2 Study Population.**

<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

Subject selection is equitable.

**Reference:**
- Tip Sheet #1

**Comments:**
- Justification for the inclusion of any vulnerable population
- Inclusion/ Exclusion criteria are appropriate
- A certain group is not targeted or excluded without justification
- Subject recruitment and enrollment procedures do not cause inequitable selection
- The amount and timing of payments to subjects does not cause inequitable selection
- The target number of enrollees appears appropriate given the research objective/s

**3 Privacy.**

<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

There are adequate provisions to protect the privacy of subjects.

**Reference:**
- Tip Sheet #1

**Comments:**
- Privacy is about people and refers to their interest in controlling access of others to themselves

**4 Confidentiality.**

<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

There are adequate provisions to maintain the confidentiality of the data.

**Reference:**
- Tip Sheet #1

**Are you recommending that the investigator obtain a Certificate of Confidentiality?**
- Yes
- No

**Comments:**
- Confidentiality is about data, and about agreements and procedures for limiting access of others to data

**5 Does this submission include any recruitment materials?**

- Yes - recruitment materials are included
- No - no recruitment materials are being utilized
5a **Recruitment continued**

<table>
<thead>
<tr>
<th>Not Relevant (explain)</th>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Continues to be Met</strong></td>
<td>The recruitment process and recruitment materials are fair and appropriate.</td>
<td></td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #3

Comments:

5b **Do the research procedures meet the following VA requirements for contacting Veterans?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>If NO, modifications must be requested</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

- During the recruitment process, researchers must make initial contact with the patient in person and/or through a letter prior to any phone contact and provide a telephone number or other means that veterans can use to verify the validity of the study;
- Phone and other contacts with veterans are restricted to only those procedures and data elements outlined in the IRB approved protocol application, and, in these contacts, research staff must not request social security numbers; and
- The informed consent document includes information about where and how a veteran can verify the validity of a study and authorized contacts.

5c **Do the investigators propose to use protected health information from data repositories or medical records to identify potential participants (including their own patients) to recruit for the research?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- If **YES**, has the investigator requested, or hold, a Waiver of Informed Consent for Recruitment and a Waiver of Authorization for Recruitment?
  - Yes - Criteria met
  - No - Modifications must be requested

5d **Does the investigator propose enrolling non-veterans in the VA protocol or at the VA site?**

<table>
<thead>
<tr>
<th>Yes, answer 5.e.</th>
<th>No, proceed to 6</th>
</tr>
</thead>
</table>

5e **Are the following criteria for allowing enrollment of non-veterans met?**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

1. Research is relevant to the care of veterans or active duty military personnel, AND
2. Researcher has made a compelling argument for the inclusion of non-veterans (e.g., insufficient veterans are available to complete the study, survey of VA employees, study of active duty military, study involving veterans’ family members)
### Incentives or reimbursements.

<table>
<thead>
<tr>
<th>Criteria Not Met</th>
<th>Compensation amounts and disbursement methods are not coercive or they do not present undue influence.</th>
</tr>
</thead>
</table>

Reference:
- Tip Sheet #3

<table>
<thead>
<tr>
<th>Yes</th>
<th>Does the proposed payment or reimbursement scheme for research subjects meet the following criteria?</th>
</tr>
</thead>
</table>
| No  | Payment is prohibited if the research is integrated with the patient’s medical care and when it makes no special demands on the patient beyond those of usual medical care. Payment may be permitted, with IRB approval, if:  
  - The study is not being performed to directly enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and the standard practice in affiliated non-VA institutions is to pay subjects in this situation;  
  - The research is a multi-institutional study, and subjects at a collaborating non-VA institution are to be paid for the same participation in the same study at the same rate proposed;  
  - In other comparable situations in which, in the opinion of the IRB, payment of subjects is appropriate; or  
  - Transportation expenses are incurred by the subject that would not be incurred in the normal course of receiving treatment and are not reimbursed by any other mechanism. |

### Are any vulnerable populations to be recruited for this research?

<table>
<thead>
<tr>
<th>Yes</th>
<th>If YES, specify which populations:</th>
</tr>
</thead>
</table>
| No  | - Pregnant Women (complete #7a, b)  
- Decisionally or Cognitively Impaired (complete #7a, c, d)  
- Other (specify on line below and complete 7a and other section 7 questions that apply to the population) |

**Explain why this population is considered vulnerable:**

### Vulnerable Populations.

<table>
<thead>
<tr>
<th>Criterion Not Met</th>
<th>If applicable, additional safeguards are provided for populations vulnerable to coercion and undue influence.</th>
</tr>
</thead>
</table>

Reference:
- Tip Sheet #1

- Consider whether appropriate additional safeguards are in place to protect vulnerable populations from coercion.
7b If pregnant women are to be recruited for the research, have all the VA requirements for approval and inclusion of this vulnerable population been met?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Please also complete the review guide for pregnant women, neonates and fetuses

- The proposed research meets the requirements of 45 CFR 46.204
- Provisions for consent are consistent with those listed at 45 CFR 46.204(d)

7c If decisionally or cognitively impaired persons will be recruited for the research, are the requirements in VHA handbook 1200.05, paragraphs 36 and 49 met?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Please also complete the review guide for decisionally impaired adults

- Criteria for determining and documenting a lack of decision-making capacity are met
- Informed consent from LARs as defined in paragraph 36 will be obtained
- Procedures for respecting dissent are appropriate
- Need for obtaining assent has been ascertained and, if required, plan is adequate
- Need for additional safeguards has been ascertained
- Inclusion of individuals lacking decision-making capacity meets one or more of the criteria in Handbook 1200.05, paragraph 49.d.

If no, explain:

7d If decisionally or cognitively impaired individuals will be recruited, additional safeguards included in protocol are adequate?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If no, explain:

7e If the research includes children, are the following requirements met?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Please also complete the review guide for children

- A waiver from the Chief Research and Development Officer (CRADO) has been submitted and research will not begin until approval received from CRADO
- The research poses no more than minimal risk
### Evaluation of Risks

#### 8a

<table>
<thead>
<tr>
<th>Risks to subjects are minimized by using procedures consistent with sound research design and that do not unnecessarily expose subjects to risk.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Continues to be Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #1

Comments:

#### 8b

<table>
<thead>
<tr>
<th>Risks to subjects are minimized, when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Relevant</td>
</tr>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Continues to be Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
</tbody>
</table>

If such procedures are not relevant to the research context, this strategy for minimizing risks should be marked Not Applicable

Reference:
- Use of standard of care procedures when possible
- Tip Sheet #1

Comments:

#### 8c

<table>
<thead>
<tr>
<th>Risks to subjects are reasonable in relationship to the potential benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Continues to be Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
</tbody>
</table>

Reference:
- Consider whether the investigator’s description of new literature changes this criterion
- Tip Sheet #1

Comments:

### Data Monitoring Plan

<table>
<thead>
<tr>
<th>The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Relevant (explain)</td>
</tr>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Continues to be Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheets #1-2

Comments:

Changes to provisions of DSMP and/or recommend DSMB/DMC:
10 Does the research involve (or propose changes in the exposure to) ionizing radiation or recombinant DNA, infectious agents and/or toxins?

<table>
<thead>
<tr>
<th>Yes</th>
<th>If YES, has documentation of review and approval by the Radiation Safety Officer/Radiation Safety Committee or Institutional Biosafety Committee been submitted?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>No (modifications may be required)</td>
</tr>
</tbody>
</table>

11a Does the research involve the banking of tissues?

| Yes | No (skip to #12) |

Reference:
- Tip Sheets #20-21

11b If yes to above (11a), Are the tissues being banked at a VA-sponsored (i.e., typically a VA facility) or VA-approved (see approved list) banking facility?

| Yes | No |

Please note that IRB approval cannot be granted until documentation of the approved Off-Site Tissue Banking Waiver is submitted.

Reference:
- Tip Sheet #20

12 Does the research involve recording of voice or video or taking pictures of the subject?

| Yes | No |

If YES, are the following true?
- Subjects will sign and date VA form 10-3203

| Yes | No (modifications may be required) |

Reference:
- Tip Sheets #5, 8, 22

13 Informed Consent Process. (Select either Box 1 or Box 2 and confirm whether criteria have been met / continue to be met)

Box 1: Informed consent will be/ will continue to be obtained from the subject or the subject’s legally authorized representative. (38 CFR 46.111(a)(4); 38.116(a), (b))

| Not Applicable | Criterion Met | Criterion Not Met |

Reference:
- Tip Sheets #5, 8, 22

- Researcher or appropriately delegated and trained research personnel will obtain legally effective consent from subject or LAR
- The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence
- No information will be provided to the subject or the representative that waives or appears to waive any of the subject’s legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence
- Individuals communicating information to the subject or LAR during the consent process will convey that information in language understandable to the subject or representative
- All required and appropriate disclosures will be provided either to the subject or to the subject’s representative
Box 1a: Research involves subjects whose decision-making capacity may be diminished and the study provides safeguards to ensure an appropriate consent process.

- Not Applicable, research does not involve subjects with diminished decision-making capacity
- Criterion Met
- Criterion Not Met

Even when subjects are judged capable of providing informed consent, the possibility exists that environmental, medical, mental or social circumstances may diminish their understanding of the consent process and decision-making ability. Examples may include participants who are educationally or economically disadvantaged, terminally ill, alcohol or substance abusers, or pre- or post an invasive medical procedure.

- extent of safeguards should be guided by the complexity of the study, risks, and potential for subjects to be recruited who may be capable of providing informed consent but due to circumstances have a diminished decision-making ability.
- Most frequently utilized approach is to have researcher assess participants understanding and decision-making ability by asking questions concerning the nature of the research and their participation; consequences of their participation, particularly risks, benefits or impact on their health; and alternatives to participation. Depending on the study and population, the IRB may require additional safeguards, including a witness, formal assessment of capacity to consent or use of a subject advocate/ombudsperson.

If criterion is not met, describe why and recommend appropriate safeguards:

Box 2: The consent procedure will be waived or altered.
(If deception is used, the elements of alteration of consent must be met.)

- Not Applicable
- Approved for all of the research
- Approved only for the following research components (specify):
- Criterion for waiver or alteration not met

Reference:
- Tip Sheets #7

If a waiver or alteration is approved for all or some of the research, complete either a). or b). Below.

a).
    i) Protocol specific findings justifying the determination that the research (or portion where consent is waived or altered) involves no more than minimal risk
    Document reasoning (required):

ii) Protocol specific findings justifying the determination that the waiver will not adversely affect the rights and welfare of subjects
    Document reasoning (required):
iii) Protocol specific findings regarding whether it is appropriate to provide subjects with additional pertinent information after participation
   Document reasoning (required):

iv) Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration
   Document reasoning (required):

OR

b). i). Research is conducted under the direction of state or local government officials AND is designated to study public benefit/service programs, procedures for obtaining public benefits/services, changes or alternatives to public benefit/service programs, or levels of payment for public benefits/services
   AND

ii). Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration
   Document reasoning (required):

13a Are the VA consent form(s) written on the appropriate VA Form (10-1086)?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
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</tbody>
</table>

13b Informed consent document contains required basic and additional elements. Also, at continuing review, the current consent provided by the investigator remains accurate and complete.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #5, 22

13c If the research involves subjects with fluctuating decision making capacity or with decreasing capacity to give consent, is a re-consenting process with surrogate consent necessary?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
13d Is a witness required to sign the consent document? (e.g., IRB may require this when study involves an invasive intervention or an investigational drug or device). This is always required when a short form consent is used.

<table>
<thead>
<tr>
<th></th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
</table>

If yes, should the witness observe only the subject's or LAR signature (only requirement) or witness the consent process (discretion of IRB or sponsor)

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Explain:

14 Consent Documentation. (Select Box 1, 2, or 3 below and confirm whether criteria have been met. If a long form consent will be used for English-speaking subjects and a short form will be used for non-English speaking subjects, select Boxes 1 and 2.)

Box 1: Informed consent will be documented using the long form consent document.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>The consent form includes the required elements and appropriate disclosures</td>
<td>The investigator will give either the subject or the LAR adequate opportunity to read the consent document before it is signed</td>
<td>The subject or the LAR will sign and date the written consent form</td>
<td>A copy of the consent form will be given to the person signing the consent (subject or LAR)</td>
</tr>
<tr>
<td>When appropriate, a witness will sign and date the written form</td>
<td>When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness' signature line</td>
<td>For VA Research: VA Form 10-1086 must be used</td>
<td>investigator must give either the subject or the representative adequate opportunity to read it before it is signed</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #5, 6, 22

Box 2: Informed consent will be documented using the short form consent document.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent document states that the elements of informed consent required by 46.116 and 50.25 have been presented orally to the subject or the subject's LAR</td>
<td>a written summary of what is to be said to the subject or the representative and includes the basic and required additional elements of disclosure is provided</td>
<td>Witness will be present at the oral presentation</td>
<td>Review documents and description of process to ensure 1. subject or LAR will sign short form consent, 2. witness will sign short form consent and written summary and 3. person obtaining consent will sign written summary</td>
</tr>
<tr>
<td>Witness should not be the individual obtaining consent</td>
<td>Subject or LAR should receive signed copies of short form consent and written summary</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Box 3: The requirement to obtain a signed consent form will be waived.

<table>
<thead>
<tr>
<th>Reference:</th>
<th>Check if applicable:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip Sheet: #5,6,8, 22</td>
<td>- An oral or written consent script was submitted</td>
</tr>
<tr>
<td></td>
<td>- The oral or written consent script includes the required and appropriate additional elements of disclosure</td>
</tr>
</tbody>
</table>

#### Check applicable category of waiver of documentation below:

- (i) The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context.

- OR

- (ii) The only record linking the subject and the research is the consent document and the principal risk is loss of confidentiality. The research is not FDA-regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.

**Justify:**

**Check if written statement is required.**

- The PI is required to provide subjects with a written statement about the research.

### 15 HIPAA Authorization and/or Waivers. *(If granting a HIPAA waiver, please make a consistent determination in the Informed Consent Sections.)*

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>- No PHI used/disclosed in this research <em>(skip to 16)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>HIPAA Authorization document submitted/approved with NO Waivers</td>
<td></td>
</tr>
<tr>
<td>Waiver and/or Alteration of HIPAA requested/approved - for ALL of the research</td>
<td></td>
</tr>
<tr>
<td>Waiver and/or Alteration of HIPAA requested/approved - for SOME of the research</td>
<td></td>
</tr>
<tr>
<td>Waiver(s) and/or alteration(s) fulfill ALL requirements for waiver under 45 CFR 164.512</td>
<td></td>
</tr>
</tbody>
</table>

- Use or disclosure of PHI involves no more than minimal risk
- Waiver will not adversely affect the privacy rights and welfare of subjects
- Research would be so difficult as to be nearly impossible without access to and use of PHI
- Risks are reasonable in relation to anticipated benefits to subjects and importance of knowledge gained
- Adequate plans and procedures in place to protect against improper use and disclosure of PHI
- Identifiers will be destroyed at the earliest opportunity (unless retention required by law)
- Written assurances that PHI will not be reused or shared unless required by law or this regulation

**Specify the purposes for which a waiver or alteration of HIPAA is approved:**
### 15a Is the authorization form written on the template form?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not Applicable</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 15b Does the authorization form contain the required template language?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Not Applicable</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
</tbody>
</table>

### 16 Does the research involve, or make changes to, the use and disclosure of protected health information related to the treatment of alcoholism, drug abuse, sickle cell anemia, or infection with Human Immunodeficiency Virus (HIV)?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<tbody>
<tr>
<td><strong>Not Applicable</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
</tbody>
</table>

If **YES**, use and disclosure of this information requires EITHER:

- A written authorization signed by the research subject that describes the information to be disclosed in a specific and meaningful fashion and specifically identifies that the information to be released concerns alcoholism, drug abuse, sickle cell anemia, or testing for or infection with Human Immunodeficiency Virus (HIV); **OR**
- If the investigator is requesting a waiver of authorization and informed consent, assurance in writing (i.e., within protocol) from the VA researcher that the purpose of the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.

### 17 Is the protocol document, informed consent document, and HIPAA authorization form consistent?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not Applicable - Explain:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No - Modifications must be requested.</strong> (Explain which documents are incorrect either here or at the end of the review guide.)</td>
<td></td>
</tr>
</tbody>
</table>

### 18 Initial Reviews (or amendments adding the VA as a performance site) Only

#### 18a Does the submission contain a complete R&D Packet?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Not Applicable</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
</tbody>
</table>
**18b Does the research need to be flagged in CPRS?**

- **Yes** - the research is to be flagged, as it meets one of the criteria listed below.
- **No** - the research does not meet the following criteria:

  - Any invasive research procedure (e.g., muscle biopsy or bronchoscopy);
  - Interventions that will be used in the medical care of the subject, or that could interfere with other care the subject is receiving or may receive (e.g., administration of a medication, treatment, or use of an investigational device);
  - Clinical services that will be used in the medical care of the subject (e.g., orders for laboratory tests or x-rays ordered as a part of the study), or that could interfere with other care the subject receives or may receive;
  - The use of a survey or questionnaire that may provoke undue stress or anxiety unless the IRB determines that mandatory flagging is not in the best interests of the subject (e.g., an interview study of victims of sexual assault).
  - In other situations, the IRB determines if flagging is necessary.

  **Explain:**

**18c Does the investigator need to maintain a master list of subjects?**

- **N/A** - the investigator is not required to obtain informed consent for the purposes of the research.
- **Yes** - the investigator must maintain a master list of all subjects from whom informed consent was obtained.
- **No** - the investigator is not required to maintain a master list of subjects as the research meets the following criteria:

  - There is a waiver of documentation of informed consent, AND
  - The inclusion of subjects on the master list poses a potential risk to the subjects from a breach of confidentiality.

**Justify** *(Written documentation justifying the master list is required in the minutes)*:
### 19 Continuing Reviews Only

#### 19a For continuing review, are all of the items below included?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not Applicable</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Yes</strong></td>
<td></td>
</tr>
<tr>
<td><strong>No</strong></td>
<td></td>
</tr>
</tbody>
</table>

- Brief summary of the research methodology and the research procedures;
- Number of subjects entered and withdrawn (reasons for withdrawals) since the last review and study inception;
- A summary of complaints regarding the research since the last IRB review;
- Gender and minority status of subjects enrolled in the protocol;
- Number of subjects considered as members of specific vulnerable populations;
- A copy of the current informed consent form(s) and any new proposed informed consent form along with a description of changes in the new form;
- A copy of the current HIPAA authorization document;
- A list of all amendments to the protocol since the last IRB initial or continuing review and approval;
- Information that may impact on the risk benefit ratio, such as SAEs and complaints regarding the research;
- Summaries, recommendations, or minutes of the DMC meetings (if applicable) or findings based on information collected by the data and safety monitoring plan submitted in the initial proposal;
- An assurance that all identified unanticipated internal or local SAEs, whether related or unrelated to the research, have been reported as required to the IRB of record;
- A summary of all unanticipated problems involving risks to subjects or others, and all internal or local SAEs;
- Research findings to date, if available;
- Any relevant multi-center trial reports;
- New scientific findings in the literature, or other relevant findings, that may impact on the research;
- A statement signed by the PI certifying that all subjects entered onto the master list of subjects for the study signed an informed consent form prior to undergoing any study interactions or interventions, unless the IRB has granted a waiver of informed consent, or a waiver of the signed informed consent form.

#### 19b On continuing review, is verification needed from sources other than the investigator that no material changes have occurred since the previous IRB review? If not applicable, skip question.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Y</strong></td>
<td></td>
</tr>
<tr>
<td><strong>N</strong></td>
<td></td>
</tr>
</tbody>
</table>

- Does information contained in the continuing review report raise concerns about possible material changes in the study occurring without IRB approval?
- Has the investigator previously failed to comply with the requirements of the HHS regulations at 45 CFR part 46 or the requirements or determinations of the IRB?
- Does the protocol involve a complex design or unusual levels or types of risk?

#### 19c On continuing review, do any new significant findings that arise from the review process and that may relate to the subjects' willingness to continue participation need to be provided to subjects?

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Y</strong></td>
<td></td>
</tr>
<tr>
<td><strong>N</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Explain if YES.**
19d On continuing review, has the investigator provided confirmation that he/she has maintained a master list of subjects?

☐ N/A - the investigator is not required to maintain a master list of subjects based on the IRB’s previous determination.

☐ Yes - the investigator has maintained a master list of all subjects from whom informed consent was obtained

☐ No - the investigator has not maintained a master list of all subjects from whom informed consent was obtained

Explain:

20 Review frequency.

Select Review Frequency:

☐ 12 Months

☐ 6 Months

☐ Other:

21 Approval Recommendation.

☐ Approved

☐ Risk level: Greater than Minimal Risk

☐ Risk level: Minimal Risk, keep at convened review

☐ Risk level: Minimal Risk, eligible for expedited review (attach Expedited Addendum )

☐ Modifications required (list all, including informed consent document and HIPAA authorization matters, in comments section below)

☐ Refer to Convened Review - Further review required by full IRB

☐ With modifications noted below or on attached page

☐ Copies Only

☐ Deferred (only if being reviewed at convened meeting)

☐ Disapproved (only if being reviewed at convened meeting)

☐ Suspension
Expedited Addendum
Initial and Continuing Review ● Review Guide Checklist

Instructions:

- Please attach as an addendum to the appropriate IR/CR review guide
- Provide an explanation in the space provided or on an attached sheet, if necessary.
  
  *For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.*
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

The IRB may use an expedited procedure for initial review of research if ALL of the following criteria are true (check applicable boxes):

- The research presents no more than minimal risk to participants.
- The identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The research is not classified.
- The research falls into one or more of the following categories (check all that apply):

**Category 1**

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Clinical studies of drugs and medical devices only when ONE of the following conditions is met:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td>● Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.</td>
</tr>
<tr>
<td></td>
<td>● Research on medical devices for which one of the following is true:</td>
</tr>
<tr>
<td></td>
<td>● An investigational device exemption application (21 CFR Part 812) is not required.</td>
</tr>
<tr>
<td></td>
<td>● The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.</td>
</tr>
</tbody>
</table>
### Category 2

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</th>
</tr>
</thead>
</table>
| Criteria Not Met | - From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.  
- From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. |

### Category 3

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Prospective collection of biological specimens for research purposes by noninvasive means</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td>- such as hair and nail clippings, deciduous or permanent teeth if routine patient care care indicates a need for extraction, excreta and external secretions (including sweat) and other specimens outlined in the regulations.</td>
</tr>
</tbody>
</table>

### Category 4

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice ... Where medical devices are employed, they must be cleared/approved for marketing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td>- excluding procedures involving x-rays or microwaves, such as magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.</td>
</tr>
</tbody>
</table>

### Category 5

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td></td>
</tr>
</tbody>
</table>

### Category 6

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Collection of data from voice, video, digital, or image recordings made for research purposes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td></td>
</tr>
</tbody>
</table>

### Category 7

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td></td>
</tr>
<tr>
<td>Category 8(a)</td>
<td>Criteria Met</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------</td>
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<td></td>
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<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Category 8(b)</th>
<th>Criteria Met</th>
<th>No subjects have been enrolled and no additional risks have been identified.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Category 8(c)</th>
<th>Criteria Met</th>
<th>The remaining research activities are limited to data analysis.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Category 9</th>
<th>Criteria Met</th>
<th>Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Criteria Not Met</td>
<td>-</td>
</tr>
</tbody>
</table>

**Expedited Approval Recommendation.**

The research is:

- [ ] Eligible for review using the expedited procedure under category:  
- [x] NOT eligible for review using the expedited procedure

**Comments.** *(Write comments in space provided; attach additional sheet of paper, if necessary.)*

---

**Signature**

**Date**

**Printed Name**
Review Guide Checklist ● Development Only Addendum

University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 1.1, dated September 30, 2009

Research Protocol #: __________________________________________
Investigator Full Name: ________________________________________
Research Protocol Title: _______________________________________

Instructions:

- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.
  
  For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

Review Type.

- Expedited review (attach Expedited Addendum)
- Convened
- Initial Review
- Continuing Review

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Does the proposed activity meet the definition of a proposal lacking definite plans for the involvement of human subjects?</th>
</tr>
</thead>
</table>
| Criterion Not Met |               | • Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal.  
  • Activities include:
    - Institutional type grants when selection of specific projects is the institution's responsibility
    - Research training grants in which the activities involving subjects remain to be selected
    - Projects in which human subjects' involvement will depend on the completion of instruments, prior animal studies, or purification of compounds. |

For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.
Approval Recommendation.

- Approved  Proposal meets the definition of a proposal lacking definite plans
- Modifications required (list in comments section below)
- Refer to Convened Review - Further review required by full IRB
  (document reasons in comments section below or on attached blank page)
- Eligible for Expedited Review under Category/s _______________
  (attach Expedited Review Guide)
- Exemption

Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

- Accept pre-review comments
- Accept pre-review comments with modifications
- Do not accept pre-review comments

Signature ___________________________ Date ____________

Printed Name ___________________________
Amendment Review Guide Checklist


Research Protocol #: __________________________ Amendment #: __________________________
Investigator Full Name: __________________________
Research Protocol Title: ______________________________________________

Instructions:

● Please check the applicable boxes.
● Provide an explanation in the text box if necessary.
  For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.
● If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.
● Refer to Tip Sheet #16 for the expedited review categories

1. Appropriate Level of Review: Expedited Review
   (Select either Box 1 or Box 2 and confirm whether criteria have been met / continue to be met)

Box 1. If the research was previously determined to be greater than minimal risk, does this amendment meet the criteria for minor changes to previously approved research:

Not Applicable
Eligible for Expedited
Refer to Convened

a) Proposed changes do not alter the risk/benefit assessment
   Explain:

b) Proposed changes do not substantially alter the specific aims of the research
   Explain:

c) Proposed changes do not substantially alter the specific design of the research
   Explain:

d) Proposed changes are eligible for the expedited review process
   Explain:
1. **Appropriate Level of Review: Expedited Review.** (Continued)

**Box 2. If the research was previously determined to be minimal risk, does this amendment meet the criteria for minor changes to previously approved research:**

| Not Applicable | Eligible for Expedited | Refer to Convened |

**Significant new findings/notes:**

- a) Proposed changes do not alter the risk/benefit assessment
  
  **Explain:**
  
- b) Proposed changes do not substantially alter the specific aims of the research OR, if specific aims are altered, there is no negative impact on the risk/benefit assessment
  
  **Explain:**
  
- c) Proposed changes do not substantially alter the specific design of the research OR, if the specific design is altered, there is no negative impact on the risk/benefit assessment
  
  **Explain:**
  
- d) Proposed changes are eligible for the expedited review process
  
  **Explain:**
2 Changes Proposed by Amendment.

- Please consider whether the proposed amendment affects the approval criteria listed below.
- If the proposed amendment does not affect the criteria for approval below, please indicate below and skip to the end of the form to make your determination and sign the form.
  - For example, if a change in key research personnel does not affect any criteria for approval, then mark the box below and skip to the end of the form.
  - If, for example, there is a change to the performance site that does not affect the criteria for approval, then verify that the pre-review confirms that the appropriate documentation is in place and skip to the end of the form and sign the form.

☐ Check here if the amendment is the result of any reports of deviations, protocol events, non-compliance or subject complaints that represent unanticipated events or problems involving risks to subjects or others or serious or continuing non-compliance.

☐ The proposed Amendment does not affect any of the criteria for approval

☐ The proposed Amendment affects the criterion/criteria for approval:
  - If the proposed amendment affects the criteria of approval below, please mark each criterion affected.
  - It is possible that the proposed amendment may affect more than one criterion.

☐ Risks to subjects (complete section 3a)
☐ The risk/benefit ratio (complete section 3b)
☐ Equitable selection of subjects (complete section 3c)
☐ Recruitment materials/ Payment (complete section 3d)
☐ Informed consent process (complete section 3e)
☐ Informed consent documentation (complete section 3f)
☐ Data monitoring plan (complete section 3g)
☐ Provisions to protect subject privacy or data confidentiality (complete section 3h)
☐ Safeguards to protect vulnerable populations (complete section 3i)
☐ HIPAA (complete section 3j)

3 Approval criterion/criteria changed by proposed Amendment.

- Complete this section only if the proposed Amendment affects the criterion/criteria for approval.
- Select and complete only the sections for the Criteria for Approval that the amendment affects (should correspond to the criteria you selected in Section 2).
- If a criterion in this section is not checked, it is assumed that it is not applicable and no change has occurred.

3a Risks to subjects.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reference:</strong></td>
<td></td>
</tr>
<tr>
<td>The research uses procedures consistent with sound research design</td>
<td></td>
</tr>
<tr>
<td>The research design is sound enough to yield the expected knowledge</td>
<td></td>
</tr>
<tr>
<td>Avoids unnecessary exposure to risks</td>
<td></td>
</tr>
<tr>
<td>In making this determination, the IRB considers physical, psychological, social, economic, and legal risks</td>
<td></td>
</tr>
<tr>
<td>Risk to subjects are minimized, when appropriate, by using procedures already being performed for diagnostic or treatment purposes</td>
<td></td>
</tr>
<tr>
<td>Use of standard of care procedures when possible</td>
<td></td>
</tr>
</tbody>
</table>
### 3b. The risk/anticipated benefit ratio.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Risks are reasonable compared to benefits and are justified by importance of information to be gained from the study</td>
<td></td>
</tr>
<tr>
<td>- All known risks are identified</td>
<td></td>
</tr>
<tr>
<td>- Any direct benefits are identified</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

### 3c. Equitable selection of subjects.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Inclusion of any vulnerable population is justified</td>
<td></td>
</tr>
<tr>
<td>- Appropriate additional protections are in place for any vulnerable populations</td>
<td></td>
</tr>
<tr>
<td>- No group inappropriately targeted or excluded</td>
<td></td>
</tr>
<tr>
<td>- Target numbers of subjects sufficient</td>
<td></td>
</tr>
<tr>
<td>- Inclusion/exclusion criteria appropriate</td>
<td></td>
</tr>
<tr>
<td>- Setting where study will be conducted is appropriate</td>
<td></td>
</tr>
<tr>
<td>- Regulatory criteria have been met when vulnerable populations are involved</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

### 3d. Recruitment/ Payment. *(Circle applicable)*

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Recruitment procedures are fair and appropriate</td>
<td></td>
</tr>
<tr>
<td>- Payment amount is justified, fair, and appropriate</td>
<td></td>
</tr>
<tr>
<td>- Payment amount is reasonable, meaning not likely to be coercive</td>
<td></td>
</tr>
<tr>
<td>- Payment amount is dispersed at appropriate intervals</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheets #3-4

### 3e. Informed Consent Process. *(Check either Box 1 or Box 2 and confirm whether criteria have been met/continue to be met)*

#### Box 1: Informed consent will be/ will continue to be obtained from the subject or the subject's legally authorized representative. *(45 CFR 46.111(a)(4); 46.116(a), (b))*

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Researcher or appropriately delegated and trained research personnel will obtain legally effective consent from subject or LAR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No information will be provided to the subject or the representative that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Individuals communicating information to the subject or LAR during the consent process will convey that information in language understandable to the subject or representative</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- All required and appropriate disclosures will be provided either to the subject or to the subject's representative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheets 4
3e Informed Consent Process. (Continued)

Box 2: The consent procedure will be waived or altered.
(Two options acceptable; document protocol specific findings below)

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>The research must not be FDA regulated (check box to the left to confirm that the research is not FDA-regulated)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td></td>
</tr>
</tbody>
</table>

- Protocol specific findings justifying the determination that the research involves no more than minimal risk (articulate protocol specific findings in space below)
- Protocol specific findings justifying the determination that the waiver will not adversely affect the rights and welfare of subjects (articulate protocol specific findings in space below)
- Protocol specific findings justifying the determination that the research could not be practically carried out without the waiver because (i.e., increased risk of a breach of confidentiality)
- Protocol specific findings regarding whether it is appropriate to provide subjects with additional pertinent information after participation (articulate protocol specific findings in space below)

☐ The research is not FDA regulated. Check the box to indicate that the research is not FDA-funded. For FDA research, alterations or waivers are NOT permitted unless the research falls within an exception OR the research qualifies for emergency use of a test article

- Research is conducted under the direction of state or local government officials AND is designated to study public benefit/service programs, procedures for obtaining public benefits/services, changes or alternatives to public benefit/service programs, or levels of

Explain:

3f Informed Consent Documentation.
(Select Box 1, 2, or 3 below and confirm whether criteria have been met. If a long form consent will be used for English-speaking subjects and a short form will be used for non-English speaking subjects, select Boxes 1 and 2.)

Box 1: Informed consent will be documented using the long form consent document.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>The consent form includes the required elements and appropriate disclosures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria Not Met</td>
<td></td>
</tr>
</tbody>
</table>

- The investigator must give either the subject or the LAR adequate opportunity to read the consent document before it is signed
- A copy of the consent form will be given to the person signing the consent (subject or LAR)
- When appropriate, a witness will sign and date the written form
- When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness’ signature line

Reference:
- Tip Sheet #5
3f Informed Consent Documentation. (Continued)

Box 2: Informed consent will be documented using the short form consent document.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consent document states that the elements of informed consent required by 46.116 and 50.25 have been presented orally to the subject or the subject's LAR</td>
</tr>
<tr>
<td></td>
<td>a written summary of what is to be said to the subject or the representative and includes the basic and required additional elements of disclosure is provided</td>
</tr>
<tr>
<td></td>
<td>Witness will be present at the oral presentation</td>
</tr>
<tr>
<td></td>
<td>When the subject and/or subject's LAR do not speak English as their primary language, the witness must be conversant in both English and the language of the subject and/or subject's LAR</td>
</tr>
<tr>
<td></td>
<td>Review documents and description of process to ensure 1. subject or LAR will sign short form consent, 2. witness will sign short form consent and written summary and 3. person obtaining consent will sign written summary</td>
</tr>
<tr>
<td></td>
<td>Witness should not be the individual obtaining consent</td>
</tr>
<tr>
<td></td>
<td>Subject or LAR should receive signed copies of short form consent and written summary</td>
</tr>
</tbody>
</table>

Box 3: The requirement to obtain a signed consent form will be waived.

<table>
<thead>
<tr>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
</tr>
<tr>
<td>Criterion Not Met</td>
</tr>
</tbody>
</table>

Reference: Check if applicable:
- An oral consent script was submitted
- The oral consent script includes the required and appropriate additional elements of disclosure

Check applicable category of waiver of documentation below:
- The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context.
- The only record linking the subject and the research is the consent document and the principal risk is loss of confidentiality. The research is not FDA-regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
- Check if the above box is selected and the PI should be required to provide subjects with a written statement about the research.

3g Data monitoring plan.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #2
  - Plan provides adequate data monitoring
  - Plan provides adequate monitoring to ensure safety of subjects
### 3h. Provisions to protect subject privacy or data confidentiality.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● If appropriate, there are adequate provisions to protect the privacy of subjects</td>
</tr>
<tr>
<td></td>
<td>● If appropriate, there are adequate provisions to maintain the confidentiality of data</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #1

### 3i. Safeguards to protect vulnerable populations.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● Additional safeguards if subjects are likely to be vulnerable to coercion or undue influence</td>
</tr>
<tr>
<td></td>
<td>● In making this determination, the IRB has considered the research purpose, the research setting, whether subjects may be vulnerable to coercion or undue influence, the selection criteria, recruitment, and enrollment procedures and payment</td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheets #5-8

### 3j. HIPAA.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● New and/or revised HIPAA authorization materials and/or Appendix H documentation justifying the waiver resubmitted and consistent with federal and state laws</td>
</tr>
</tbody>
</table>

Comments:

4. **Y** **N** Do any new significant findings that arise from the review process and that may relate to the subjects’ willingness to continue participation need to be provided to subjects?

   **Explain if YES.**

5. **Additional Review Guide Checklists. (Complete only if not pre-reviewed; attach additional applicable review guides)**

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Review of Modifications</th>
<th>Adults Unable to Consent</th>
<th>Children</th>
<th>Wards</th>
<th>HUD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant Women/Neonates/Fetuses</td>
<td>Prisoners</td>
<td>Protocol Exception to Previously Approved Research</td>
<td>Lapse of Approval (circle: convened or expedited)</td>
<td>Prompt Reporting (circle: convened or expedited)</td>
<td></td>
</tr>
<tr>
<td>5 Approval Recommendation.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Approved</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Risk level: Greater than Minimal Risk</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Risk level: Minimal Risk, keep at convened review</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Risk level: Minimal Risk, eligible for expedited review under category(ies): _______________</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Modifications required (list in comments section below)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Refer to Convened Review - Further review required by full IRB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ With modifications noted below or on attached page</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Copies Only</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Deferred (only if being reviewed at convened meeting)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Disapproved (only if being reviewed at convened meeting)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Suspension</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments.** (Write comments in space provided; attach additional sheet of paper, if necessary.)

- Accept pre-review comments
- Accept pre-review comments with modifications
- Do not accept pre-review comments

---

**Signature**

---

**Date**

---

**Printed Name**
## JBVAMC ● Amendment
### Review Guide Checklist

<table>
<thead>
<tr>
<th>Research Protocol #:</th>
<th>Amendment#:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator Full Name:</td>
<td></td>
</tr>
<tr>
<td>Research Protocol Title:</td>
<td></td>
</tr>
</tbody>
</table>

### Instructions:
- Please check the applicable boxes. **Sections 1, 2, 3 and 12 are required for every protocol.**
- Provide an explanation in the text box if necessary.
  - For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

### 1 General Limitations.

#### 1a Does the amendment propose the addition of a fetus, in-utero or ex-utero (including human fetal tissue), or does the research involved in vitro fertilization?

- [ ] Yes
- [ ] No

  **If yes, please stop and speak with the IRB #4 Assistant Director**

#### 1b Does the amendment propose changes in the exposure to ionizing radiation or recombinant DNA, infectious agents and/or toxins?

- [ ] Yes
- [ ] No

**If YES, has documentation of review and approval by the Radiation Safety Officer/Radiation Safety Committee or Institutional Biosafety Committee been submitted?**

- [ ] Yes
- [ ] No (modifications may be required)

#### 1c Does the amendment make changes to or add to the banking of tissues?

- [ ] Yes
- [ ] No

  **If YES, answer 1d, 1e, 1f, and 1g**

#### 1d Are the tissues being banked at a VA-sponsored (i.e., typically a VA facility) or VA-approved (see approved list) banking facility?

- [ ] Yes
- [ ] No

  **Please note that IRB approval cannot be granted until documentation of the approved Off-Site Tissue Banking Waiver is submitted.**

#### 1e Has the informed consent document been revised to incorporate tissue banking language?

- [ ] Yes
- [ ] No

#### 1f Does the amendment make changes to or add genetic testing?

- [ ] Yes
- [ ] No

#### 1g If yes, to 1f, has the informed consent document been revised?

- [ ] Yes
- [ ] No
2 Appropriate Level of Review: Expedited Review
(Select either Box 1 or Box 2 and confirm whether criteria have been met / continue to be met)

<table>
<thead>
<tr>
<th>Box 1. If the research was previously determined to be greater than minimal risk, does this amendment meet the criteria for minor changes to previously approved research:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>Eligible for Expedited</td>
</tr>
<tr>
<td>Refer to Convened</td>
</tr>
</tbody>
</table>

a) Proposed changes do not alter the risk/benefit assessment
   Explain:

b) Proposed changes do not substantially alter the specific aims of the research
   Explain:

c) Proposed changes do not substantially alter the specific design of the research
   Explain:

d) Proposed changes are eligible for the expedited review process
   Explain:

2 Appropriate Level of Review: Expedited Review. (Continued)

<table>
<thead>
<tr>
<th>Box 2. If the research was previously determined to be minimal risk, does this amendment meet the criteria for minor changes to previously approved research:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Applicable</td>
</tr>
<tr>
<td>Eligible for Expedited</td>
</tr>
<tr>
<td>Refer to Convened</td>
</tr>
</tbody>
</table>

Significant new findings/notes:

a) Proposed changes do not alter the risk/benefit assessment
   Explain:

b) Proposed changes do not substantially alter the specific aims of the research OR, if specific aims are altered, there is no negative impact on the risk/benefit assessment
   Explain:
c) Proposed changes do not substantially alter the specific design of the research OR, if the specific design is altered, there is no negative impact on the risk/benefit assessment

Explain:

d) Proposed changes are eligible for the expedited review process

Explain:

### 3 Changes Proposed by Amendment

- Please consider whether the proposed amendment affects the approval criteria listed below.
- If the proposed amendment does not affect the criteria for approval below, please indicate below and skip to the end of the form to make your determination and sign the form.
  - For example, if a change in key research personnel does not affect any criteria for approval, then mark the box below and skip to the end of the form.
  - If, for example, there is a change to the performance site that does not affect the criteria for approval, then verify that the pre-review confirms that the appropriate documentation is in place and skip to the end of the form and sign the form.

- If the proposed amendment does not affect any of the criteria for approval, then verify that the pre-review confirms that the appropriate documentation is in place and skip to the end of the form and sign the form.
- The proposed Amendment does not affect any of the criteria for approval

- The proposed Amendment affects the criterion/criteria for approval:
  - If the proposed amendment affects the criteria of approval below, please mark each criterion affected. It is possible that the proposed amendment may affect more than one criterion.

- Check here if the amendment is the result of any reports of deviations, protocol events, non-compliance or subject complaints that represent unanticipated events or problems involving risks to subjects or others or serious or continuing non-compliance.

- Risks to subjects (complete section 4a)
- The risk/benefit ratio (complete section 4b)
- Equitable selection of subjects (complete section 4c)
- Recruitment materials/ Payment (complete section 4d - 5)
- Informed consent process (complete section 6a - 6d)
- Informed consent documentation (complete section 7)
- Data monitoring plan (complete section 8)
- Provisions to protect subject privacy or data confidentiality (complete section 9)
- Safeguards to protect vulnerable populations (complete section 10)
- HIPAA (complete section 11)
4  Approval criterion/criteria changed by proposed Amendment.

- Complete this section only if the proposed Amendment affects the criterion/criteria for approval.
- Select and complete only the sections for the Criteria for Approval that the amendment affects (should correspond to the criteria you selected in Section 3).
- If a criterion in this section is not checked, it is assumed that it is not applicable and no change has occurred.

### 4a  Risks to subjects.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

**Tip Sheet #1**
- The research uses procedures consistent with sound research design.
- The research design is sound enough to yield the expected knowledge.
- Avoids unnecessary exposure to risks.
- In making this determination, the IRB considers physical, psychological, social, economic, and legal risks.
- Risk to subjects are minimized, when appropriate, by using procedures already being performed for diagnostic or treatment purposes.
- Use of standard of care procedures when possible.

### 4b  The risk/anticipated benefit ratio.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Risks are reasonable compared to benefits and are justified by importance of information to be gained from the study.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- All known risks are identified.
- Tip Sheet #1

**Tip Sheet #1**
- Any direct benefits are identified.

### 4c  Equitable selection of subjects.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Inclusion of any vulnerable population is justified.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #1

**Tip Sheet #1**
- Appropriate additional protections are in place for any vulnerable populations.
- No group inappropriately targeted or excluded.
- Target numbers of subjects sufficient.
- Inclusion/exclusion criteria appropriate.
- Setting where study will be conducted is appropriate.
- Regulatory criteria have been met when vulnerable populations are involved.

### 4d  Does this amendment proposal add, remove, or change any recruitment materials?

- Yes - recruitment materials are included *(complete #4d - 4h)*
- No - no recruitment materials are being utilized or no materials are being revised *(skip to #5)*

### 4e  Recruitment.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Is the recruitment process and are recruitment materials fair and appropriate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

**Reference:**
- Tip Sheet #3

**Tip Sheet #3**
- Consider whether appropriate additional safeguards are in place to protect vulnerable populations from coercion.
4f Do the research procedures meet the following VA requirements for contacting Veterans?

<table>
<thead>
<tr>
<th>Yes</th>
<th>If NO, modifications must be requested</th>
</tr>
</thead>
</table>

- During the recruitment process, researchers must make initial contact with the patient in person and/or through a letter prior to any phone contact and provide a telephone number or other means that veterans can use to verify the validity of the study;
- Phone and other contacts with veterans are restricted to only those procedures and data elements outlined in the IRB approved protocol application, and, in these contacts, research staff must not request social security numbers; and
- The informed consent document includes information about where and how a veteran can verify the validity of a study and authorized contacts.

4g Do the investigators propose to use protected health information from data repositories or medical records to identify potential participants (including their own patients) to recruit for the research?

<table>
<thead>
<tr>
<th>Yes</th>
<th>Select YES or NO below</th>
</tr>
</thead>
</table>

If YES, has the investigator requested, or hold, a Waiver of Informed Consent for Recruitment and a Waiver of Authorization for Recruitment?

- Yes - Criteria met
- No - Modifications must be requested

4h Does the investigator propose enrolling non-veterans in the VA protocol or at the VA site?

<table>
<thead>
<tr>
<th>Yes</th>
<th>If yes, non-veterans may be enrolled only if</th>
</tr>
</thead>
</table>

1. Research is relevant to the care of veterans or active duty military personnel, and
2. Insufficient veterans are available to complete the study or researcher has made a compelling argument for the inclusion of non-veterans (e.g., survey of VA employees, study of active duty military, study involving veterans’ family members)

5 Incentives or reimbursements.

<table>
<thead>
<tr>
<th>Not appropriate</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

Are compensation amounts and disbursement methods coercive or might they present undue influence?

Reference:

- Amount is justified, fair, and appropriate
- Amount is reasonable, meaning not likely to be coercive

<table>
<thead>
<tr>
<th>Yes</th>
<th>Does the proposed payment or reimbursement scheme for research subjects meet the following criteria?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

- Payment is prohibited if the research is integrated with the patient's medical care and when it makes no special demands on the patient beyond those of usual medical care. Payment may be permitted, with IRB approval, if:
  - The study is not being performed to directly enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and the standard practice in affiliated non-VA institutions is to pay subjects in this situation;
  - The research is a multi-institutional study, and subjects at a collaborating non-VA institution are to be paid for the same participation in the same study at the same rate proposed;
  - In other comparable situations in which, in the opinion of the IRB, payment of subjects is appropriate; or
  - Transportation expenses are incurred by the subject that would not be incurred in the normal course of receiving treatment and are not reimbursed by any other mechanism.
Proposed Amendments to Informed Consent.

6a Informed Consent Process. (Check Either Box 1 or Box 2 and confirm whether criteria have been met/continue to be met)

<table>
<thead>
<tr>
<th>Box 1: Informed consent will be/ will continue to be obtained from the subject or the subject's legally authorized representative. (45 CFR 46.111(a)(4); 46.116(a), (b))</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Criterion Met</strong></td>
</tr>
<tr>
<td>Researcher or appropriately delegated and trained research personnel will obtain legally effective consent from subject or LAR</td>
</tr>
<tr>
<td><strong>Criterion Not Met</strong></td>
</tr>
<tr>
<td>The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence</td>
</tr>
<tr>
<td>No information will be provided to the subject or the representative that waives or appears to waive any of the subject's legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence</td>
</tr>
<tr>
<td>Individuals communicating information to the subject or LAR during the consent process will convey that information in language understandable to the subject or representative</td>
</tr>
<tr>
<td>All required and appropriate disclosures will be provided either to the subject or to the subject's representative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tip Sheets #5, 8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Box 2: The consent procedure will be waived or altered. (Two options acceptable; apply reasoning to regulatory requirements)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Not Applicable</strong></td>
</tr>
<tr>
<td>The research must not be FDA regulated (Check box to the left to confirm that the research is not FDA-regulated)</td>
</tr>
<tr>
<td><strong>Criterion Met</strong></td>
</tr>
<tr>
<td>Protocol specific findings justifying the determination that the research involves no more than minimal risk (articulate protocol specific findings in space below)</td>
</tr>
<tr>
<td>Protocol specific findings justifying the determination that the waiver will not adversely affect the rights and welfare of subjects (articulate protocol specific findings in space below)</td>
</tr>
<tr>
<td>Protocol specific findings justifying the determination that the research could not be practicably carried out without the waiver because (i.e., increased risk of a breach of confidentiality)</td>
</tr>
<tr>
<td>Protocol specific findings regarding whether it is appropriate to provide subjects with additional pertinent information after participation (articulate protocol specific findings in space below)</td>
</tr>
<tr>
<td><strong>Criterion Not Met</strong></td>
</tr>
<tr>
<td>The research is not FDA regulated. Check the box to indicate that the research is not FDA funded. For FDA research, alterations or waivers are NOT permitted unless the research falls within an exception OR the research qualifies for emergency use of a test article</td>
</tr>
<tr>
<td>Research is conducted under the direction of state or local government officials AND is designated to study public benefit/service programs, procedures for obtaining public benefits/services, changes or alternatives to public benefit/service programs, or levels of payment for public benefits/services</td>
</tr>
</tbody>
</table>

Explain:
6b Are the consent form(s) written on the appropriate forms (10-1086)?
- Yes
- No

6c Informed consent document contains required basic and additional elements.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>Eight basic elements of informed consent, as appropriate, prohibition against exculpatory language, and signature line; JBVAMC requirements; additional elements as appropriate; FDA requirements; UIC/NU requirements</td>
</tr>
<tr>
<td>Criterion Met</td>
<td></td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #5

6d If the research involves subjects with fluctuating decision making capacity or with decreasing capacity to give consent, a re-consenting process with surrogate consent is necessary?
- Yes
- No

Reference:
- Tip Sheet #8

7 Informed Consent Documentation. (Select Box 1, 2, or 3 below and confirm whether criteria have been met. If a long form consent will be used for English-speaking subjects and a short form will be used for non-English speaking subjects, select Boxes 1 and 2.)

Box 1: Informed consent will be documented using the long form consent document.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td>The consent form includes the required elements and appropriate disclosures (Refer to Informed Consent Tip Sheet)</td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td></td>
</tr>
</tbody>
</table>

Reference:
- Tip Sheet #22

Box 2: Informed consent will be documented using the short form consent document.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criterion Met</td>
<td>Consent document states that the elements of informed consent required by 46.116 and 50.25 have been presented orally to the subject or the subject's LAR</td>
</tr>
<tr>
<td>Criterion Not Met</td>
<td>a written summary of what is to be said to the subject or the representative and includes the basic and required additional elements of disclosure is provided</td>
</tr>
<tr>
<td></td>
<td>Witness will be present at the oral presentation</td>
</tr>
<tr>
<td></td>
<td>When the subject and/or subject's LAR do not speak English as their primary language, the witness must be conversant in both English and the language of the subject and/or subject's LAR</td>
</tr>
</tbody>
</table>

- Review documents and description of process to ensure 1. subject or LAR will sign short form consent, 2. witness will sign short form consent and written summary and 3. person obtaining consent will sign written summary
- Witness should not be the individual obtaining consent
- Subject or LAR should receive signed copies of short form consent and written summary
7 Informed Consent Documentation. (Continued)

Box 3: The requirement to obtain a signed consent form will be waived.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Check if applicable:
- An oral consent script was submitted
- The oral consent script includes the required and appropriate additional elements of

Check applicable category of waiver of documentation below:
- (i) The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context.
- Check if the above box is selected and the PI should be required to provide subjects with a written statement about the research.

OR
- (ii) The only record linking the subject and the research is the consent document and the principal risk is loss of confidentiality. The research is not FDA-regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.

Explain:

8 Data monitoring plan.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

Reference:
- Tip Sheet #2
- Plan provides adequate data monitoring
- Plan provides adequate monitoring to ensure safety of subjects

9 Provisions to protect subject privacy or data confidentiality.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- If appropriate, there are adequate provisions to protect the privacy of subjects
- If appropriate, there are adequate provisions to maintain the confidentiality of data

10 Safeguards to protect vulnerable populations.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Additional safeguards if subjects are likely to be vulnerable to coercion or undue influence
- In making this determination, the IRB has considered the research purpose, the research setting, whether subjects may be vulnerable to coercion or undue influence, the selection criteria, recruitment, and enrollment procedures and payment

10a If pregnant women are to be added to recruitment for the research, have all the VA requirements for approval and inclusion of this vulnerable population been met?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

- The proposed research meets all the requirements outlined in the VHA Handbook 1200.05, Paragraph 49;
- Adequate provision has been made to monitor risks; and
- Adequate consideration has been given to subject selection and monitoring of the informed consent process
10b If decisionally impaired or mentally incompetent persons are to be added to the recruitment for the research, have all the following VA requirements for approval been met?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Only incompetent persons or persons with impaired decision-making capacity are suitable as research subjects, and the investigator demonstrates to the IRB that there is a compelling reason to include them as participants;</td>
<td></td>
</tr>
<tr>
<td>● The research entails no significant risk, tangible or intangible, or if the research presents some probability of harm, there must be a greater possibility of direct benefit to the participant; and</td>
<td></td>
</tr>
<tr>
<td>● Procedures have been devised to ensure that participant's representative(s) are well informed regarding their roles and obligations to protect the subject. They must be given a description of proposed research studies, obligations of the person's representatives, and that their obligation is to try to determine what the prospective participant would do if competent, or if the prospective participant's wishes cannot be determined, what they think is in the incompetent person's best interest.</td>
<td></td>
</tr>
</tbody>
</table>

10c If decisionally impaired or mentally incompetent persons are to be added to the recruitment for the research, are the following procedures for recruitment and consent are clearly addressed in the protocol?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Surrogate consent will be obtained from: a health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC) or similar document; court-appointed guardians of the person, or from next-of-kin in the following order of priority: spouse, adult child (18 years or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older).</td>
<td></td>
</tr>
<tr>
<td>● The determination of incompetence will be made as established by a legal determination or in accordance with the following requirements:</td>
<td></td>
</tr>
<tr>
<td>● The practitioner in consultation with the chief of service has determined after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.</td>
<td></td>
</tr>
<tr>
<td>● Consultation with a psychiatrist or licensed psychologist will be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.</td>
<td></td>
</tr>
<tr>
<td>● The above determination will be documented in a signed and dated progress note.</td>
<td></td>
</tr>
<tr>
<td>● Disclosures required by VA requirements to be made to the subject by the investigator will be made to the subject's surrogate.</td>
<td></td>
</tr>
<tr>
<td>● If feasible, the practitioner will explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.</td>
<td></td>
</tr>
</tbody>
</table>
10d If children are to be added to the research, are the following requirements met?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● A waiver from the Chief Research and Development Officer (CRADO) been submitted and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>● The research poses no more than minimal risk</td>
<td></td>
</tr>
</tbody>
</table>

11 HIPAA.

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● New and/or revised HIPAA authorization materials and/or Appendix H documentation justifying the waiver resubmitted and consistent with federal and state laws</td>
</tr>
</tbody>
</table>

11a Is the authorization form written on the template form?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

11b Does the authorization form contain the required template language?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

11c Does the research involve, or make changes to, the use and disclosure of protected health information related to the treatment of alcoholism, drug abuse, sickle cell anemia, or infection with Human Immunodeficiency Virus (HIV)?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If YES, use and disclosure of this information requires EITHER:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>● A written authorization signed by the research subject that describes the information to be disclosed in a specific and meaningful fashion and specifically identifies that the information to be released concerns alcoholism, drug abuse, sickle cell anemia, or testing for or infection with Human Immunodeficiency Virus (HIV); OR</td>
</tr>
<tr>
<td></td>
<td>● If the investigator is requesting a waiver of authorization and informed consent, assurance in writing (i.e., within protocol) from the VA researcher that the purpose of the data is to conduct scientific research and that no personnel involved in the study may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner.</td>
</tr>
</tbody>
</table>

12 Y N Do any new significant findings that arise from the review process and that may relate to the subjects' willingness to continue participation need to be provided to subjects? Explain if YES.
13 Approval Recommendation.

☐ Approved

☐ Risk level: Greater than Minimal Risk
☐ Risk level: Minimal Risk, keep at convened review
☐ Risk level: Minimal Risk, eligible for expedited review (attach Expedited Addendum)

☐ Modifications required (list all, including informed consent document and HIPAA authorization matters, in comments section below)

☐ Refer to Convened Review - Further review required by full IRB

☐ With modifications noted below or on attached page
☐ Copies Only

☐ Deferred (only if being reviewed at convened meeting)
☐ Disapproved (only if being reviewed at convened meeting)
☐ Suspension

Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

☐ Accept pre-review comments
☐ Accept pre-review comments with modifications
☐ Do not accept pre-review comments

Signature ____________________________ Date ____________

Printed Name ____________________________
### Exemption Eligibility

**Review Guide Checklist**

University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 1.1, May 14, 2012

<table>
<thead>
<tr>
<th>Research Protocol #:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator Full Name:</td>
<td></td>
</tr>
<tr>
<td>Research Protocol Title:</td>
<td></td>
</tr>
</tbody>
</table>

**Instructions:**

- Please check the applicable boxes.
- Provide comments in the space provided or on an attached sheet, if necessary.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.
- Complete and attach electronic portion of Exemption Eligibility review
- Refer to Tip Sheet #15 for list of exempt categories

#### Conflict of Interest

- No conflict of interest declared
- Institutional conflict of interest
- Investigator conflict of interest
- New SEAM; updates
- Existing SEAM in place
- COI Office review - in process
  
  New conflict may exist based on other knowledge or preliminary investigation, more investigation and information needed

**Exemption Prohibited. (If you mark "yes" on any of the items in this section, an exemption is prohibited. Skip to Number 4)**

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The research involves prisoners as subjects</td>
<td></td>
</tr>
<tr>
<td>The research involves Human Embryonic Stem Cells</td>
<td></td>
</tr>
<tr>
<td>For Categories 1 through 5: The research is subject to FDA regulation</td>
<td></td>
</tr>
<tr>
<td>Children exclusion from Category 2b</td>
<td></td>
</tr>
</tbody>
</table>

#### Appropriate Level of Review.

<table>
<thead>
<tr>
<th>Not Eligible</th>
<th>Eligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research meets all of the criteria below. For studies previously determined to be eligible for exemption, assess the criteria to determine if the study remains exempt given the amendment:</td>
<td></td>
</tr>
<tr>
<td>Research is minimal risk</td>
<td></td>
</tr>
<tr>
<td>Research does not involve prisoners</td>
<td></td>
</tr>
<tr>
<td>Category 2 study does not involve children in surveys OR the researcher is not participating or manipulating the study</td>
<td></td>
</tr>
<tr>
<td>Study is eligible for exemption under category(s) 1-6</td>
<td></td>
</tr>
<tr>
<td>For FDA research: study is eligible under category 6</td>
<td></td>
</tr>
</tbody>
</table>
Exemption Permitted. (Complete only the category sections that apply).

Category 1 Educational Settings.

- Research conducted in established or commonly accepted educational settings
  AND
  - The research involves normal educational practices:
    - research on regular and special educational instructional strategies,
    OR
    - research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods

Category 2 Adult Population.

- The research involves the use of one or more of the following:
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
  - Survey procedures
  - Interview procedure
  - Observation of public behavior of adults
  AND
  - Information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects
  OR
  - Any disclosure of the subjects’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability or loss of insurability, or be damaging to their financial standing, employability, or reputation

Category 2 Children Population.

- The research involves the use of either or both of the following:
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
  - Observation of public behavior of children where the investigator(s) will NOT participate in the activities being observed
  - Information obtained is recorded in such a manner that subjects CANNOT be identified, directly or through identifiers linked to the subjects
  OR
  - Any disclosure of the subjects’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability or loss of insurability, or be damaging to their financial standing, employability, or reputation

Category 3

- The research is NOT exempt under Category 2 above
- The research involves the use of either or both of the following:
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
  - Survey Procedures
  - Interview Procedures
  - Observation of public behavior
- The subjects are elected or appointed public officials or candidates for public office
OR
- Federal statute(s) requires
Category 4  [For VA Research, if exemption category 4 is claimed, the investigator may not retain any of the 18 identifiers outlined in the HIPAA Privacy Rule, and the investigator may not have access to any code by which the information may be linked to individuals. When the investigator will review PHI for the research, a waiver of authorization is required.]

- The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (Material has been collected BEFORE the start of the project).
- These sources are publically available

OR

- Information is recorded by the investigator in such a manner that both statements apply:
  - Subjects cannot be directly identified AND
  - Subjects cannot be identified through identifiers linked to them

Category 5

- The project is a research or demonstration project
- The project is conducted by or subject to additional approval of Department or Agency heads
- The project is designed to study, evaluate, or otherwise examine one or more of the following:
  - Public benefit or service programs;
  - Procedures for obtaining benefits or services under those programs;
  - Possible changes in or alternatives to those programs or procedures; and/or
  - Possible changes in methods or levels of payment for benefits or services under those programs
- The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act)
- The project is conducted pursuant to specific federal statutory authority
- The project has authorization or concurrence by the funding agency
- The project does NOT involve significant physical invasions or intrusions upon the privacy or subjects

Category 6

- The research involves a taste and food quality evaluation and consumer acceptance studies
- The research involves one of the following:
  - Wholesome foods without additives will be consumed
  - A food will be consumed that contains a food ingredient when the food ingredient is at or below the level to be safe OR the food ingredient is for a use found to be safe
- A food will be consumed that contains an agricultural chemical or environmental contaminant and one of the following is true:
  - The agricultural chemical or environmental contaminant is at or below the level found to be safe by the Food and Drug Administration
  - The agricultural chemical or environmental contaminant is at or below the level approved by the Environmental Protection Agency
  - The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety or Inspection Service of the US Department of Agriculture
3. The process and documentation of informed consent is acceptable
   - Not Applicable: no interactions occurring with participants
   - Yes
   - No, explain:

4. HIPAA: HIPAA access to PHI and/or Waiver for research meeting the criteria for exemption category 4 and involving retrospective review of health care materials
   - Access to PHI APPROVED for review preparatory to research only
     - Fulfills ALL requirements for waiver for preparatory review under 45 CFR 164.512 listed below:
       - Use or disclosure is solely to review PHI as necessary to prepare a research protocol
       - No PHI will be removed from the covered entity
       - PHI sought is necessary for research purposes
   - Waiver of HIPAA APPROVED
     - Fulfills ALL requirements for waiver under 45 CFR 164.512 listed below:
       - Use or disclosure of PHI involves no more than minimal risk
       - Waiver will not adversely affect the privacy rights and welfare of subjects
       - Research would be so difficult as to be nearly impossible without access to and use of PHI
       - Risks are reasonable in relation to anticipated benefits to subjects and importance of knowledge gained
       - Adequate plans and procedures in place to protect against improper use and disclosure of PHI
       - Identifiers will be destroyed at the earliest opportunity (unless retention required by law)
       - Written assurances that PHI will not be reused or shared unless required by law or this regulation

4. Other Determinations. (Complete this section)
   - The project does NOT involve significant physical invasions or intrusions upon the privacy of the subjects
   - The protocol meets the organizations ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, maintenance of confidentiality, and protections for vulnerable populations).

   - This protocol DOES meet the criteria for exemption Category: 
   - This protocol DOES NOT meet the criteria for exemption
     - This protocol meets the criteria for:
       - Expedited Review
       - Convened Review
     - Not research
     - Not human subjects
Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

Signature  

Date  

Printed Name
JVBAMC Exemption Eligibility

University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 2.1, dated June 7, 2012

Instructions:
- Please check the applicable boxes.
- Provide comments in the space provided or on an attached sheet, if necessary.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.
- Complete and attach electronic portion of Exemption Eligibility review

Conflict of Interest
- No conflict of interest declared
- Institutional conflict of interest
- Investigator conflict of interest
- New SFI-DMP; updates
- Existing SFI-DMP in place
- COI Office review - in process
- New conflict may exist based on other knowledge or preliminary investigation, more investigation and information needed

Confirmation of Human Subjects Research
(if you mark "no" to either of the items in this section, then a Determination of Human Subjects review guide should be completed)

☐ Yes ☐ No Is the Project Research?
As defined by VHA Handbook 1200.05: "Research means a systematic investigation including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities (38 CFR 16.102(d))."

☐ Yes ☐ No Does the Research Involve Human Subjects?
As defined by VHA Handbook 1200.05: "Title 38 CFR Part 16 defines a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains either:
(a) Data through intervention or interaction with the individual; interaction includes communication or interpersonal contract between the researchers and the subject; or
(b) Identifiable private information (38 CFR 16.102 (f))."
For research covered by Food and Drug Administration (FDA) regulations, human subjects means an individual who is or becomes a participant in a clinical investigation, either as a recipient of the test article or as a control. (21 CFR 50.3(g), 21 CFR 66.102(c)).
For research covered by FDA device regulations, subject means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease (21 CFR 812.3(p))."

Exemption Prohibited (if you mark "yes" on any of the items in this section, an exemption is prohibited. Skip to Number 4)

☐ Yes ☐ No The research involves prisoners as subjects
☐ Yes ☐ No The research involves Human Embryonic Stem Cells
☐ Yes ☐ No For Categories 1 through 5: The research is subject to FDA regulation
☐ Yes ☐ No Children exclusion from Category 2b
1. **Appropriate Level of Review.**

<table>
<thead>
<tr>
<th>Not Eligible</th>
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<tbody>
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<td>For studies previously determined to be eligible for exemption, apply the following factors to determine if the study remains exempt given the amendment:</td>
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<tr>
<td>● For FDA research: study is eligible under category 6</td>
<td></td>
</tr>
</tbody>
</table>

2. **Exemption Permitted** *(complete only the category sections that apply).*

### Category 1: Educational Settings

- Research conducted in established or commonly accepted educational settings
- AND
- The research involves normal educational practices:
  - research on regular and special educational instructional strategies,
  - OR
  - research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods

### Category 2: Adult Population

- The research involves the use of one or more of the following:
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
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  - Interview procedure
  - Observation of public behavior of adults
- AND
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- Any disclosure of the subjects’ responses outside the research could NOT reasonably place them at risk of criminal or civil liability or loss of insurability, or be damaging to their financial standing, employability, or reputation
### Category 3
- The research is NOT exempt under Category 2 above
- The research involves the use of either or both of the following:
  - Educational tests (cognitive, diagnostic, aptitude, achievement)
  - Survey Procedures
  - Interview Procedures
  - Observation of public behavior
- The subjects are elected or appointed public officials or candidates for public office
  OR
  - Federal statute(s) requires

### Category 4
- [For VA Research, if exemption category 4 is claimed, the investigator may not retain any of the 18 identifiers outlined in the HIPAA Privacy Rule, and the investigator may not have access to any code by which the information may be linked to individuals. When the investigator will review PHI for the research, a waiver of authorization is required.]
- The research involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens (Material has been collected BEFORE the start of the project).
  OR
  - These sources are publically available
  OR
  - Information is recorded by the investigator in such a manner that both statements apply:
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### Category 5
- The project is a research or demonstration project
- The project is conducted by or subject to additional approval of Department or Agency heads
- The project is designed to study, evaluate, or otherwise examine one or more of the following:
  - Public benefit or service programs;
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  - The agricultural chemical or environmental contaminant is at or below the level approved by the Environmental Protection Agency
  - The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety or Inspection Service of the US Department of Agriculture

### 3 The process and documentation of informed consent is acceptable.

- Not Applicable: no interactions occurring with the participants
- Yes
- No, explain:

### HIPAA

- HIPAA access to PHI and/or Waiver for research meeting the criteria for exemption category 4 and involving retrospective review of health care materials

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- Waiver of HIPAA APPROVED
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    - Identifiers will be destroyed at the earliest opportunity (unless retention required by law)
    - Written assurances that PHI will not be reused or shared unless required by law or this regulation

The process and documentation of informed consent is acceptable.

Not Applicable: no interactions occurring with the participants

Yes

No, explain:
3. Other Determinations (Complete this section)

The project does NOT involve significant physical invasions or intrusions upon the privacy of the subjects

The protocol meets the organizations ethical standards governing the conduct of research (e.g., acceptable risk-benefit relationship, equitable selection, informed consent, protections of privacy, maintenance of confidentiality, and protections for vulnerable populations).

This protocol DOES meet the criteria for exemption

This protocol DOES NOT meet the criteria for exemption

This protocol meets the criteria for:

☐ Expedited Review
☐ Convened Review

☐ Not research
☐ Not human subjects

Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

Signature

Date

Printed Name
**Determination of Whether an Activity Represents Human Research at UIC**

**Review Guide Checklist**

- IRB Number: 1 2 3 4
- Research Protocol #: ____________________________
- Investigator Full Name: ____________________________
- Research Protocol Title: ____________________________

**Instructions:**
- Please check the applicable boxes.
- Provide comments in the space provided or on an attached sheet, if necessary.
- If you complete this form, you are confirming that you do not have a conflict of interest.
- Complete and attach electronic portion of review.
- Refer to UIC HSPP policy *Institutional Authorization for Determining Whether Research or Other Activities Represent Human Subjects Research at UIC*

**Does the proposed research activity meet any of the criteria of activities determined by OPRS not to represent Human Subjects Research?**

- [ ] Access to specified public use datasets;
- [ ] Research is limited to commercially available, de-identified non-human embryonic cell lines.
- [ ] Case reports involving the observation of a single patient whose novel condition or response to treatment was guided by the care provider’s judgment regarding the best interest of the individual;
- [ ] Research which is limited to death records, autopsy records, or cadaver specimens provided that the cadaveric tissues/cells are not used for clinical investigations.

**Does the research involve the Federal Bureau of Prisons?**

- [ ] Yes  [ ] No
- If Yes, does the research involve the implementation of Bureau programmatic or operational initiatives made through pilot projects?
  - [ ] Yes - This is not considered to be research.
  - [ ] No

**Activity is Human Research According to DHHS regulations (All of the following below are true)**

- [ ] (1) The activity involves research because **ALL** of the following are true:
  - The activity is a systematic investigation, including research development, testing and evaluation
- [ ] (2) EITHER of the following is true:
  - The activity is designed to develop generalizable knowledge **OR**
  - The activity is designed to contribute to generalizable knowledge.

CONTINUED
The activity involves human participants because BOTH of the following are true:

- The data the investigator is planning to obtain are about living individuals
- EITHER of the following is true:
  - The investigator plans to obtain the data through ONE OR MORE of the following:
    - Physical procedures performed on those individuals
    - Manipulation of those individual
    - Manipulation of those individuals’ environments
    - Communication with those individuals
    - Interpersonal contact with those individuals OR
  - The information to be obtained is BOTH:
    - Private, because EITHER of the following is true:
      - The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
      - The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record)
    - Individually identifiable, because EITHER of the following is true:
      - The identity of the participant is or may readily be ascertained by the investigator
      - The identity of the participant is or may readily be associated with the information

The activity involves an FDA regulated test article because ONE OR MORE of the following is true:

1. The activity involves the use of a drug, other than the use of an marketed drug in the course of medical practice:
   - The activity will involve the use of a drug, meaning one of the following:
     - An article recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them
     - An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals
     - An article (other than food) intended to affect the structure or any function of the body of humans or other animals
     - An article intended for use as a component of any article specified in the above items

2. EITHER of the following is true:
   - The drug is NOT approved by the FDA for marketing
   - The drug is NOT being used in the course of medical practice

3. The activity involves the use of a medical device, other than the use of an marketed medical device in the course of medical practice:
   - The activity will involve the use of a medical device, meaning one of the following:
     - Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them
     - Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals
     - Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes

CONTINUED
[4] EITHER of the following is true:
- The medical device is **NOT** approved by the FDA for marketing
- The medical device is **NOT** being used in the course of medical practice

[5] The activity is otherwise subject to FDA regulation:
- Data from the activity will be submitted to, or held for inspection by, the FDA.
- The activity involves an FDA-regulated article **ONE OR MORE** of the following:
  - Food or dietary supplement that bears a nutrient content or a health claim
  - Food or color additive for human consumption
  - Infant formula
  - Biological product for human use
  - Electronic product for human use
  - Other article subject to the FD&C Act

[6] The activity involves human participants (healthy individuals or patients) because one or more of the following is true:
- The test article will be used on one or more humans either as a recipient of the test article or as a control
- **ALL** of the following are true:
  - The test article is a medical device
  - The medical device will be used on human specimens
  - The activity is being done to determine the safety or effectiveness of the device
  - Data from the activity will be submitted to, or held for inspection by, the FDA.

<table>
<thead>
<tr>
<th>The Activity is Human Research according to VA Regulations <em>(Any of the following are true):</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>[1]</strong> The study involves research because <strong>ALL</strong> of the following are true:</td>
</tr>
<tr>
<td>- The testing of concepts by the scientific method of formulating a hypothesis or research question</td>
</tr>
<tr>
<td>- Systematically collecting and recording relevant data</td>
</tr>
<tr>
<td>- Interpreting the results in terms of the hypothesis or question</td>
</tr>
<tr>
<td><strong>[2]</strong> The activity involves human participants because <strong>BOTH</strong> of the following are true:</td>
</tr>
<tr>
<td>- The data the investigator is planning to obtain are about living individuals (this includes investigators, technicians, and others assisting investigators when they serve in a “subject” role by being observed, manipulated, or sampled).</td>
</tr>
<tr>
<td><strong>[3]</strong> <strong>EITHER</strong> of the following is true</td>
</tr>
<tr>
<td>- The investigator plans to obtain the data through one or more of the following:</td>
</tr>
<tr>
<td>- Physical procedures performed on those individuals</td>
</tr>
<tr>
<td>- Manipulation of those individuals</td>
</tr>
<tr>
<td>- Manipulation of those individuals’ environments</td>
</tr>
<tr>
<td>- Communication with those individuals</td>
</tr>
<tr>
<td>- Interpersonal contact with those individuals</td>
</tr>
</tbody>
</table>

*As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.*

CONTINUED
The information to be obtained is both:

- Private, because **EITHER** of the following is true
  - The information is about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
  - The individual has provided the information for specific purposes and can reasonably expect that the information will not be made public (for example, a medical record)

- Individually identifiable, because **EITHER** of the following is true:
  - The identity of the subject is or may readily be ascertained by the investigator
  - The identity of the subject is or may readily be associated with the information

**Determination.**

- Determined to be human research (Meets either definition)
  - If determined to be human research,
    - Exempt
    - Expedited
    - Convened

- Determined to **NOT** be human research (Meets neither definition)
  - Not human subjects
    - Explain:

- Not research
  - Explain:

- Determined to **NOT** engage UIC (Does not meet definition)
  - Explain:

**Comments.** *(Write comments in space provided; attach additional sheet of paper, if necessary.)*

________________________  ______________________
Signature                           Date

________________________
Printed Name
### Review Guide Checklist ● Review of Modifications Required by the IRB

**University of Illinois at Chicago ▪ Office for the Protection of Research Subjects ▪ Version 1.2, dated June 7, 2012**

<table>
<thead>
<tr>
<th>Research Protocol #:</th>
<th>Investigator Full Name:</th>
<th>Research Protocol Title:</th>
<th>Date Submitted to OPRS:</th>
</tr>
</thead>
</table>

**Instructions:**
- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

#### Type of Response

<table>
<thead>
<tr>
<th>Initial Review</th>
<th>Continuing Review</th>
<th>Amendment #</th>
<th>Final Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemption</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Final Approval of Amendments - Reviewer Determination

**Approved.** The modifications have been approved under expedited procedures for the review of minor changes to previously approved research [45 CFR 46.110(b)(2) and if applicable 21 CFR 56.110(b)(2)].

- If a waiver/alteration is granted as part of the amendment, document the protocol specific justification for each waiver criterion below in the Waivers/Alterations section.

#### Final Approval of Initial Review Application - Reviewer Determination

**Approved:** Research was reviewed and modifications were requested to secure approval by convened IRB.

**Approved:** Research involves minimal risk and was reviewed through expedited review procedures and requires the following additional determinations:

- Review Frequency:  
  - 12 months
  - 6 months
  - Other

- Expedited Category (1-7):

The research involves **vulnerable populations** (i.e., Children, Prisoners, Pregnant Women or fetuses, and requires additional determinations as noted in the comments section below or attached).
### Waivers/Alterations

<table>
<thead>
<tr>
<th>Waiver of Informed Consent Approved. [45 CFR 46.116(d)] OR Alteration of Informed Consent Approved. [45 CFR 46.116(d)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>- If a waiver/alteration is granted, document the protocol specific justification for each waiver criterion.</td>
</tr>
<tr>
<td>□ No more than minimal risk to the subjects</td>
</tr>
<tr>
<td>Justification:</td>
</tr>
<tr>
<td>□ Waiver does not adversely affect the rights and welfare of the subjects</td>
</tr>
<tr>
<td>Justification:</td>
</tr>
<tr>
<td>□ Impracticable to carry out research without the waiver</td>
</tr>
<tr>
<td>Justification:</td>
</tr>
<tr>
<td>□ When appropriate, subjects will be provided with additional information after participation</td>
</tr>
<tr>
<td>Justification:</td>
</tr>
</tbody>
</table>

### Waiver of Documentation of Signed Informed Consent Approved. [45 CFR 46.117(c)]

- Check the box next to the statement that applies and explain in space provided.

□ The only record linking the subject and the research is the consent document and potential harm is breach of confidentiality. Each subject will be asked whether they want documentation. OR

□ No more than minimal risk of harm to subject and involves no procedures for which written consent is normally required outside of the research context.

Explain:

- Check the box next to the statement(s) that apply and explain in space provided.
- No more than minimal risk to privacy
  Explain:

- Protections in place
  Justification:

- ID removed OR
  Justification:

- ID needed
  Justification:

- Impracticable to conduct without the waiver
  Explain:

- Impracticable to conduct without access to/use of PHI
  Explain:
Approved: Research was reviewed by the convened IRB and does not require further determinations at this time.

Approved: Research involves minimal risk and was reviewed through expedited review procedures originally or now qualifies for expedited continuing review and requires the following additional determinations:

<table>
<thead>
<tr>
<th>Review Frequency:</th>
<th>12 months</th>
<th>6 months</th>
<th>Other</th>
</tr>
</thead>
</table>

- Expedited Category (1-9): 

The research involves **vulnerable populations** (i.e., Children, Prisoners, Pregnant Women or fetuses, and requires additional determinations as noted in comments section below or attached).

**Exempt Research**

- Modifications to the exemption request are appropriate and the exemption request is approved.
  - OPRS staff member may make this determination on pre-review. If a VA protocol, the reviewer must be an IRB member.
  - Exemption Category (1-6): 

- Refer for Expedited IRB Review with Modifications

- Not Human Subjects

- Not Research
  
  Explain:

**Final Report**

- Approved

- Modifications needed
  
  Explain:
Modification(s) or additional information is required.

- List any further modifications or information required for the research protocol, application form, Appendix H, the authorization form, recruitment materials, and/or consent form in the comments section below. Write any comments as you would like it to appear in the letter to the investigator.

- Include modification noted in pre-review.
- Include modification noted below.

Refer for convened IRB review with modifications:

- Copies only.
- With modifications listed in comments section below.

**Comments.** (Write comments in space provided; attach additional sheet of paper, if necessary.)

- Accept pre-review comments
- Accept pre-review comments with modifications
- Do not accept pre-review comments

______________________________  ________________________
Signature                                                                 Date

______________________________
Printed Name
### Protocol Exception to Previously Approved Research

**Review Guide for IRB Members and OPRS Staff** (version #3.2, 5-25-12)

<table>
<thead>
<tr>
<th>Research Protocol No:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator Full Name:</td>
<td></td>
</tr>
<tr>
<td>Research Protocol Title:</td>
<td></td>
</tr>
<tr>
<td>Performance Sites:</td>
<td>UIC</td>
</tr>
</tbody>
</table>

**OPRS STAFF PRE-REVIEW:**

The protocol exception request represents:

- An exception to the protocol to allow the enrollment of or modification of procedures for a single subject. Complete questions 1-3.
- An exception to the protocol to allow the enrollment of or modification of procedures for a small number of subjects (justification for why an amendment is not warranted is required.) Complete questions 1-3.
- An exception to allow currently enrolled subjects to continue some or all research activities during a lapse in IRB approval or suspension. Enrollment of new subjects is not allowed, except in extraordinary circumstances. Refer to Chair or designee.

1. Does this change in the protocol meet the criteria for a protocol exception?
   - No If no, return to PI with instructions regarding the correct submission process.
   - Yes If yes, verify the submission is complete and schedule for review through the appropriate process (expedited or convened).

2. If applicable, are copies of the sponsor/funding agency and FDA (if applicable) approval for the exception attached?
   - N/A Not industry sponsored/funded, sponsor pre-approval not required
   - N/A Not an IDE device study that requires FDA pre-approval
   - Yes If yes, schedule for review via the appropriate review process.
   - No If no and industry sponsored, contact the PI for the missing documentation.

3. The protocol exception represents:
   - More than minor change or risk level of greater than minimal; referred to convened.
   - Minor change or risk level of no greater than minimal; review by chair or designee.
IRB MEMBER REVIEW

Determination

☐ IRB Chair or designee

☐ IRB member at convened meeting

Complete for Exceptions to the Protocol for Single Patient (or less commonly, multiple)

1. Based upon the information provided, is the exception to the research protocol and the alteration in risk to the subject(s) justified (i.e. will not adversely affect the subject or the integrity of the study data)?
   ☐ Yes ☐ No ☐ Further Information Required

2. If request for more than one subject, why is a protocol amendment not indicated?

3. Determination:
   ☐ Exception approved

   ☐ Exception approved with acceptance by investigator of modifications listed below.

   ☐ Request for further information (below)

   ☐ Referral to convened IRB (review by Chair or designee only)

   ☐ Deferral-Further justification or information required (convened review only)

   ☐ Disapproved (convened review only)

Complete for exception requests to allow some or all currently enrolled subjects to continue some or all research activities during a lapse or suspension in IRB approval

1. Based on the information provided, do over-riding safety concerns or ethical issues indicate that it is in the best interest for at least some of the subjects identified by the investigator to continue participation in the requested research activities?
   ☐ Yes ☐ No ☐ Further Information Required

2. Determination:
   ☐ Exception approved
Approval is for:
☐ all currently enrolled subject
☐ only the following subjects, identify:

Approval is for:
☐ all research activities
☐ only the following activities, identify:

☐ Exception approved with acceptance by investigator of modifications listed below.

Approval is for:
☐ all currently enrolled subject
☐ only the following subjects, identify:

Approval is for:
☐ all research activities
☐ only the following activities, identify:

☐ Request for further information (below)

☐ Referral to convened IRB (review by Chair or designee only)

☐ Deferral-Further justification or information required (convened review only)

☐ Disapproved (convened review only)

Comments
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

REVIEWER SIGNATURE:

<table>
<thead>
<tr>
<th>Reviewer Signature:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Printed Name:

Protocol Exception
### 1. When research is reviewed at a convened meeting, a member (or ad hoc consultant) knowledgeable about and experienced with the mentally disabled or cognitively or decisionally impaired is present.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not applicable, research is being reviewed by expedited procedures and the reviewer is qualified</td>
</tr>
</tbody>
</table>

### 2. EITHER of the following statements are true:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only decisionally or cognitively impaired individuals are suitable as research subjects and competent individuals are not suitable for the proposed research.</td>
<td></td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The use of decisionally or cognitively impaired individuals can be justified even if competent people may also be enrolled (decisionally or cognitively impaired individuals must not be subjects in research simply because they are readily available).</td>
<td></td>
</tr>
</tbody>
</table>

**Explain:**

### 3. UIC Research: ONE of the following statements are true:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The proposed research entails no greater than minimal risks.</td>
<td></td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The risks of the research are greater than minimal and the research offers the probability of direct benefit to the subject</td>
<td></td>
</tr>
</tbody>
</table>

OR

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The risks of the research are greater than minimal and the research offers only indirect benefit to the subject; however, the outcome of the study will be highly valuable to the general field of study</td>
<td></td>
</tr>
</tbody>
</table>

**Explain:**
3. **JBVAMC Research: ONE of the following statements are true (VHA Handbook 1200.05, paragraph 49.d):**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>Yes</td>
<td>The proposed research entails no greater than minimal risks.</td>
</tr>
<tr>
<td>OR</td>
<td>Yes</td>
<td>If the research presents some probability of harm, there must be at least a greater probability of direct benefit to the subject.</td>
</tr>
<tr>
<td>OR</td>
<td>Yes</td>
<td>Greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.</td>
</tr>
<tr>
<td>OR</td>
<td>Yes</td>
<td>The disorder (e.g., Alzheimer's) leading to the individual's lack of decision-making capacity is being studied, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke), but only if the study cannot be performed with only persons who have decision-making capability.</td>
</tr>
<tr>
<td>OR</td>
<td>Yes</td>
<td>The subject of the study is not directly related to the individual's lack of decision-making capacity, but the investigator can make a compelling argument for including individuals who lack decision-making capacity in the study (e.g., transmission of methicillin-resistant Staphylococcus aureus (MRSA) infections in a nursing home where both individuals with, and those without, decision-making capacity are affected).</td>
</tr>
</tbody>
</table>

4. **The following statement is true:**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>Are the procedures for identifying and selecting the legally authorized representative adequate?</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>Procedures have been devised to ensure that subjects' representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity.</td>
</tr>
</tbody>
</table>

Describe:

5. **Is the proposed plan for the assessment of the capacity to consent adequate?**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

Explain:
6  Is the assent of the subjects a requirement?
   Yes
   No
   If no, justify:

   If yes, is the plan for assent and respecting dissent adequate?
   Yes
   No

   Explain:
   VA RESEARCH: Does the study include appropriate procedures for respecting dissent.
   Yes
   No

7  If the subject's decision-making capacity likely to fluctuate or change (increase or decrease) during the study?
   Yes
   No

   If yes, is the plan for periodic re-assessment of decision-making capacity and re-consenting (subject or LAR) adequate?
   Yes
   No

   Explain:

**Determination.**

The proposed involvement of subjects with the research is:
   ☐ Approvable *(At least ONE of the statements in EACH of the boxes above, except 6, is marked "YES.")*
   ☐ NOT approvable *(list any modification required in the comments section below)*
### Instructions:
- Add this review guide to the core IR/CR/AM review guides only when applicable.
- Please indicate whether each statement below is “true” or “false.”
- If the response to any question is “False,” the research is not approvable by the IRB at this time.
- Please indicate any clarifications or further information required to address the statements below.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.
- Refer to Tip Sheet #12.

#### Department of Defense Research:
In applying Subpart B, the Department of Defense substitutes the phrase, “biomedical knowledge” with “generalizable knowledge.” If this study represents Department of Defense supported research, the reviewer should follow this practice in addressing the questions. While DoD applies Subpart B only to greater than minimal risk research, UIC applies it to both minimal and greater than minimal risk research.

<table>
<thead>
<tr>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>UIC</td>
</tr>
<tr>
<td>JBVAMC</td>
</tr>
</tbody>
</table>

- Fetuses, in vitro fertilization, or embryonic stem cells must NOT be involved in research (including use of laboratories, x-rays, or facility space) conducted by VA investigators while on official duty, or at VA facilities, or at approved off-site facilities.

2. **45 CFR 46.203 Inclusion of pregnant women, fetuses or neonates in this research is justified.**
   - Yes
   - No

3. **45 CFR 46.204 Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women, fetuses or neonates.**
   - Yes
   - No

If research involves pregnant women or fetuses, answer statements 4 through 11. If not, skip to 12.

4. **45 CFR 46.204 One of the following statements, 4a or 4b, is true. (Check box next to the true statement)**

   - 4a The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit to the woman or the fetus.
   - 4b There is no prospect of direct benefit for the woman or the fetus; and the risk to the fetus is not greater than minimal; and the purpose of the research is the development of important biomedical knowledge; and the biomedical knowledge cannot be obtained by other means.

Explain your response to either 4a or 4b above using protocol specific information:
5 45 CFR 46.204 Any risk is the least possible for achieving the objectives of the research.

| Yes | No |

6 45 CFR 46.204 One of the following statements, 6a, 6b, 6c or 6d, is true (check box next to the true statement).

- [ ] 6a  The research holds out the prospect of direct benefit to the pregnant woman and the woman's consent (or, if meeting the criteria, a waiver of consent) will be obtained.
- [ ] 6b  The research holds out the prospect of direct benefit both to the pregnant woman and the fetus and the woman's consent (or, if meeting the criteria, a waiver of consent) will be obtained.
- [ ] 6c  The research holds out no prospect of direct benefit to the pregnant woman or the fetus, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means; and the woman's consent (or, if meeting the criteria, a waiver of consent) will be obtained.
- [ ] 6d  The research holds out the prospect of direct benefit only to the fetus and the consent of the pregnant woman and father (or, if meeting the criteria, a waiver of consent) will be obtained, unless the father is unavailable, incompetent, temporarily incapacitated, or the pregnancy resulted from rape or incest.

Explain your response to 6a-6d above using factual information in the protocol:

7 45 CFR 46.204 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

| Yes | No |

8 One of the following statements, 8a, 8b, or 8c, is true. (Check box next to the true statement)

- [ ] 8a  The research does not involve pregnant women under 18 years of age.
- [ ] 8b  The research involves pregnant women under 18 years of age, the proposed research involves medical or surgical procedures expected to be performed in pregnant women by the individuals listed in the Illinois Consent by Minors to Medical Procedures Act and consent will be obtained from the pregnant minor.
- [ ] 8c  The research involves pregnant women under 18 years of age, the proposed research activities or personnel performing the procedures are not consistent with those described in the Illinois Consent by Minors to Medical Procedures Act for which pregnant minors may consent, and process for assent of the minor subject and permission of their parents or guardian as described in the UIC policy and procedure, Research Involving Children, will be followed.
9  No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

   True
   False

10 Researchers will not have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

   True
   False

11 Researchers will not have any part in determining the viability of a fetus.

   True
   False

If research involves neonates of uncertain viability, answer statements 12 through 15. If not, skip to 16.

12 45 CFR 46.205 Researchers will not have any part in determining the viability of a neonate.

   True
   False

13 45 CFR 46.205 One of the following statements, 13a or 13b, is true. (Check box next to the true statement)

   ☐ 13a The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability and any risk is the least possible for achieving that objective.

   ☐ 13b The main purpose of the research is the development of important medical knowledge, which cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research

Explain your response to 13a-13b above using factual information in the protocol:
14 45 CFR 46.205 One of the following statements, 14a or 14b, is true. (Check box next to the true statement)

- 14a  The legally effective informed consent of either parent of the neonate will be obtained; except, the consent of the father need not be obtained if the pregnancy resulted from rape or incest.
- 14b  If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent’s legally authorized representative will be obtained; except, the consent of the father’s legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

Explain your response to 14a-14b above using factual information in the protocol:

<table>
<thead>
<tr>
<th>15 45 CFR 46.205 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>

If research involves nonviable neonates, answer statements 16 through 21. If not, skip to 22.

<table>
<thead>
<tr>
<th>16 The vital functions of the neonate will not be artificially maintained.</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>17 The research will not terminate the heartbeat or respiration of the neonate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>18 There will be no added risk to the neonate resulting from the research.</th>
</tr>
</thead>
<tbody>
<tr>
<td>True</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>19 The purpose of the research is the development of important medical knowledge, which cannot be obtained by other means.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
</tr>
</tbody>
</table>
20 The legally effective informed consent of both parents will be obtained. Waiver or alteration of consent or obtaining consent of a legally authorized representative of either or both of the parents will not be allowed. The informed consent of one parent will suffice if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity. The consent of the father need not be obtained if the pregnancy resulted from rape or incest.

Yes

No

21 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

Yes

No

If research involves viable neonates, answer statement 22. If not, skip to 23.

22 Appendix B—Children as Subjects in Research is completed and attached to the application.

Yes

No

If research involves, after delivery, the placenta, dead fetus, or fetal material, answer statement 23. If not, skip to 24.

23 One of the following statements, 24a or 24b, is true. (Check box next to the true statement)

- 23a No information associated with the material will be recorded for research purposes in any way that living individuals (i.e., parents) will be identifiable (including the 18 HIPAA elements), either directly or indirectly and Determination of Whether an Activity Represents Human Subject Research at UIC form is completed and attached.

- 23b Information associated with the material described is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, and those individuals are treated as research participants and all pertinent human research subject regulations are followed.

Explain your response to 23a-23b above using protocol specific information:
### 24 Determination.

- [ ] The proposed involvement of pregnant women or fetuses is approvable (applicable sections are marked YES).
- [ ] The proposed involvement of neonates is approvable (applicable sections are marked YES).
- [ ] Further information or clarification is needed before a determination on the proposed involvement of pregnant women, fetuses or neonates can be made (explain in comments section below).
- [ ] The proposed involvement of pregnant women or fetuses is not approvable (list modification in comments section below).
- [ ] The proposed involvement of neonates is not approvable (list modifications in comments section below).

### Comments. *(Write comments in space provided; attach additional sheet of paper, if necessary.)*

---

Signature  

Date

Printed Name
Prisoners

Initial, Continuing, and Amendments • Review Guide Checklist

University of Illinois at Chicago • Office for the Protection of Research Subjects • Version 1.2, dated May 7, 2012

Instructions:

● Add this review guide to the core IR/CR/AM review guides only when applicable.
● Please check the applicable boxes.
● Provide an explanation in the space provided or on an attached sheet, if necessary.
   For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.
● If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

1. Conditions for Conducting Prisoner Research

1.a. When research is reviewed at a convened meeting or by expedited procedures, is at least one IRB member reviewing the research a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity?
   - Yes
   - No
   - N/A

1.b. If research is being reviewed by expedited procedures, the research meets the Subpart C definition of minimal risk AND research does not involve interactions with prisoners.
   - Yes
   - No
   - N/A
   MINIMAL RISK: the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

1.c. The research does not involve medical, cosmetic, or pharmaceutical experiments involving prisoners.
   - True
   - False
   These experiments are prohibited. If you checked "False", see OPRS Director.

1.d. The research does not involve the VA.
   - True
   - False
   This research is prohibited by the VA unless: Research involving prisoners must not be conducted by VA investigators while on official duty or at VA or approved off-site facilities unless a waiver has been granted by the Chief Research and Development Officer (CRADO). (VHA Handbook 1200.05) Notify the OPRS Director or Associate Director.

2. The research under review represents ONE of the following categories of permissible research:
   - Yes
   - No
   Check the category that applies and state your reasons in the space provided.
45 CFR 46.306(a)(2)(i)
- The research involves the study of the possible causes, effects, and processes of incarceration, and of criminal behavior.
- The research presents no more than minimal risk and no more than inconvenience to the participants.
- If the research is funded by DHHS, a concurrence will be obtained by UIC OPRS/IRB
- OR
- If the research is NOT funded by DHHS, a concurrence may be obtained but will not be required

Explain:

45 CFR 46.306(a)(2)(ii)
- The research involves the study of prisons as institutional structures or of prisoners as incarcerated persons.
- The research presents no more than minimal risk and no more than inconvenience to the subjects.
- If the research is funded by DHHS, a concurrence will be obtained by UIC OPRS/IRB
- OR
- If the research is NOT funded by DHHS, a concurrence may be obtained but will not be required

Explain:

45 CFR 46.306(a)(2)(iii)
- The research is on conditions particularly affecting prisoners as a class (for example, research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).
- If the research is funded by DHHS:
  - The Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics.
  - The Secretary has published notice, in the Federal Register, of his intent to approve such research.
- OR
- If the research is NOT funded by DHHS, the UIC IRB will provide copies of the protocol and minutes to the UIC HPA for a determination as to whether an ad hoc panel of experts should be convened to review the research in a process parallel to that of DHHS expert panel review.

Explain:
45 CFR 46.306(a)(2)(iv)

- The research is on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
- If the research does NOT require the assignment of prisoners to control groups that may not benefit from the research
  - If the research is funded by DHHS, a concurrence will be obtained by UIC OPRS/IRB
    OR
    If the research is NOT funded by DHHS, a concurrence may be obtained but will not be required

OR

If the research does require the assignment of prisoners to control groups that may not benefit from the research
- If the research is funded by DHHS:
  - The Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics.
  - The Secretary has published notice, in the Federal Register, of his intent to approve such research.
    OR
  - If the research is NOT funded by DHHS, the UIC IRB will provide copies of the protocol and minutes to the UIC HPA for a determination as to whether an ad hoc panel of experts should be convened to review the research in a process parallel to that of DHHS expert panel review.

68 FR 36929 (Federal Register on June 20, 2003)

- The sole purposes of the research are ONE or more of the following:
  - To describe the prevalence or incidence of a disease by identifying all cases
  - To study potential risk factor associations for a disease.
- Both of the following are true:
  - The research presents no more than minimal risk and no more than inconvenience to the prisoner-participants.
  - Prisoners are not a particular focus of the research.
- If the research is funded by DHHS, a concurrence will be obtained by UIC OPRS/IRB
  OR
  If the research is NOT funded by DHHS, a concurrence may be obtained but will not be required

Explain:
3. SPECIAL PROTECTIONS FOR RESEARCH INVOLVING PRISONERS

3.a. All of the following is TRUE:

- [ ] Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
- [ ] The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- [ ] Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.
- [ ] The information is presented in language that is understandable to the participant population.
- [ ] Adequate assurance exists that parole boards will not take into account a prisoner’s participation in the research in making decisions regarding parole.
- [ ] Each prisoner will be clearly informed in advance that participation in the research will have no effect on his or her parole.

Explain:

3.b. If the research requires the assignment of prisoners to control groups that may not benefit from the research, ONE of the following is TRUE:

- [ ] Control participants will be selected randomly from the group of available prisoners who meet the characteristics needed for the research project.
- [ ] The principal investigator has provided justification to the IRB in writing for following other procedures.

Explain:
3.c. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners’ sentences, and for informing participants of this fact.

<table>
<thead>
<tr>
<th>Yes</th>
<th>State your reasons in the space provided.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

Explain:

4. BUREAU OF PRISONS RESEARCH (complete only when research involves the Bureau of Prisons)

4.a. Is a letter of cooperation from the Bureau of Prisons been provided?

<table>
<thead>
<tr>
<th>Yes</th>
<th>If no, request before approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

4.b. Does the project have an adequate research design and contribute to the advancement of knowledge about corrections?

<table>
<thead>
<tr>
<th>Yes</th>
<th>If no, research is not approvable</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

4.c. Is the selection of participants within any one Bureau of Prisons organization equitable?

<table>
<thead>
<tr>
<th>Yes</th>
<th>If no, research is not approvable</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

4.d. All of the following are true:

- does not involve medical experimentation, cosmetic research, or pharmaceutical testing
- research design is compatible with operation of prison facilities and protection of human participants
- Incentives are not offered to help persuade inmate participants to participate, except soft drinks and snacks to be consumed at the test setting or reasonable accommodations such as nominal monetary recompense for time and effort to non-confined research participants who are no longer in Bureau of Prisons custody and participating in authorized research being conducted by Bureau employees or contractors
- The researcher has academic preparation or experience in the area of study of the proposed research

If no, research is not approvable

List the areas of deficiency:
4.e. The protocol has the following measures, if relevant, in place to protect confidentiality:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

If no, research is not approvable

- Any records being requested from the Bureau are not individually identifiable and are to be used solely as a statistical research or reporting record
- Unless noted on Appendix C and included in the consent form, the researcher will not provide research information that identifies a participant to any person
- No records that contain non-disclosable information directly traceable to a specific person will be stored in, or introduced into, an electronic retrieval system at other than an official Department of Justice site

4.f. The consent contains the following elements:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

If no, research is not approvable

- Identification of the researchers
- Anticipated uses of the results of the research
- Statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable)
- Statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law.
- Statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility

5 Approval Determination.

The proposed involvement of prisoners is:

- Approvable (there are no applicable restrictions on the research noted in #1, an applicable review category has been indicated in #2 above and protections in #3 are included)
- NOT approvable (list any modification required in the comments section below)

Comments. *(Write comments in space provided; attach additional sheet of paper, if necessary.)*

__Signature__

__Date__

__Printed Name__
Children

Research Protocol #: __________________________
Investigator Full Name: __________________________
Research Protocol Title: __________________________

Instructions:
● Add this review guide to the core IR/CR/AM review guides only when applicable.
● Please check the applicable boxes.
● Provide an explanation in the space provided or on an attached sheet, if necessary.
  For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.
● If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

1 Performance Site.

☐ UIC
☐ JBVAMC

If JBVAMC, is the research minimal risk?
☐ Yes (VA Research involving children requires CRADO (Chief Research and Development Officer) approval after IRB approval is granted. Complete the review guide and notify the IRB Assistant Director.)
☐ No (STOP - This research is prohibited by the VA)

2 The research under review represents ONE of the following categories of permissible research:

   ☐ Yes
   ☐ No

   Check the category that applies and state your reasons in the space provided.

   45 CFR 46.404/ 21 CFR 50.51 Category 1: Research not involving greater than minimal risk.
   ALL of the following are TRUE:
   a) No greater than minimal risk to children is presented.
      Explain:
   
   b) The research makes adequate provisions for soliciting the assent of children (verbal assent for children 12 and under where appropriate; written assent for ages 13-17)
      Explain:
   
   c) Adequate provisions for soliciting the assent of children
      Explain:
d) Choose one of the following:

- Permission of one parent is sufficient.
- Permission of both parents required (unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child)

**Explain:**

<table>
<thead>
<tr>
<th>45 CFR 46.405</th>
<th>21 CFR 50.52 Category 2: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual participants.</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALL of the following are TRUE:</td>
<td>a) Greater than minimal risk to children and presents either (or both) of the following (select the appropriate description):</td>
</tr>
<tr>
<td></td>
<td>an intervention that holds out the prospect of direct benefit for each individual subject. OR</td>
</tr>
<tr>
<td></td>
<td>a monitoring procedure that is likely to contribute to the participant’s well-being.</td>
</tr>
<tr>
<td><strong>Explain:</strong></td>
<td>b) The risk is justified by the anticipated benefit to the subjects.</td>
</tr>
<tr>
<td><strong>Explain:</strong></td>
<td>c) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.</td>
</tr>
<tr>
<td><strong>Explain:</strong></td>
<td>d) The research makes adequate provisions for soliciting the assent of the children (verbal assent for children 12 and under, where appropriate; written assent for age 13-17)</td>
</tr>
<tr>
<td><strong>Explain:</strong></td>
<td>e) Choose one of the following:</td>
</tr>
<tr>
<td></td>
<td>Permission of one parent is sufficient.</td>
</tr>
<tr>
<td></td>
<td>Permission of both parents required (unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child)</td>
</tr>
<tr>
<td><strong>Explain:</strong></td>
<td></td>
</tr>
</tbody>
</table>
45 CFR 46.406/ 21 CFR 50.53 Category 3: Research involving greater than minimal risk and no prospect of
direct benefit to individual subject, but likely to yield generalizable knowledge about the subject’s disorder
or condition.

ALL of the following are TRUE:

a) More than minimal risk to children is presented by an intervention or procedure that does not hold
out the prospect of direct benefit for the individual participant, or by a monitoring procedure, which
is not likely to contribute to the well-being of the participant.

Explain: (Make sure to briefly describe the risks, your reasoning for any risk determinations, any disorders/conditions,
and the knowledge to be gained):

b) The risk represents a minor increase over minimal risk.

Explain:

c) The intervention or procedure is likely to yield generalizable knowledge about the subjects’
disorder or condition which is of vital importance for the understanding or amelioration of the
subjects’ disorder or condition.

Explain:

d) The research meets BOTH of the following: (indicate acceptance by checking each box)

[ ] The research makes adequate provisions for soliciting the assent of the children
(Verbal assent for children 12 and under where appropriate; written assent
for age 13-17)

[ ] Confirm that permission of BOTH parents is required unless one parent is deceased,
unknown, incompetent, or not reasonably available, or only one parent has
legal responsibility for the care and custody of the child.

Explain:

45 CFR 46.407 Category 4: Research not otherwise approvable, which presents an opportunity to
understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

The following are TRUE:

- Research not otherwise approvable under 404, 405 or 406 BUT
- Research presents a reasonable opportunity to further the understanding, prevention, or
amelioration of a serious problem affecting the health or welfare of children.
- Adequate provisions are made for soliciting the assent of the child and the permission of the
parent/guardian

Explain:
### a). Complete when research is DHHS supported.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>If the research is supported by DHHS, <strong>ALL</strong> of the following must be true to meet the criteria for approval</em></td>
<td></td>
</tr>
</tbody>
</table>

**Check if applicable:**

- The research is conducted, funded, or otherwise subject to regulation by DHHS
- The Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined that EITHER of the following is true:
  - The research in fact satisfies the conditions of 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406 above.
  - **All of the following are true:**
    - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
    - The research will be conducted in accordance with sound ethical principles
    - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians

### b). Complete when research is FDA-regulated.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>If the research is FDA-regulated, <strong>ALL</strong> of the following must be true to meet the criteria for approval</em></td>
<td></td>
</tr>
</tbody>
</table>

**Check if applicable:**

- The research is subject to FDA regulation
- The Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined that EITHER of the following is true:
  - The research in fact satisfies the conditions of 21 CFR 50.51, 21 CFR 50.52, 21 CFR 50.53 above.
  - **All of the following are true:**
    - The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children
    - The research will be conducted in accordance with sound ethical principles
    - Adequate provisions are made for soliciting and the permission of their parents or guardians
3  Assent.

3a  For categories 404 through 407, assent is a requirement of:

- All Children (skip to #3d)
- Some Children
- None of the Children

3b  When assent is not a requirement of some or all children, please describe the children who are not required to assent

Describe:

3c  When assent is not a requirement of some or all children, please indicate and explain whether:

- The children are not capable of providing assent based on their age, maturity, or psychological state.
- The capability of the children is so limited that they cannot reasonably be consulted.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well being of the children and is available only in the context of research.
- The assent can be waived using the criteria for waiver of the consent process.

Explain:

3d  When assent is a requirement, will the assent be documented?

- Not applicable
- Yes  If YES, please describe the process to document assent.
- No

Describe:

4  Re-Consent Process for Minors Who become Adults

4a.  Will any of the children originally enrolled by assent and/or permission from their parents or guardian reach the age of majority (18 years or old) while participating in this study?

- Yes, answer 4.b.
- No, Proceed to 5

4b.  Is the plan for soliciting and obtaining legally effective consent from the now adult subjects appropriate?

- Yes
- No

Explain:
5 Parental Permission

5.a. Will permission from the parent or guardian be obtained?

| Yes, proceed to 5.b. |
| No, a waiver or alteration of parental permission is requested- proceed to 6. |

5.b. Permission will be obtained from:

| One parent or guardian (research meets 404 or 405 criteria) |
| One parent or guardian (research meets 406 or 407 criteria; however, one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child) |
| Both parents or guardians |

5.c. Parental permission will be/ will continue to be obtained from one or both parents or guardians (46.116(a), (b) and 46.408(d)).

<table>
<thead>
<tr>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

- Researcher or appropriately delegated and trained research personnel will obtain legally effective consent from parent or guardian
- The circumstances of consent provide the parent or guardian sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence
- No information will be provided to the parent or guardian that waives or appears to waive any of subject's legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence
- Individuals communicating information to the parent or guardian during the consent process will convey that information in language understandable to the subject or representative
- All required and appropriate disclosures will be provided either to the parent or guardian

5.d. Parental permission will be documented using the long form consent document.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

- The parental permission form includes the required elements and appropriate additional disclosures
- When the research requests access to educational records, the consent/permission describes the following: records that may be disclosed, purpose of disclosure and identity of the party or class of parties to whom records may be disclosed.
- When the research involves the administration of surveys, analyses or evaluations to students, the consent/permission indicates the right of the parent to review a copy of the questions asked of or materials that will be used with your child and how privacy will be protected
- The investigator will give the parent or guardian adequate opportunity to read the parental permission document before it is signed
- One or both parents or guardians will sign and date the written permission form
- A copy of the permission form will be given to the person(s) signing the document
- When appropriate, a witness will sign and date the written form
- When a witness signs, the relationship of the witness to the research and/or the subject will be noted under the witness' signature line

Explain, if criterion are not met:
5.e. **Parental permission will be documented using the short form consent document.**

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>●</strong> Permission document states that the elements of informed consent required by 46.116 and 50.25 have been presented orally to the parent or guardian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>●</strong> a written summary of what is to be said to the parent or guardian and includes the basic and required additional elements of disclosure is provided</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>●</strong> Witness will be present at the oral presentation</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>●</strong> When the parent or guardian do not speak English as their primary language, the witness must be conversant in both English and the language of the parent or guardian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>●</strong> Review documents and description of process to ensure 1. parent or guardian will sign short form consent, 2. witness will sign short form consent and written summary and 3. person obtaining consent will sign written summary</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>●</strong> Witness should not be the individual obtaining consent</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>●</strong> Parent or guardian should receive signed copies of short form consent and written summary</td>
<td></td>
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</tr>
</tbody>
</table>

5.f. **The requirement to obtain a signed parental permission form will be waived.**

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criterion Met</th>
<th>Continues to be Met</th>
<th>Criterion Not Met</th>
</tr>
</thead>
</table>

Check if applicable:
- [ ] An oral consent script was submitted
- [ ] The oral consent script includes the required and appropriate additional elements of disclosure

Check applicable category of waiver of documentation below:
- [ ] (i) The research involves no more than minimal risk and involves no procedures for which written consent is normally required outside the research context.
- OR
- [ ] (ii) The only record linking the subject and the research is the consent document and the principal risk is loss of confidentiality. The research is not FDA-regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.

Check if (i) or (ii) is selected:
- [ ] The PI should be required to provide subjects with a written statement about the research.
If a waiver or alteration is approved for all or some of the research, complete either a), b), or c). below.

<table>
<thead>
<tr>
<th>a)</th>
<th>Protocol specific findings justifying the determination that the research (or portion where consent is waived or altered) involves no more than minimal risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>i)</td>
<td>Protocol specific findings justifying the determination that the waiver will not adversely affect the rights and welfare of subjects</td>
</tr>
<tr>
<td>ii)</td>
<td>Protocol specific findings regarding whether it is appropriate to provide subjects with additional pertinent information after participation</td>
</tr>
<tr>
<td>iii)</td>
<td>Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration</td>
</tr>
</tbody>
</table>

OR

| b) | Research is conducted under the direction of state or local government officials AND is designated to study public benefit/service programs, procedures for obtaining public benefits/services, changes or alternatives to public benefit/service programs, or levels of payment for public benefits/services AND |
| i) | Protocol specific findings regarding whether it would be impracticable to conduct the research without a waiver or alteration |
Document reasoning (required):

OR

c). The research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects
An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

Explain:

If the researcher is requesting to access education records for minor students without parental permission, the following must be completed and the criterion met along with the 116 or 408 criteria for approval of waiver.

Box 6a: One or more of the following criteria must be met to allow access to minor student education records without parental permission.

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion met</th>
<th>Criterion not met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclosure of directory information.</td>
<td>Studies for, or on behalf, of the institution to develop, validate, or administer predictive tests; administer student aid programs; or improve instruction</td>
<td>Removal of all personally identifiable information</td>
</tr>
</tbody>
</table>

Reference:
● Tip Sheet #7

If the researcher is funded by the Department of Education and is requesting to conduct surveys, analyses or evaluations of students without parental permission, the following must be completed and the criterion met along with the 116 or 408 criteria for approval of waiver.

Box 6b: The student survey, analysis or evaluation does not involve any of the 8 PPRA "protected information survey" areas (refer to Tip sheet #7 for a listing of the 8 areas).

<table>
<thead>
<tr>
<th>Not Applicable</th>
<th>Criterion met</th>
<th>Criterion not met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For surveys administered to students that are not funded by the Department of Education and reveal information concerning one or more of the 8 PPRA protected areas, refer to the local school's PPRA policy to guide the waiver determination

7 The research involves Wards of the State or any other agency, institution, or entity.
Yes
No If YES, complete the Wards review guide.

8 Approval Determination
The proposed involvement of children is:
Approvable (quick check: #2 is yes, provisions for assent and parental permission are appropriate and meet criterion)
NOT approvable (list any modification required in the comments section below)
<table>
<thead>
<tr>
<th>IRB Number: 1 2 3 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Wards</strong></td>
</tr>
<tr>
<td>University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 1.1, dated September 30, 2009</td>
</tr>
</tbody>
</table>

**Research Protocol #:**

**Investigator Full Name:**

**Research Protocol Title:**

<table>
<thead>
<tr>
<th>Instructions:</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Add this review guide to the core IR/CR/AM review guides only when applicable.</td>
</tr>
<tr>
<td>● Please check the applicable boxes.</td>
</tr>
<tr>
<td>● Provide an explanation in the space provided or on an attached sheet, if necessary.</td>
</tr>
<tr>
<td><em>For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.</em></td>
</tr>
<tr>
<td>● If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.</td>
</tr>
</tbody>
</table>

**1 The research involves Wards of the State or another agency, institution, or entity.**

| Yes |
| No |

If YES, complete this guide. If NO, stop.

**2 At least one of the following is TRUE:**

| True |
| False |

Check the box next to the statement that applies.

- The research is related to the children's status as wards
- The research will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards

**3 One or more individuals will be appointed as a [research] advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis.**

| Yes |
| No |

**4 The [research] advocate or advocates will have the background and experience to act in, and agree to act in, the best interests of the child for the duration of the child's participation in the research.**

| Yes |
| No |

**5 The [research] advocate or advocates are not associated in any way (except in the role as advocate or member of the IRB) with ANY of the following:**

- The research
- The investigator(s)
- The guardian organization

Check the box next to the statement that applies.
### 6 A copy of the DCFS approval is attached.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

### 7 Approval Determination.

The proposed involvement of children who are wards is:

- [ ] Approvable (*quick check: #1-6 are Yes/True*)
- [ ] Modifications required
- [ ] NOT approvable (list any modification required in the comments section below)

**Comments.** *(Write comments in space provided; attach additional sheet of paper, if necessary.)*

---

**Signature**

**Date**

**Printed Name**
Department of Defense Supported Research

University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 1.1, dated April 10, 2012

Complete this review guide for research supported by a DoD component at time of initial review, amendments adding DoD support or involving a significant change in the research and continuing reviews when there is a significant change in the research.

Instructions:
- Add this review guide to the core IR/CR/AM review guides only when applicable.
- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.

For example, if modifications are needed to meet a criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.

- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.
- Refer to UIC Policy # 619, Research Involving DoD Components

DoD Component supporting research:

1 Performance Site.

- UIC
- JBVAMC: Not currently approved for DoD research

2 The investigator is aware of the DoD and DoD Component specific requirements for conducting human subject research
- Yes
- No

3 The scientific review supports the merit of the research and soundness of the aims and research design
- Yes
- No, please explain.
- Not Applicable

If no, explain:

4 The research does not involve detainees [i.e., person captured, detained, held or otherwise controlled under the control of DoD personnel (military and civilian or contractor employee)] as human subjects.
- Yes
- No

If no, refer to Chair or OPRS Director

5a Risk Level of the Research

- Minimal Risk, proceed to 5.b.
- More than Minimal Risk, complete 5c-d

For DoD supported research, the definition of minimal risk as “…ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests” should not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, research risks imposed on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).
5.b. A research monitor is required even though the level of risk of the research is minimal.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No, Proceed to 6.a.</td>
<td>Not applicable if the risks of the study are greater than minimal.</td>
</tr>
<tr>
<td>Not Applicable.</td>
<td>Proceed to 5.c.</td>
</tr>
</tbody>
</table>

If yes, please explain and complete 5.c.:

5.c. The following are true concerning the research monitor:

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

- an independent research monitor has been identified by name or documentation of a waiver for the requirement of a research monitor from the head of the DoD component is provided
- if a research monitor is appointed, monitor
  - is independent of research team
  - possesses sufficient education and professional experience consistent with research risks and to perform the assigned oversight functions
  - has confirmed their acceptance
  - is assigned duties that are appropriate based on protocol specific risks or concerns
  - will promptly report observations and findings to the IRB or other designated official
  - has authority to stop the research in progress, remove individual subjects from the research, and take whatever steps are necessary to protect the safety and well-being of the subjects until the IRB can assess the monitor’s report

If no, explain:

Indicate any recommended additions or deletions to the monitor’s assigned duties:

5.d. Select the appropriate box(es) concerning coverage for research related injury:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>DoD personnel do not have primary involvement in the conduct of the research and consent includes UIC's standard research injury coverage language</td>
</tr>
<tr>
<td>☐</td>
<td>DoD personnel have primary involvement in the conduct of the research and documentation of coverage of medical expenses for injury and ORS approval are provided. Consent includes DoD required disclosure</td>
</tr>
<tr>
<td>☐</td>
<td>DoD personnel have primary involvement in the conduct of the research and the DoD component head has provided a waiver from the requirement to cover medical expenses for subject injury. Consent includes UIC’s standard research injury coverage language.</td>
</tr>
<tr>
<td>☐</td>
<td>For Department of Navy research only, arrangements for providing emergency care and necessary follow-up of any research-related injury are documented, authorized by ORS and described in consent</td>
</tr>
</tbody>
</table>

5.e. For Department of Navy research only, arrangements for providing emergency care and necessary follow-up of any research-related injury are documented, authorized by ORS and described in consent

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Not Applicable</td>
<td>check not applicable if not supported by Department of Navy</td>
</tr>
</tbody>
</table>

If no, explain:
6.a.  The research involves DoD personnel (military or civilian) as human subjects.

- Yes, complete 6b-c
- No, proceed to 7

6.b. The following are all true concerning recruitment and consent of DoD personnel:

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

- measures ensure that an individual's decision about participation will not be influenced by supervisors (military or civilian), unit officers or senior noncommissioned officers (NCOs)
- measures exclude supervisors, unit officers and senior NCOs from recruitment sessions or during the consent process for individuals under their command or supervision
- When relevant, separate recruitment and consent sessions are for supervisors, officers and NCOs excluded from sessions held for their units
- Documentation of approval (or that approval is not needed) from supervisor to recruit DoD personnel

If no, explain:

6.c. Recruitment occurs in group setting and appointment of ombudsman to monitor recruitment and consent is (check all that apply):

- Not Applicable (recruitment does not occur in group setting)
- required as research involves DoD military personnel and greater than minimal risk
- recommended for DoD military personnel even though minimal risk
- recommended for DoD civilian personnel
- not recommended as research is minimal risk and/or involves DoD civilian personnel

Explain reason for recommending or not recommending ombudsman when research is minimal risk or involves civilians:

7. The following are all true concerning compensation of personnel as research subjects (check not applicable if no compensation is being offered):

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
</tr>
</thead>
</table>

- On-duty federal personnel are not compensated for their research participation, except up to $50 per blood draw. Payment is from federal or nonfederal source.
- Off-duty federal personnel are compensated a reasonable amount for research participation, however compensation from federal funds is limited to $50 per blood draw.
- Non-federal personnel are compensated a reasonable amount from federal or nonfederal funds, however payment for blood draws from federal funds is limited to $50 each.

If no, explain:
8.a. When research is not exempt or not limited to use of existing specimens or data and involves an interaction or intervention with the subject (check not applicable when research falls outside these criteria), the research does not involve a waiver of informed consent unless the Asst Sec of Def (R&E) or delegate approves the waiver.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
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</thead>
<tbody>
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</tbody>
</table>

- The above description refers to the DoD research category, research involving human beings as experimental subjects.
- Waiver of consent for recruitment is acceptable under this requirement

If no, explain:

8.b. When research meets criteria for research involving human beings as an experimental subject described in 8.a. and consent by a legally authorized representative on behalf of the subject (e.g., children, decisionally impaired subject) is being requested, the research offers a benefit to the individual subject.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Select "Not Applicable" when research does not meet criteria of research involving human beings as an experimental subject or consent will only be obtained from subjects

If no, explain:

9 For research involving subjects who are not U.S. citizens or DoD personnel and is conducted in a foreign country (check Not Applicable if research does not meet these criteria):

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Not Applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

- laws and requirements of foreign country have been met
- research follows customs, practices and cultural sensitivities of host country
- permission of host country obtained (for Department of Navy only)
- an ethics review by the host country, or local Naval IRB with host country representation, will take place.

If no, explain:

10 Approval Determination

The proposed involvement of children is:

- Approvable (quick check: #2, 3, 4, 5b, 5c, 6b, 7, 8a and 8b are yes or Not Applicable)
- NOT approvable (List any modification required in the comments section below)

Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

Signature
Date

Printed Name
### Review Guide Checklist ● Humanitarian Use Device ● Initial and Continuing Review

**University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 1.2, dated February 6, 2012**

<table>
<thead>
<tr>
<th>Research Protocol #:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator Full Name:</td>
<td></td>
</tr>
<tr>
<td>Research Protocol Title:</td>
<td></td>
</tr>
</tbody>
</table>

**Instructions:**

- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.
  
  *For example, if modifications are needed to meet an approval criteria, please explain what is lacking and what the investigator would need to change or provide to meet this criteria.*
- If a 45 CFR 46.111 approval criteria is “not appropriate” based on the type of research, explain why.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.
- This form may be used for reviewing and approving the clinical use of the HUD and research activities accompanying this use.

**Review Type. Check applicable boxes. If an answer to an applicable question below is “No,” then modifications must be requested.**

<table>
<thead>
<tr>
<th>Initial Review (performed at a convened IRB meeting)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuing Review (may be performed either by expedited or convened review)</td>
<td></td>
</tr>
<tr>
<td>Expedited review</td>
<td></td>
</tr>
<tr>
<td>Convened</td>
<td></td>
</tr>
</tbody>
</table>

### Y N Does the investigator plan to collect safety and efficacy data involving the use of the HUD?  
*If yes, the submission represents a clinical investigation and questions labeled “RESEARCH” must be.*

### Y N RESEARCH: For initial review, does the investigator have the resources necessary to protect subjects before conducting the research study?

### Y N RESEARCH: On continuing review, does the investigator continue to have the resources necessary to protect subjects before conducting the research

- Resources might include personnel, time, and access to a study population
- Sufficient time to conduct and complete the research
- Researchers should stop a study if resources become unavailable

### Y N On continuing review, is verification needed from sources other than the investigator that no material changes have occurred since the previous IRB review?

*If not applicable, skip question.*

### Y N On continuing review, do any new significant findings that arise from the review process and that may relate to the subjects’ willingness to continue participation need to be provided to subjects?

- Review any Medical Device Reporting forms since the last appraval
- Have the risks or benefits changed

**Explain if “yes.”**
1. **HUD Use and RESEARCH: Study Population.**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Not appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is subject selection equitable?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Justification for the inclusion of any vulnerable population
- Inclusion/Exclusion criteria are appropriate
- A certain group is not targeted or excluded without justification
- The setting in which the research would be conducted does not cause inequitable selection

- Subject recruitment and enrollment procedures do not cause inequitable selection
- The amount and timing of payments to subjects does not cause inequitable selection

2. **HUD Use.**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Not appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Does the proposed use of the HUD correspond with the current labeling and not exceed the scope of the FDA approved indication?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*If no, please discuss with the Executive Chair. Unless the request represents emergency or compassionate use, requests for off-label use will only be considered after IRB approval of use for HDE-labeled indication and then on a case by case basis. If off-label use is part of a clinical investigation, the biomedical initial review form should be used and an IDE is required.*

3. **HUD Use and RESEARCH: Patients.**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Not appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Are the number AND POPULATION of patients appropriate?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. **Health Care Provider Qualifications.**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Not appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the health care provider qualified through training and expertise to use the device?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Consider the training and expertise described in the approved product labeling and HDE approval order
- Ensure health care provider has completed or plan is provided for completion of any training required to be provided by the HDE-holder in the approved labeling or HDE approval order

5. **RESEARCH: Vulnerable Populations.**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Not Applicable</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>If applicable, are additional safeguards provided for populations vulnerable to coercion and undue influence?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Consider whether appropriate additional safeguards are in place to protect vulnerable populations from coercion
- Vulnerable populations include: pregnant women, fetuses, neonates, prisoners, children, cognitively impaired, decisionally impaired, and economically disadvantaged
- Vulnerable populations may include any other group vulnerable to coercion that may need additional protections to prevent coercion, including but not limited to, the terminally ill and students

6. **RESEARCH: Privacy.**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Not Appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>If appropriate, are there adequate provisions to protect the privacy of subjects?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Privacy protections adequate
### 7 RESEARCH: Confidentiality.

<table>
<thead>
<tr>
<th>Not Appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>If appropriate, are there adequate provisions to maintain the confidentiality of the data?</td>
<td></td>
<td></td>
<td>● Plan to protect confidentiality of data adequate</td>
</tr>
</tbody>
</table>

### 8 HUD Use and RESEARCH: Risks to subjects are minimized by using procedures consistent with standard clinical practice (when considering HUD use) and sound research design (when considering research activities) that do not unnecessarily expose subjects to risk.

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>● Procedures are consistent with sound research design and do not expose subjects unnecessarily to risk</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● When considering use of HUD, this determination should include selection of patients, procedures involved with placement of HUD, and follow-up monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● Evaluate the risks described in the product labeling and ensure that the risks are minimized</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● The research design is sound and may possibly yield the expected knowledge</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● Whenever appropriate, research uses procedures already being performed for diagnostic or treatment purposes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>● In making this determination, the IRB considers physical, psychological, social, economic, and legal risks</td>
<td></td>
<td></td>
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</tbody>
</table>

### 9 RESEARCH: Risks to subjects are minimized, when appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

<table>
<thead>
<tr>
<th>Not Appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments:</td>
<td></td>
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</table>

### 10 HUD Use and RESEARCH: Risks to subjects are reasonable in relationship to the anticipated benefits of the proposed use of the device.

<table>
<thead>
<tr>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comments:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 11 HUD Use and RESEARCH: Data Safety Monitoring Plan/Data Safety Monitoring Board.

<table>
<thead>
<tr>
<th></th>
<th>Not Appropriate</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Where appropriate, the plan for use of the HUD adequately monitors the safety of subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Provides adequate data monitoring
- Provides adequate monitoring to ensure safety of subjects
- Provides adequate frequency of review

**Recommended frequency of reports (if applicable):**

### 12 RESEARCH: Recruitment.

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Are recruitment procedures and materials fair and appropriate?</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

**Comments:**

### 13 RESEARCH: Incentives or Reimbursements. *(Refer to the informed consent document for this information.)*

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Are compensation amounts and disbursement methods coercive or might they present undue influence?</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

- Amount is justified, fair, and appropriate
- Amount is reasonable, meaning not likely to be coercive

### 14 HUD Use: Informed Consent Document.

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criteria Met</th>
<th>Continues to be Met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The informed consent document, when applicable, and/or other documents contain the recommended sections and recommended language in the UIC HUD consent template.</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**Explain:**

FDA approved patient information is appropriate to substitute for certain required sections of the UIC HUD template consent.
**Reference:**
- Laminates #5-8

---

**15 RESEARCH: Informed Consent Document contains required basic and additional elements and will be documented using the long form consent document:**

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criteria Met</th>
<th>Continues to be met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eight basic elements of informed consent, as appropriate, prohibition against exculpatory language, and signature line; additional elements as appropriate; FDA requirements; UIC requirements. Short form or waiver of documentation should not be used.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**16 HUD Use and RESEARCH: Informed Consent Process.**

<table>
<thead>
<tr>
<th></th>
<th>Not Applicable</th>
<th>Criteria Met</th>
<th>Continues to be met</th>
<th>Criteria Not Met</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed consent will be/will continue to be obtained from the subject or the subject’s legally authorized representative, as applicable.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Criteria Met**
- The circumstances of consent provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and minimize the possibility of coercion or undue influence
- The information that will be given to the subject or the representative will be in a language understandable to the subject or representative
- No information will be provided to the subject or the representative that waives or appears to waive any of the subject’s legal rights, or releases or appears to release the investigator, the institution, or its agents from liability or negligence
- All required and appropriate disclosures will be provided either to the subject or to the subject’s representative

**Criteria Not Met**

---

**17 RESEARCH: HIPAA Authorization**

- NA - No PHI accessed in this research
- HIPAA Authorization language within the informed consent document approved with NO Waivers

---

**18 Review frequency**

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does this protocol meet criteria (listed below) for protocols that will generally be reviewed more often than annually?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Novel high-risk study involving new therapeutic modality
- Phase I study of a new drug or biologic that has never been tested in humans
- Study involving a novel significant risk medical device which has never been tested in humans
- High-risk study as IRB members deem appropriate (includes research for which IRB determines that reports to the IRB of monitoring data should be more than annually)

**Select Review Frequency:**

<table>
<thead>
<tr>
<th></th>
<th>12 Months</th>
<th>6 Months</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 19 Approval Recommendation for

**HUD Use**

- [ ] Approved
  - Keep at Convened Review
  - Perform subsequent reviews at Expedited Level

**Conditions for approval**

- [ ] None
- [ ] Limit use based on one or more measures of disease progression. Specify:
- [ ] Prior use and failure of alternative treatments. Specify:
- [ ] Reporting requirements to IRB or IRB Chair. Specify:
- [ ] Other criteria. Specify:

**Modifications required (list in comments section below)**

- [ ] Refer to Convened Review - Further review required by full IRB
- [ ] Deferred (only if being reviewed at convened meeting)
- [ ] Disapproved (only if being reviewed at convened meeting)
- [ ] Suspend

### RESEARCH Activities Related to Use of HUD

- [ ] Approved
  - Keep at Convened Review
  - Perform subsequent reviews at Expedited Level

**Modifications required (list in comments section below)**

- [ ] Refer to Convened Review - Further review required by full IRB
- [ ] Deferred (only if being reviewed at convened meeting)
- [ ] Disapproved (only if being reviewed at convened meeting)
- [ ] Suspend
Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)

- Accept pre-review comments
- Accept pre-review comments with modifications
- Do not accept pre-review comments

Signature ___________________________ Date __________

Printed Name ___________________________
IRB Number: 1 2 3 4

Research Protocol #: ____________________________
Investigator Full Name: __________________________
Research Protocol Title: __________________________
Date Submitted to OPRS: __________________________
Date of Event: __________________________________
Subject study ID# (if applicable): __________________

Instructions:

- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

Indicate the Event(s) Denoted on the Prompt Reporting Form

☐ a. Local, serious unanticipated adverse event
☐ b. Unanticipated adverse device effect
☐ c. Serious unanticipated problem
☐ d. Major protocol violation
☐ e. Apparent serious noncompliance
☐ f. Apparent continuing noncompliance
☐ g. Changes to the protocol made without IRB approval to eliminate apparent immediate harm to subjects
☐ h. Incarceration of a subject in a protocol not approved to enroll prisoners
☐ i. Local unanticipated adverse event or problem (not serious)
☐ j. External unanticipated adverse event or problem
☐ k. New information indicating an unexpected change to the risks or benefits of the research
☐ l. Administrative hold
☐ m. Other events requiring prompt reporting by sponsor, describe: ____________________________

Problem or Adverse Event [complete for items a, b, c, d (when unintentional), h, i, j, k]

1 For item a, b, or c, does the adverse event or problem meet the following criteria?

- occurred locally AND
- unanticipated in terms of occurrence, frequency or severity AND
- serious

  ... death, life-threatening injury, hospitalization or prolongation of hospitalization, persistent or significant disability, or congenital anomaly or requires intervention to prevent one of these outcomes OR

  ... substantive harm to the safety, rights, or welfare of human subjects, research staff or others; or substantively compromises the effectiveness of the UIC human subject protection program

☐ Yes, this event meets the reporting requirements of a local serious unanticipated adverse event or problem

- Refer report to IRB chair (or designee) for determination
- Determination required within 5 days of submission
- Consult with the chair (or designee) to determine if immediate action is needed to protect the rights and welfare of subjects
No, this event is not:

- local
- unanticipated
- related
- serious

- If only serious was checked Go to question 2; else Proceed to the NonCompliance section

2 For item h, i, j or k, does the adverse event or problem meet the following criteria?

- unanticipated in terms of occurrence, frequency or severity AND
- places subjects at a greater risk of harm than previously known AND
- (for item J only) related or possibly related to the research AND

- Yes, this event meets the reporting requirements of an unanticipated adverse event or problem
- If yes, are the risks:
  - Minimal
  - Greater than minimal
  - Refer report to IRB chair (or designee) for determination.
  - Determination required within 15 days of submission

- No, this event is not unanticipated, does not place subjects at a greater risk of harm, is not related to the research (item J only) or no analysis was provided by sponsor or others (item J only).
  - Return report to the investigator with explanation that the problem does not meet criteria for prompt reporting.

3 Further information is needed

Details:

Apparent Noncompliance (complete for items d, e, f, g)

1 Does this report involve a change to the protocol prior to IRB approval?

- No  Go to question 2
- Yes  If YES, check which of the statements below are TRUE.
  - The change was necessary to eliminate immediate harm to subjects or others.
  - There was insufficient time to contact the IRB.

- If answer above is yes and both statements are true, refer report to convened IRB as changes to the protocol made without IRB approval to eliminate immediate harm to subject
- If answer above is yes and only one or none of the statements are true, refer report to IRB chair (or designee) as apparent serious noncompliance
2 If this report involves research conducted at JBVAMC, is the report consistent with one or more of the examples of apparent serious or continuing noncompliance provided in subparagraphs 7.f. and g. of VHA Handbook 1058.01?

- [ ] Not applicable  Go to question 3
- [ ] No  Go to question 3
- [x] Yes  Refer report to convened IRB as apparent serious or continuing noncompliance

3 Does the event indicate that research was conducted in a manner that intentionally or unintentionally failed to comply with federal or state regulations, VHA Handbook 1200.05 (if applicable), or the requirements or determinations of the IRB?

- [ ] No  Send report to the investigator explaining the event does not represent noncompliance
- [x] Yes  Go to question 4

4 Did the incident
- [ ] increase the risks to subjects, OR
- [ ] decrease the potential benefits, OR
- [ ] affect the validity of the research data, OR
- [ ] compromise the integrity of the human subject protection program, OR
- [ ] indicate a pattern of persistent failure to conduct research in compliance with federal or state regulations, VHA Handbook 1200.05 (if applicable), or requirements or determinations of the IRB?

- [ ] No  Refer report to IRB chair (or designee) as apparent non-compliance
- [x] Yes  Refer report to IRB chair (or designee) as apparent serious or continuing non-compliance

5 [ ] Further information is needed

Details:
<table>
<thead>
<tr>
<th>Administrative Hold (complete when applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator-Initiated</td>
</tr>
<tr>
<td>Sponsor-Initiated (Suspension/Termination)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Refer for review by convened IRB.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Further information needed.</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Details:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Comments. (Write comments in space provided; attach additional sheet of paper, if necessary.)</th>
</tr>
</thead>
</table>

Signature: ________________________________  Date: ________________

Printed Name: ________________________________________________
Review Guide Checklist ● Prompt Reporting ● For Use by:
Expedited ● IRB Chair or Designee OR
Convened IRB for non-JBVAMC Research OR
Convened IRB for JBVAMC Research When Not Reviewed by Chair or Designee

<table>
<thead>
<tr>
<th>Research Protocol #:</th>
<th>Investigator Full Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Protocol Title:</td>
<td></td>
</tr>
<tr>
<td>Date Submitted to OPRS:</td>
<td></td>
</tr>
<tr>
<td>Date of Event:</td>
<td></td>
</tr>
<tr>
<td>Subject study ID# (if applicable):</td>
<td></td>
</tr>
</tbody>
</table>

Instructions:
- Please check the applicable boxes.
- Provide an explanation in the space provided or on an attached sheet, if necessary.
- Events/incidents may represent both unanticipated problems and noncompliance
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

Problem or Adverse Event (Includes Reports of New Information)

Section Not Applicable (Proceed To Noncompliance Determination)

1. Does the problem or adverse event meet the following criteria?
   - occurred locally AND
   - unanticipated in terms of occurrence, frequency or severity AND
   - related or possibly related to the research AND
   - serious

   Yes, this event represents a local serious unanticipated adverse event or serious unanticipated problem
   - Refer to next convened IRB meeting for review of corrective actions
   - For JBVAMC research, notify Facility Director of Chair's determination within 5 days

   No, this event does not represent a local serious unanticipated adverse event or serious unanticipated problem
   - Notify investigator that the event does not meet criteria of unanticipated problem

2. Does the adverse event or problem meet the following criteria?
   - unanticipated in terms of occurrence, frequency or severity AND
   - places subjects at a greater risk of harm than previously known AND
   - related or possibly related to the research AND
   - (for external events) analysis provided by sponsor to support the 3 preceding criteria

   Yes, this event represents an unanticipated problem and, while not serious, does indicate the research is associated with a greater risk of harm than previously known
   - If yes, are the risks:
     - Minimal
     - Greater than minimal
     - Go to questions 4 and 5 and indicate whether any corrective actions are needed

   No, this event does not represent an unanticipated problem
   - Notify investigator that the event does not meet criteria of unanticipated problem
3 Further information is needed before a final determination can be made

Details:

4 Is action needed to prevent immediate harm to subjects?

- Yes
  - Indicate action in question 5

- No

5 Indicate, what if, any actions are needed:

- Modification of protocol (when IRB reviewing JBVAMC research document decision in minutes)
  - Should previously enrolled subjects be notified of the modification?
    - Yes
    - If yes, when should this notification take place:
      - If yes, how should notification be documented:
    - No

- Modification of consent document/process (when IRB reviewing JBVAMC research document decision in minutes)
  - Should previously enrolled subjects be notified of the modification?
    - Yes
    - If yes, when should this notification take place:
      - If yes, how should notification be documented:
    - No

- Notification of current subjects (must occur when such information may relate to the subject's willingness to continue participation)
- Provide additional information to subjects who have completed the research
- Oversight or educational measures
- Re-consent current subjects to participation
- Modification of frequency of continuing review
- Refer event or problem for non-compliance review
- Suspend part or all of research (address further actions under suspension below)
- Terminate the research (address further actions under termination below)
- Referral to other organizational entities (e.g., ORS, ethics officer, Associate Director for Compliance, Radiation Safety)
- None

Describe:

Apparent Noncompliance

- Section Not Applicable (Proceed To Suspension Determination)

1 Does this report involve a change to the protocol prior to IRB approval?

- No
  - Go to question 2

- Yes
  - If YES, check which of the statements below are TRUE.
    - The change was necessary to eliminate immediate harm to subjects or others.
    - There was insufficient time to contact the IRB.

- If answer above is yes and both statements are true refer report to convened IRB as changes to the protocol made without IRB approval to eliminate immediate harm to subject
- If answer above is yes and only one or none of the statements are true, refer report to convened IRB as apparent serious noncompliance
- Go to question 6
2  Does the event indicate that research was conducted in a manner that intentionally or unintentionally failed to comply with federal or state regulations, VHA Handbook 1200.05 (if applicable), or the requirements or determinations of the IRB?

☐ No  Send report to the investigator explaining the event does not represent noncompliance

☐ Yes  Go to question 3

3  Did the incident:
- increase the risks to subjects, OR
- decrease the potential benefits, OR
- affect the validity of the research data, OR
- compromise the integrity of the human subject protection program, OR
- indicate a pattern of persistent failure to conduct research in compliance with federal or state regulations, VHA Handbook 1200.05 (if applicable), or requirements or determinations of the IRB?

☐ No  Send report to the investigator explaining the event represents noncompliance that is not serious or continuing

☐ Yes

☐ Refer report to convened IRB as apparent serious or continuing non-compliance

☐ Go to question 6

4  Further information is needed before a determination can be made

Details:

5  Is action needed to prevent immediate harm to subjects?

☐ Yes

☐ Indicate action in question 6

☐ No

6  Indicate what, if any, actions are needed:

☐ Modification of protocol

 Should previously enrolled subjects be notified of the modification?

☐ Yes

 If yes, when should this notification take place:

☐ No

 If yes, how should notification be documented:

☐ Modification of consent document/process

 Should previously enrolled subjects be notified of the modification?

☐ Yes

 If yes, when should this notification take place:

☐ No

 If yes, how should notification be documented:
Notification of current subjects (must occur when such information may relate to the subject's willingness to continue participation)

Provide additional information to subjects who have completed the research

Oversight or educational measures

Re-consent current subjects to participation

Modification of frequency of continuing review

Refer event or problem for non-compliance review

Suspend part or all of research (address further actions under suspension below)

Terminate the research (address further actions under termination below)

Referral to other organizational entities (e.g., ORS, ethics officer, Associate Director for Compliance, Radiation Safety)

None

Describe:

### Suspension: Actions to Protect Rights and Welfare of Subject

**Recommend suspension of all or part of research.**

**Is further action regarding the event needed?**

- **Yes**
  - Notify current subjects of the suspension through oral or written communications approved by the IRB
  - Allow currently enrolled subjects to continue if it is in their best interest (for research at the JBVAMC, the Chair will consult with the COS in making this decision)
  - Change the following to correct any deficiencies and protect the rights and welfare of subjects:
    - Protocol
    - Consent document
    - Other, Specify:
    - Withdrawal of current subjects from research and, if deemed necessary (for research at the JBVAMC, the Chair will consult with the COS in making this decision):
      - Transfer of subjects to another investigator;
      - Arrange for clinical care outside of the research;
      - Continue some research activities under the supervision of an individual monitor;
      - Permit follow-up for safety reasons
      - No additional safeguards necessary
    - Follow-up procedures permitted or required by the IRB
    - Reporting of unanticipated problems involving risks to subjects or others required if follow-up procedures are permitted.

- **No**

**Details:**

### Comments

(Write comments in space provided; attach additional sheet of paper, if necessary.)

**Signature**

**Date**

**Printed Name**

---

1. Indicate what, if any, actions are needed:
   - Modification of protocol (document decision in minutes)
     Should previously enrolled subjects be notified of the modification?
     - Yes
     - If yes, when should this notification take place:
       - If yes, how should notification be documented:
     - No
   - Modification of consent document/process (document decision in minutes)
     Should previously enrolled subjects be notified of the modification?
     - Yes
     - If yes, when should this notification take place:
       - If yes, how should notification be documented:
     - No
   - Notification of current subjects (must occur when such information may relate to the subject's willingness to continue participation)
   - Provide additional information to subjects who have completed the research
   - Oversight or educational measures
   - Re-consent current subjects to participation
   - Modification of frequency of continuing review
   - Refer event or problem for non-compliance review
   - Suspend part or all of research (address further actions under suspension below)
   - Terminate the research (address further actions under termination below)
   - Referral to other organizational entities (e.g., ORS, ethics officer, Associate Director for Compliance, Radiation Safety)
   - None
     Describe:

2. Further information is needed before a final determination can be made
   Details:
## Change to the Protocol Made without IRB Approval to Eliminate Immediate Harm to Subject

1. **Does this report involve a change to the protocol prior to IRB approval?**
   - No
   - Yes  
     - If YES, check which of the statements below are TRUE.
       - The change was necessary to eliminate immediate harm to subject.
       - There was insufficient time to contact the IRB.
     - If answer above is yes and both statements are true, this report represents a change to the protocol made without IRB approval to eliminate immediate harm to subject. Notify investigator of the determination.
     - If answer above is yes and only one or none of the statements are true, evaluate report as apparent serious noncompliance

2. **Indicate what actions, if any, should be implemented to prevent the occurrence of this event in the future:**
   - **Modification of protocol**
     - Should previously enrolled subjects be notified of the modification? Yes
     - If yes, when should this notification take place: 
     - If yes, how should notification be documented: 
   - **Modification of consent document/process**
     - Should previously enrolled subjects be notified of the modification? Yes
     - If yes, when should this notification take place: 
     - If yes, how should notification be documented: 
   - **Notification of current subjects (must occur when such information may relate to the subject's willingness to continue participation)**
   - **Oversight or educational measures**
   - **Provide additional information to subjects who have completed the research**
   - **Re-consent current subjects to participation**
   - **Modification of frequency of continuing review**
   - **Referral to other organizational entities (e.g., ORS, ethics officer, Associate Director for Compliance, Radiation Safety)**
   - **None**
   - **Describe:**

3. **Further information is needed before a final determination can be made**
   - **Details:**
### Apparent Serious or Continuing Noncompliance

1. Does the event indicate that research was conducted in a manner that intentionally or unintentionally failed to comply with federal or state regulations, VHA Handbook 1200.05 (if applicable), or the requirements or determinations of the IRB?
   - [ ] No  Send report to the investigator explaining the event does not represent noncompliance
   - [ ] Yes  Go to question 2

2. Did the incident:
   - increase the risks to subjects, OR
   - decrease the potential benefits, OR
   - affect the validity of the research data, OR
   - compromise the integrity of the human subject protection program.
   - [ ] No  ● This incident represents noncompliance that is not serious.
             ● Report this finding to the investigator.
             ● Indicate any corrective actions in question 4.
             ● Continue to question 3
   - [ ] Yes  ● This incident represents serious noncompliance.
             ● Notify investigator of this finding
             ● Reporting required as described in the UIC HSPP policy **Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-compliance**.
             ● Indicate any corrective actions in question 4.
             ● Continue to question 3

3. Did the incident indicate a pattern of persistent failure to conduct research in compliance with federal or state regulations, VHA Handbook 1200.05 (if applicable), or requirements or determinations of the IRB?
   - [ ] No  ● This incident represents noncompliance that is not continuing.
             ● Report this finding to the investigator.
             ● Indicate any corrective actions in question 4.
   - [ ] Yes  ● This incident represents continuing noncompliance.
             ● Notify investigator of this finding
             ● Reporting required as described in the UIC HSPP policy **Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-compliance**.
             ● Indicate any corrective actions in question 4.

4. Indicate what, if any, actions are needed:
   - Modification of protocol
     - Should previously enrolled subjects be notified of the modification?
       - [ ] Yes  If yes, when should this notification take place:
       - [ ] No  If yes, how should notification be documented:
Modification of consent document/process
Should previously enrolled subjects be notified of the modification?
☑ Yes
☐ No
If yes, when should this notification take place:
If yes, how should notification be documented:

Notification of current subjects (must occur when such information may relate to the subject's willingness to continue participation)
☐ Provide additional information to subjects who have completed the research
☐ Oversight or educational measures
☐ Re-consent current subjects to participation
☐ Modification of frequency of continuing review
☐ Refer event or problem for non-compliance review
☐ Suspend part or all of research (address further actions under suspension below)
☐ Terminate the research (address further actions under termination below)
☐ Referral to other organizational entities (e.g., ORS, ethics officer, Associate Director for Compliance, Radiation Safety)
☐ None
Describe:

5 ☐ Further information is needed before a final determination can be made
Details:

Administrative Hold

1 Approval of the administrative hold.
☐ Yes
☐ No
If YES, indicate below the actions that should be taken and provide details in the space provided:
☐ Notification of subjects of the hold through oral or written communications approved by the IRB
☐ Implement more frequent monitoring of research or consent process
☐ Modifications to the protocol or consent process
☐ Other measures to protect the rights and welfare of subjects
Details:

2 Disapproval of the administrative hold.
☐ Yes
☐ No
If YES, indicate below the actions that should be taken and provide details in the space provided:
☐ Suspend part or all of research (address further actions under suspension below)
☐ Terminate research (address further actions under termination below)
☐ Refer event or problem for non-compliance review
☐ Other measures to protect the rights and welfare of subjects
Details:
Further information is needed.

Details:

---

**Suspension: Actions to Protect Rights and Welfare of Subject**

**Section Not Applicable**

**Recommend suspension of all or part of research.**

<table>
<thead>
<tr>
<th>Yes</th>
<th>Is further action regarding the event needed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>If YES, indicate below the actions that should be taken and provide details in the space provided:</td>
</tr>
</tbody>
</table>

- Notify current subjects of the suspension through oral or written communications approved by the IRB
- Allow currently enrolled subjects to continue if it is in their best interest (for research at the JBVAMC, the Chair will consult with the COS in making this decision)
- Change the following to correct any deficiencies and protect the rights and welfare of subjects:
  - [ ] Protocol
  - [ ] Consent document
  - [ ] Other, Specify:

Withdrawal of current subjects from research and, if deemed necessary (for research at the JBVAMC, the Chair will consult with the COS in making this decision):

- [ ] Transfer of subjects to another investigator;
- [ ] Arrange for clinical care outside of the research;
- [ ] Continue some research activities under the supervision of an individual monitor;
- [ ] Permit follow-up for safety reasons
- [ ] No additional safeguards necessary
- [ ] Follow-up procedures permitted or required by the IRB
- [ ] Reporting of unanticipated problems involving risks to subjects or others required if follow-up procedures are permitted.

Details:
## Termination: Actions to Protect Rights and Welfare of Subject

Section Not Applicable

### Recommend termination of research

<table>
<thead>
<tr>
<th>Yes</th>
<th>Is further action regarding the event needed?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>If YES, indicate below the actions that should be taken and provide details in the space provided:</td>
</tr>
</tbody>
</table>

- Notify current subjects of the termination through oral or written communications approved by the IRB
- Withdrawal of current subjects from research and, if deemed necessary (for research at the JBVAMC, the Chair will consult with the COS in making this decision):
  - transfer of subjects to another investigator;
  - arrange for clinical care outside of the research;
  - continue some research activities under the supervision of an individual monitor;
  - permit follow-up for safety reasons
  - no additional safeguards necessary
- Follow-up procedures permitted or required by the IRB
- Reporting of unanticipated problems involving risks to subjects or others required if follow-up procedures are permitted.

### Details:

### Comments. *(Write comments in space provided; attach additional sheet of paper, if necessary.)*

---

Signature ___________ Date ___________

Printed Name ___________
Research Protocol No.: 
Investigator Full Name: 
Research Protocol Title: 
Performance Sites: UIC  JBVAMC  Other: Specify__________

Meeting Date: Site: UIC  JBVAMC  IND/IDE/HDE Number:________
Date of use of test article: Name of Investigational Drug, Device or Biologic:

**IRB MEMBER REVIEW**

Verification by IRB Chair, Designated Member of the IRB or OPRS Director that all of the following criteria for emergency use of a test article at 21 CFR 56.102(d) are met.

- The individual is confronted by a life-threatening, including severely debilitating, disease or condition requiring the use of the test article.
- No standard acceptable treatment is available.
- There is not sufficient time to obtain IRB review and approval prior to use of the test article.
- This is the first emergency use of this test article at UIC or JBVAMC, or this would be the second use of the test article and the IRB has not had sufficient time to convene a meeting to review this issue.
- The activity is not a systematic investigation designed to develop or contribute to generalizable knowledge.

Has (will) informed consent been (be) obtained?  Yes  No
Note: Informed consent is required, unless the exception for the requirement of informed consent is met. The requirements for consent process and consent documentation are the same as any other FDA-regulated research study.

If no, the IRB Chair, Designated Member of the IRB or OPRS Director verifies that all of the following criteria from 21 CFR 50.23(a) are met:

- The individual is confronted by a life-threatening situation necessitating the use of the test article.
- Informed consent cannot be obtained from the individual because of an inability to communicate with, or obtain legally effective consent from, the individual.
- Time is not sufficient to obtain consent from the individual’s legal representative.
- There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.
- The above certifications have been obtained from: the investigator physician who is not otherwise involved in the research.

**Reviewer Determination**

Check the appropriate box. Return this form and all the references copies of the research protocol and consent form(s) to the OPRS staff.

- Acknowledge emergency use of test article
  - I concur that emergency use of the investigational agent is warranted and meets FDA requirements at 21 CFR 56.102(d).
  - I concur that the exceptions for the requirement for informed consent at 21 CFR 50.23(a) are met.
☐ Modification(s) or additional information required *

☐ Proposed use does not qualify as an emergency use (provide the rationale below)

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* List any modifications or additional information required for the research protocol and/or the consent form below. Please write clearly ALL the modifications or additional information required and the reasons for your decision(s) so that the OPRS can communicate the information in the IRB’s letter to the investigator. When you require changes to the consent form, you may list them here or you may write the changes legibly directly on the consent form and make a note here that you have done so.

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Modifications/Additional Information Required:

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REVIEWER SIGNATURE:
Reviewer Signature:          Date:   
Printed Name:
**University of Illinois at Chicago**

**Emergency Use of a Test Article: Five-Day Follow-Up**

**Review Guide for IRB Members** (version #1.0, 7-15-2008)

### Research Protocol

- **No.:**
- **Investigator Full Name:**
- **Title:**

### Performance Sites:

- [ ] UIC
- [ ] JBVAMC
- [ ] Northwestern
- [ ] Other: Specify_____________

### Meeting Date:

- **Site:**
  - [ ] UIC
  - [ ] JBVAMC
- **IND/IDE/HDE Number:**

### Date of use of test article:

- **Name of Investigational Drug, Device or Biologic:**

---

**IRB MEMBER REVIEW**

Verification by IRB reviewer that **all** of the following criteria for emergency use of a test article at 21 CFR 56.102(d) are met:

- [ ] The individual was confronted by a life-threatening disease, including severely debilitating, or condition requiring the use of the test article.
- [ ] No standard acceptable treatment was/is available.
- [ ] There was insufficient time to obtain IRB review and approval prior to use of the test article.
- [ ] This was the first emergency use of this test article at UIC or JBVAMC, or this would be the second use of the test article and the IRB had insufficient time to convene a meeting to review this issue.
- [ ] The activity is not a systematic investigation designed to develop or contribute to generalizable knowledge.

Was informed consent obtained?  [ ] Yes  [ ] No

Note: Informed consent is required, unless the exception for the requirement of informed consent is met. The requirements for consent process and consent documentation are the same as any other FDA-regulated research study.

If no, the IRB Chair, Designated Member of the IRB or OPRS Director verifies that **all** of the following criteria from 21 CFR 50.23(a) for waiver of informed consent are met:

- [ ] The individual was confronted by a life-threatening situation necessitating the use of the test article.
- [ ] Informed consent could not be obtained from the individual because of an inability to communicate with, or obtain legally effective consent from, the individual.
- [ ] Time was insufficient to obtain consent from the individual's legal representative.
- [ ] There was available no alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the individual.
- [ ] The above certifications are obtained from the investigator and a physician who is not otherwise involved in the research.
Reviewer Determination
Check the appropriate box. Return this form and all the references copies of the research protocol and consent form(s) to the OPRS staff.

☐ Acknowledge emergency use of test article

☐ I concur that emergency use of the investigational agent is warranted and meets FDA requirements at 21 CFR 56.102(d).

☐ I concur that the exceptions for the requirement for informed consent at 21 CFR 50.23(a) were met.

☐ Modification(s) or additional information required *

☐ Proposed use does not qualify as an emergency use (provide the rationale below)

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* List any modifications or additional information required for the research protocol and/or the consent form below. Please write clearly ALL the modifications or additional information required and the reasons for your decision(s) so that the OPRS can communicate the information in the IRB’s letter to the investigator. When you require changes to the consent form, you may list them here or you may write the changes legibly directly on the consent form and make a note here that you have done so.

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Modifications/Additional Information Required:

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REVIEWER SIGNATURE:

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<tr>
<th>Reviewer Signature:</th>
<th>Date:</th>
</tr>
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<tbody>
<tr>
<td>Printed Name:</td>
<td></td>
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</tbody>
</table>
Lapse of IRB Approval

Expedited IRB Chair or Designee (version #1.1, 08/24/12)

Research Protocol Number:

Investigator Full Name:

Research Protocol Title:

Performance Sites:  □ UIC  □ JBVAMC  □ Northwestern  □ Other: Specify________

Lapse in IRB approval beginning midnight ________________

Risk Level
What is the level of the risk associated with this problem?

☐ Minimal: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

☐ Greater than minimal

Evaluation of Noncompliance
1. Did the event increase the risks to subjects, decrease the potential benefits, affect the validity of the research data or compromise the integrity of the human subject protection program?

☐ Yes  ☐ No

A response of YES may represent serious noncompliance.

2. Does the pattern of noncompliance observed with this protocol or investigator suggest a likelihood that instances of noncompliance will continue without intervention?

☐ Yes  ☐ No

A response of YES may represent continuing noncompliance.

☐ Further information needed.

Detail:

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Determination-Noncompliance

☐ Event does not represent non-compliance

☐ Event represents non-serious and non-continuing non-compliance
   Actions to be taken include:
   • None
   • Oversight or educational measures.
   • More frequent monitoring
   • Changes to protocol or consent
   • Modification of continuing review schedule
   • Close study

Detail:
__________________________________________________________________________________________
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☐ Event likely represents serious and/or continuing non-compliance and is referred to convened IRB for a final determination.
   Is suspension of all or part of the research or other actions needed to protect the rights and welfare of subjects until the convened IRB meeting?  ☐ Yes  ☐ No

If yes, describe:
__________________________________________________________________________________________
__________________________________________________________________________________________
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__________________________________________________________________________________________
__________________________________________________________________________________________

IRB Chair or Designee Signature:

Signature:  Date:

Printed Name:
**Review Guide Lapse of IRB Approval Convened** (version #1.1, 08/24/12)

<table>
<thead>
<tr>
<th>Research Protocol Number:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Investigator Full Name:</td>
<td></td>
</tr>
<tr>
<td>Research Protocol Title:</td>
<td></td>
</tr>
<tr>
<td>Performance Sites:</td>
<td>UIC</td>
</tr>
</tbody>
</table>

**Lapse in IRB approval beginning midnight ______________________**

**Risk Level**
What is the level of the risk associated with this problem?
- [ ] Minimal: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests
- [ ] Greater than minimal

**Evaluation of Noncompliance**

1. Did the event increase the risks to subjects, decrease the potential benefits, affect the validity of the research data or compromise the integrity of the human subject protection program?
   - [ ] Yes
   - [ ] No

   A response of YES may represent serious noncompliance.

2. Does the pattern of noncompliance observed with this protocol or investigator suggest a likelihood that instances of noncompliance will continue without intervention?
   - [ ] Yes
   - [ ] No

   A response of YES may represent continuing noncompliance.

**Determination-Noncompliance**
- [ ] Event does not represent non-compliance
- [ ] Event represents non-serious and non-continuing non-compliance
  - Actions to be taken include:
    - [ ] None
    - [ ] Oversight or educational measures.
    - [ ] More frequent monitoring
    - [ ] Changes to protocol or consent
    - [ ] Modification of continuing review schedule
    - [ ] Close Study

- [ ] Further information needed.

**Detail:**
____________________________________________________________________________________
______________________________________________________________________________________
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______________________________________________________________________________________
☐ Event represents serious non-compliance.
☐ Event represents continuing non-compliance.
   Actions to be taken for a finding of serious and/or continuing noncompliance include:
   ☐ Suspension of part or all of research (address further actions under suspension below)
   ☐ Termination of research approval (address further actions under termination below)
   ☐ Notification of currently enrolled subjects (required when information related to the non-compliance issue may relate to the subject’s willingness to continue to participate in the research)
   ☐ Imposition of ethics and/or human subjects research education for the investigator and/or research staff
   ☐ Modification of the protocol or consent process
   ☐ Providing information to past participants
   ☐ Requiring re-consent of current participants
   ☐ Modification of the continuing review schedule
   ☐ Monitoring of the research
   ☐ Monitoring of the consent process
   ☐ Referral to other UIC officials or committees for possible review
   ☐ Other

   Detail:

☐ Further information needed.

Detail: __________________________________________________________
__________________________________________________________
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IRB Reviewer Signature:

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Date:</th>
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</table>

Printed Name:
# Final Report

**Review Guide Checklist**

University of Illinois at Chicago ● Office for the Protection of Research Subjects ● Version 2.0, dated February 20, 2012

<table>
<thead>
<tr>
<th>Research Protocol #:</th>
<th>Investigator Full Name:</th>
<th>Research Protocol Title:</th>
</tr>
</thead>
</table>

**Instructions:**
- Please fill in the check boxes.
- Please indicate any clarifications or further information required to address the statements below.
- If you complete this form, you are confirming that you do not have a conflict of interest and either you (for expedited) or the IRB (for convened) have the appropriate expertise to review this research.

## 1 Site.

<table>
<thead>
<tr>
<th>Site</th>
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<tbody>
<tr>
<td>UIC</td>
</tr>
<tr>
<td>JBVAMC</td>
</tr>
</tbody>
</table>

## 2 Current Research Status.

<table>
<thead>
<tr>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research was never initiated or research was initiated but no subjects were enrolled</td>
</tr>
<tr>
<td>Research completed at UIC, no further data collection &amp; analysis of identifiable or coded data</td>
</tr>
<tr>
<td>Research terminated by the investigator</td>
</tr>
<tr>
<td>Research terminated by the Faculty Sponsor/Department Head</td>
</tr>
<tr>
<td>Research terminated by the sponsor</td>
</tr>
</tbody>
</table>

## 3 Since the last review, is there any information as to the results or findings, publications, or other relevant information that requires any clarification from the investigator or that should be provided to the subjects?

<table>
<thead>
<tr>
<th>Clarification</th>
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<tbody>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
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</tbody>
</table>

## 4 Since the last review, are there any issues related to the informed consent process, subject enrollment or demographics, subject complaints, subject withdrawals, subjects declining to participate in the research, or suspension of subject enrollment that need to be clarified by the investigator?

<table>
<thead>
<tr>
<th>Clarification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
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<tr>
<td>No</td>
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</tbody>
</table>

## 5 Were any adverse events, unanticipated adverse events, protocol deviations or violations that occurred since the last review properly handled in accordance with UIC policy and procedure?

<table>
<thead>
<tr>
<th>Handling</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA - No events occurred</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
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</tbody>
</table>

## 6 Are there any regulatory or compliance issues to address based on the final report?

<table>
<thead>
<tr>
<th>Clarification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
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<tr>
<td>No</td>
</tr>
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</table>
### Retention/Disposition of Data/Specimens

- Data and/or specimens will be stripped of personal or private identifiers and the key destroyed.
- De-identified data and/or specimens will be maintained indefinitely under the supervision of the PI.
- Data and/or specimens will be added to an existing data bank/repository.
- Audio and/or video recordings will be transcribed and then destroyed or modified to eliminate the possibility that study participants could be identified.
- Personal or private identifiers and/or codes linking the data and/or specimens to identifiers will be maintained in a secure manner only to fulfill Sponsor agreement and/or regulatory requirements, but no future research will be conducted.
- Other (explain)

### Will the data/specimens will be managed in an appropriate manner?

- Yes
- No

### Determination.

- Approved: Research was **never initiated or no subjects were enrolled**, appropriate signatures obtained
- Approved: Research is **completed** and the final report/ additional information provided is adequate
- Approved: Research is **terminated** and the final report/ additional information provided is adequate
- Modifications Required

**Comments.** *(Write comments in space provided; attach additional sheet of paper, if necessary.)*

- Accept pre-review comments
- Accept pre-review comments with modifications
- Do not accept pre-review comments

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