The TVAMC Human Research Protection Program (HRPP) Standard Operating Procedures #5 provide for review of research involving human subjects exempt under federal regulations. The exempt categories and exceptions are described in this form. This form must be submitted with the Checklist for Submission of Research Study and other related research project application materials. The IRB Chair (or his/her designated experienced IRB member) will review and make a recommendation regarding exemption from IRB oversight. Exempt research approved by the Chairs of the IRB and R&D Committee is in accordance with the requirements outlined in the TVAMC HRPP SOP and federal regulations. If you have questions regarding whether or not your research may qualify for Exemption, please call the Coordinator of R&D at ext. 3819, prior to submission of this form.

HOW TO USE THIS FORM: This form is a Word document. Save the document first before filling it out. Use the “TAB” key to move to the next item. Double click on checkboxes and click on “Checked” then OK.

<table>
<thead>
<tr>
<th>CERTIFICATION OF EXEMPTION</th>
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<tr>
<td>NAME OF PRINCIPAL INVESTIGATOR AND DEGREES HELD:</td>
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<td>TELEPHONE NO. AND EXTENSION:</td>
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<tr>
<td>STUDY COORDINATOR/CONTACT PERSON: (Check box if you prefer that all correspondence be sent to this person)</td>
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<td>E-MAIL ADDRESS:</td>
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<td>TELEPHONE/PAGER NO. OF STUDY COORDINATOR/CONTACT PERSON:</td>
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<td>STUDY TITLE:</td>
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1. Please indicate the category(ies) under which this research project qualifies for exemption. Please refer to the categories below for a description of the exempt categories.

   [ ] 1    [ ] 2    [ ] 3    [ ] 4    [ ] 5    [ ] 6

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Research Qualifying for Exemption from Federal Regulations for the Protection of Human Subjects

[Quoted directly from the Code of Federal Regulations, Title 38, Part 16.101(b).]

1. **Educational Research Conducted in Educational Settings:** “Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   (i) research on regular and special education instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”

2. **Survey/Interview/Observational Research:** “Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, UNLESS:
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects

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AND
(ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability or reputation.

3. **Survey/Interview Research not Exempted in 2 Above:** "Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2.ii. of this section, if:
(i) the human subjects are elected or appointed public officials or candidates for public office; or
(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter."

4. **Secondary Use of Existing Data:** "Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

5. **Evaluation and Demonstration Projects of Federal Programs:** “Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, which are designed to study, evaluate, or otherwise examine:
(i) public benefit or service programs
(ii) procedures for obtaining benefits or services under those programs
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs

*Note:* The research or demonstration project for this category must be conducted pursuant to specific federal statutory authority *(such as the Under Secretary for Health on behalf of the Secretary of Veterans Affairs, after consultation with Office of Research and Development, the office of Research Oversight, the Office of General Counsel, and other experts, as appropriate); have no statutory requirement that the project be reviewed by an IRB; not involve significant physical invasions or intrusions upon the privacy interests of participants, and have authorization or concurrence by the funding agency.

6. **Taste and Food Quality Studies:** “Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) of the Food Safety and Inspection Service of the U.S. Department of Agriculture. This also applies to FDA regulated research.

*Note:* These exemptions are not available for all kinds of research (38CFR16.101(i)). Restrictions based on the populations to be studied exist: No research involving prisoners, or focused primarily on pregnant women, human in vitro fertilization or fetuses may be exempted, and research that falls in category 2. may not be exempted when children are subjects if the investigator will interact with the child, as in survey or interview research.
2. Human Subjects:
   A. Are any subjects under 19 years of age involved?  ☐ YES  ☐ NO
   B. Are personally identifiable records (medical (CPRS or paper), academic, etc.) used without written consent?  ☐ YES  ☐ NO
   C. Are data from subjects (responses, information, specimens) directly or indirectly identifiable?  ☐ YES  ☐ NO
   D. Are data damaging to subjects’ financial standing, employability or reputation?  ☐ YES  ☐ NO
   E. Is material obtained at autopsy used in the research?  ☐ YES  ☐ NO

Investigator Assurances

1. I certify that the information provided, regarding the proposed research project is complete and accurate.
2. I certify to the best of my ability that this research project qualifies for exemption from IRB oversight and review.
3. The research project will be conducted in accordance with institution policies and state and federal regulations.
4. Any proposed modification(s) to this research project, which may no longer qualify the research project to be exempt from human subjects regulations and IRB oversight will be immediately reported to the VA TVAMC IRB and R&D Committee approvals will be sought prior to implementation.

_____________________________________________________  ________________________
PRINCIPAL INVESTIGATOR  Date

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☐ DISAPPROVED

☐ Concur with PI’s determination of exempt category. (______________). This research project qualifies for an exemption from IRB oversight and review based on the categories of exempt research as stipulated in 38 CFR 16.101 (b).

_____________________________________________________  ________________________
IRB MEMBER REVIEWER (IF DIFFERENT FROM THE CHAIR)  Date

_____________________________________________________  ________________________
IRB CHAIR  Date

_____________________________________________________  ________________________
RESEARCH & DEVELOPMENT COMMITTEE CHAIR  Date