

**Department of Veterans Affairs
Tuscaloosa VA Medical Center**

Human Research Protection Program SOP #5

October 11, 2007

EXEMPT RESEARCH

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to the mission of fostering a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the TVAMC. In addition, the TVAMC HRPP is committed to providing an efficient, ethical and safe mechanism for review of research protocols and their amendments, including the use of a review process for a limited class of research that are exempt from applicable federal, state, and local regulations.

It is the policy of the TVAMC HRPP to ensure that the applicable federal, state, and local regulations are carried out in protecting the rights and welfare of subjects who participate in research. This Standard Operating Procedures (SOP) is a written documentation of the procedures for determining when studies are exempt from applicable federal, state, and local regulations and for addressing protection of participants in research deemed exempt. This policy establishes procedures for a review process for exempt research that is conducted in accordance with the requirements of the TVAMC HRPP and federal regulations.

2. RESPONSIBILITIES

TVAMC Medical Center Director: The Director is the responsible Institutional Official who maintains ultimate responsibility for oversight of all research at the TVAMC.

Coordinator for Research and Development (C/R&D) and R&D Administrative Officer (R&D AO): The C/R&D and R&D AO maintain responsibility for procedures, policies, and execution of the research program (including review of exempt research) conducted at the TVAMC.

IRB Chairperson: On behalf of the IRB, the IRB Chairperson is responsible for review and determination of exempt status or is responsible for designating the review and determination to an experienced IRB member. The IRB Chairperson may grant approval, approval with stipulations/modifications, or referral to the full IRB board for review and determination at a convened IRB meeting.

Experienced IRB members: Experienced IRB members are those IRB members who have at least 6 months of experience working on the IRB. Experienced IRB members are

designated by the IRB Chairperson to conduct reviews of research for exempt status and are responsible for the thorough review and recommendation to the Chairperson for approval, approval with stipulations/modifications, or referral to the full IRB board.

Principal Investigators (PI): The PI must abide by this HRPP SOP when applying for determination of research that meets the appropriate definitions and limits described in this SOP for exempt research.

3. DEFINITIONS OR CRITERIA

- a. **Exempt Research:** Research from one of the approved categories listed below is considered exempt from review by the IRB. The exempt categories of research define types of research for which the IRB regulations do not apply.
- b. **Specific Categories of Exempt Research** listed in [38 CFR 16.101(b)(1-6i)] and VHA Handbook 1200.5 Appendix A are:
 1. 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. 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; 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, loss of insurability, or reputation.
 3. 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) 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. Research, involving the collection or study of existing data documents, records, pathological specimens, or diagnostic specimens, if these specimens 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. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and 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 evaluation and consumer acceptance studies,
 - (i) If wholesome foods without additives are consumed or
 - (ii) 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

4. PROCEDURES

- a. **The Submission of Exempt Research:** The investigator submits the application using the identical initial review requirements along with the Application for Review of Exempt Research requesting approval of exempt status and providing the information needed to judge eligibility for exempt status (i.e. naming the applicable criteria listed above that defines the research study). For approval of exempt status, the research must meet one or more criteria listed above.
- b. **The Review of Exempt Research:** The IRB Chair or designated experienced IRB member reviews the submission to determine if a study meets the above listed criteria for exemption from IRB review. Exempt determinations are not to be made by investigators or others who might have an apparent or real conflict of interest regarding the study. The review must be conducted in a timely fashion, the determination must be based on the criteria for exemption listed above, and the decision must be recorded in writing. The IRB Chairperson or designee may grant approval, approval with stipulations/modifications, or referral to the full IRB for review and determination at a convened IRB meeting. The justification for the exemption (i.e. category) and action are documented in a memo to the investigator and communicated to the IRB and the R&D in the agenda and minutes.
- c. **Research Not Allowed for Exempt Status:** Studies involving pregnant women may not be considered exempt. Studies involving the use of FDA regulated products may not be considered for an exemption from IRB regulation unless the PI receives a written waiver from the FDA [21 CFR 56.105]. Even if the FDA grants a waiver from IRB review, the IRB may still require submission, review and approval of the

study. The TVAMC does not conduct research or allow exempt research on children or prisoners.

- d. **Procedures for addressing Protection of Participants in Exempt Research:** When a research study is determined to be exempt, there are no regulatory requirements. For example, there is no requirement for IRB review or informed consent. There is also no regulatory prohibition against the use of coercion, undue influence or deception to recruit participants. The categories are based solely on methods of research and do not take the level of risk into consideration. Although most exempt research requires no further oversight to be conducted ethically, some exempt research raises ethical concerns or requires measures to protect participants (i.e. observational studies on person drinking alcohol in public and how groups make decisions on who will drive the car). It is imperative that human research participants receive the highest level of protection possible and that any questions or any legal or ethical ambiguities always be resolved in favor of the human research participant. The Chairperson or designee who makes the determination of exemption and may also request modifications or stipulations that address any ethical issues or require that the PI include safety measures or procedures in the research for ethical protection of human subjects. These stipulations are communicated in writing, may require follow-up documentation of the modifications from the investigator in order to secure approval, and are communicated in writing to the IRB and R&D Committee.
- e. **Communication to the convened IRB and R&D Committee.** All actions taken through the review of exempt research will be reported to the convened IRB for review and if necessary, further discussion or action. If the item submitted does not meet criteria or eligibility for exempt review, the item is referred for review and action by the convened IRB. All actions taken regarding exempt research are reported in the IRB minutes as communication to all IRB members. As further communication, the R&D Committee subsequently reviews and accepts the IRB minutes.

5. **REFERENCES**

- VHA Handbook 1200.5 Appendix A
- 38 CFR 16.101
- 45 CFR 46.101
- 21 CFR 56.104

6. **ATTACHMENTS**

Application For Review Of Exempt Research

7. **RESCISSIONS**

HRPP SOP#5 dated May 7, 2007

8. **REVIEW DATE**

January 1, 2012

Signature on File in R&D Office

Lori L. Davis, MD

Coordinator of Research and Development