OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

GUIDANCE ON EXEMPT RESEARCH DETERMINATION

Date: October 20, 2014

SCOPE: Research activities in which the only involvement of human subjects will be in one or more of the categories outlined in 38 CFR 16.101(b), are exempt from the provisions of VHA Handbook 1200.05 and the Common Rule (38 CFR Part 16), including being exempt from IRB-approval requirements. The Common Rule exemptions at 38 CFR 16.101(b) may not be applied to FDA-regulated research (see 21 CFR 56.104 for exemptions applied to FDA-regulated research). Because of the potential for conflict of interest, investigators do not have the authority to make the exempt determination independently and must submit the proposed research to the IRB for a determination. The R&D Committee maintains oversight of all exempt research (VHA Handbook 1200.01).

1. What materials must be provided to the IRB?
2. Who may determine that the research is exempt?
3. Documentation of exempt status.
4. What should investigators do when considering changes to exempt studies?
5. What should the R&D Committee review?

1. WHAT MATERIALS MUST BE PROVIDED TO THE IRB?

The investigator must submit the proposed research study and the request for exemption to the IRB. The information submitted must provide sufficient detail to allow a reviewer to make a correct determination. An institution may craft a checklist for certain exemption categories, with questions that are easily answered “yes” or “no” by an investigator, with certain answers leading to a clear conclusion that the study is exempt. However, the proposed study materials must corroborate the statements on the checklist.

2. WHO FROM THE IRB MAY DETERMINE THAT THE RESEARCH IS EXEMPT?

Institutional policies and procedures should identify clearly who is responsible for making exemption decisions. This may be done in a variety of ways, including delegation by name, role, or position. Individuals authorized by the institution must have the appropriate training and experience to make an exemption determination. Generally, this would be the IRB Chair or an experienced IRB voting member designated by the Chair, but may include IRB administrators or IRB staff who have the appropriate training and experience to make a correct determination. Note that this decision may be audited by ORO or OHRP for compliance with the regulations.

3. DOCUMENTATION OF EXEMPT STATUS.

When an exemption determination is made, the specific exemption category or categories should be included in the IRB records and this information should be available for oversight and

audit purposes. Documentation must include the title of the proposed research study, who made the determination, and communication of the decision to the investigator. The R&D Committee must also receive documentation of the determination. If the request for exemption was denied, the communication with the investigator must include the reason for denial and a statement that a full IRB application must be submitted and approved before the research can begin.

4. WHAT SHOULD INVESTIGATORS DO WHEN CONSIDERING CHANGES TO EXEMPT STUDIES?

Investigators must consider whether changes to the exempt study would affect the exempt determination. Investigators may consult with the appropriate IRB authority whenever questions arise about whether planned changes to an exempt study might make that study nonexempt human subjects research. Prior to implementing any changes, investigators must file an amendment to the study with the appropriate research review committee according to local policy. The research review committee may require a formal review by the IRB for a determination that the study continues to meet exempt criteria as defined in VHA Handbook 1200.05.

5. WHAT SHOULD THE R&D COMMITTEE REVIEW?

The R&D Committee may establish a research review sub-committee for exempt research or serve as the research review committee itself. This committee or subcommittee must conduct initial and continuing review, and review of amendments or other changes to the research. The exempt research should be reviewed according to the review criteria established by local policy in accordance with VHA Handbook 1200.01. Exempt research must be reviewed annually according to local policy.

REGULATORY AND VHA POLICY REFERENCES:

38 CFR 16.101(b) – Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(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, 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 (b)(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 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) 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.

(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.

VHA Handbook 1200.05 – 5.d. Research activities in which the only involvement of human subjects will be in one or more of the Common Rule categories outlined in Appendix A, may be exempt from the provisions of this Handbook. ***NOTE:*** *The Common Rule exemptions may not be applied to FDA-regulated research (see 21 C.F.R. § 56.104 for exemptions applied to FDA-regulated research). The R&D Committee has oversight for all exempt research (see Handbook 1200.01).*
6.c. All research subject to this Handbook must be reviewed and approved by an IRB designated in the facility's FWA (the IRB of Record), and will be subject to continuing review and oversight by the IRB of Record. ***NOTE****: Research that meets the exempt categories are not subject to IRB review but must be reviewed by the R&D Committee (see Appendix A.).*

VHA Handbook 1200.01 -- The R&D Committee is responsible for establishing policy to ensure that all research in which the facility is to be engaged has been reviewed and approved for the ethical use of human subjects, animals, and biohazards. This review must promote:

(1) Maintenance of high standards of protocol review, and relevance to the mission of VA;
(2) Protection of human subjects (including privacy and confidentiality), and the implementation of adequate safety measures for research subjects and personnel;
(3) Welfare and appropriate use of animals in research;
(4) Safety of personnel engaged in research;
(5) Security of research laboratories where hazardous agents are stored or utilized and of all Biosafety Level 3 (BSL-3) research laboratories; and
(6) Security of VA data and VA sensitive information.

OHRP Guidance-- http://answers.hhs.gov/ohrp/categories/1564