EXEMPT RESEARCH

1. POLICY

The Birmingham VA Medical Center (BVAMC) 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 BVAMC. In addition, the BVAMC 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 BVAMC 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 BVAMC HRPP and federal regulations.

2. RESPONSIBILITIES

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

Associate Chief of Staff, Research and Development (ACOS/R&D): The ACOS/R&D maintains responsibility for procedures, policies, and execution of the research program conducted at the BVAMC.

IRB Chairperson: On behalf of the IRB, the IRB Chairperson is responsible for review and determination of exempt status (based on federal criteria for exemption) or is responsible for designating the review and determination to a qualified designee. 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.

Research and Development Committee (R&D Committee): The R&D Committee is responsible for the final review and approval of all studies determined to be Exempt from IRB review. The R&D Committee is responsible for continually reviewing the study on an annual basis to ensure the PI is continuing to follow VA, federal, state and local policies as they pertain to the research determined to be exempt from IRB review.
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

See SOP #24 – HRPP Definitions

4. EXEMPT RESEARCH CRITERIA

Exempt activities must follow the requirements of this section and as specified in the applicable exempt categories listed below.

A. There are six categories of exempt research activities described below for research that is subject to the pre-2018 Requirements. NOTE: None of the exempt research categories in the pre-2018 Requirements include a provision for use of a limited IRB review.

B. There are eight categories of exempt research activities described that must be compliant with the 2018 Requirements. Four of the categories include a provision for use of a limited IRB review.

Exempt determinations may be made by the IRB Chair, an experienced IRB member, or qualified administrative staff with expertise in applying human research exempt regulations. NOTE: If the exempt activity involves PHI, a waiver of HIPAA authorization must be approved by the appropriate authority (IRB or Privacy Board or designated member of the IRB or Privacy Board), a written HIPAA authorization must be obtained from the subject or subject’s LAR or a DUA for use or disclosure of a limited data set must be obtained.

For exempt research activities involving the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally: (1) The activity is research; (2) Participation is voluntary; (3) Permission to participate can be withdrawn; (4) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and (5) Contact information for the VA Investigator.

If an exempt activity requires a limited IRB review, the limited IRB review must be completed prior to approval by the R&D Committee. When a limited IRB review is conducted, the IRB is not required to evaluate whether all of the IRB approval criteria in this SOP are satisfied. When a limited IRB review is required for an exempt activity as described in this SOP, the IRB must review the research to ascertain whether specific IRB approval criteria are met as described in this SOP. Exempt categories 2 and 3 listed below require use of a limited IRB review if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. The IRB is required to
conduct a limited review to make the determinations required i.e., to determine that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data). Exempt categories 7 and 8 always require use of a limited IRB review and broad consent. (1) Research activities described in exempt category 7 require that an IRB conduct a limited review and make the determination required. Research activities described in exempt category 8 require an IRB to conduct a limited review to make the determinations required (i.e., to determine that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data). Additionally, the exemption requires that an IRB conduct a limited review to make the determination that the research to be conducted is within the scope of the broad consent under which the identifiable private information or identifiable biospecimens were collected. The following requirements must also be satisfied and documented as part of the limited IRB review for exempt category that (a) Broad consent was obtained in accordance with this SOP and (b) Documentation of informed consent was obtained in accordance with this SOP. Limited IRB review for applicable exempt activities may be done by the convened IRB, the IRB Chair, or delegated to one or more experienced reviewers from among voting IRB members. Research determined to be exempt requires approval by the R&D Committee and requires continuing review by the R&D Committee as required by VHA Directive 1200.05 unless it is under the oversight of another subcommittee (e.g., Safety Review Subcommittee).

Specific Categories of Exempt Research

Pre-2018 Requirements listed in [38 CFR 16.101(b)(1-6i)] and VHA Directive 1200.05 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) with out 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 and must be conducted pursuant to specific federal
statutory authority including no statutory requirement that the project be reviewed
by the IRB:

(i) Public benefit or service programs; (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).
(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 determination of exempt status for these research and demonstration
projects must be made by 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.

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.

2018 Requirements listed in [38 CFR 16.104(d)(1-8iv)] and VHA Directive
1200.05 Appendix B are:

1. Research, conducted in established or commonly accepted educational settings,
that specifically involves normal educational practices that are not likely to
adversely impact students' opportunity to learn required educational content or the
assessment of educators who provide instruction. This includes most research on
regular and special education instructional strategies, and research on the
effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §16.111(a)(7).

3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

   (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

   (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

   (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §16.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.
(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

   (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.
(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
(ii) [Reserved]

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.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §16.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
   (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §16.116(a)(1) through (4), (a)(6), and (d);
   (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §16.117;
   (iii) An IRB conducts a limited IRB review and makes the determination required by §16.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

5. PROCEDURES
   a. The Submission of Exempt Research: The investigator submits the Request for Exemption Form along with a copy of the protocol and any other applicable documents (i.e. consent form, HIPAA waiver, survey). For approval of exempt status, the research must meet one or more criteria listed above.
b. The Review of Exempt Research: The IRB Chair, an experienced IRB member, or qualified administrative staff with expertise in applying human research exempt regulations (who do not have an apparent or real conflict of interest regarding the study) 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 investigator(s). 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 to the investigator. 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. The R&D Committee must approve the study for IRB Exemption prior to initiation and must review and approve the study on an annual basis.

c. Research Not Allowed for Exempt Status: For Pre-2018 requirement, studies involving pregnant women may not be considered exempt and the BVAMC does not conduct research or allow exempt research on children or prisoners. The 2018 Exemption Requirements do not apply to research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners. For children, 2018 Exempt category 2a. and b. may only apply to research subject to 45 CFR 46, Subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph 2.b.(3) of this section may not be applied to research subject to 45 CFR 46, Subpart D.

d. Procedures for Addressing Protection of Participants in Exempt Research:
When a research study is determined to be exempt, the Information Security Officer and Privacy Officer are required to review the research to assure that protection is in place to protect subjects and their data (including PHI, sensitive and non-sensitive information). There are no other 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 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.

f. **Continuing Review.** The R&D Committee subsequently reviews and approves Exempt studies, initially and must review annually. Request for continuing review must be sent to the R&D Committee program support assistant.

6. **REFERENCES**
   - VHA Directive 1200.05 Appendix A
   - VHA Directive 1200.05 Appendix B
   - VHA Directive 1200.01 Research and Development Committee
   - 38 CFR 16.104
   - 38 CFR 16.101
   - 38 CFR 16.107(f),
   - 21 CFR 56.104
   - 21 CFR 56.105
   - 21 CFR 56.102
   - 45 CFR 46.101

7. **ATTACHMENTS**
   Request for Exemption Form

8. **RESCISSIONS**

9. **REVIEW DATE**
   January 1, 2020

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Louis Dell’Italia, MD
ACOS, Research and Development