Veterans Health Administration
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Addendum:
Exemptions and Expedited Review Categories

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Exemption for Educational Research [38 CFR 16.101(b)(1)]

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  - research on regular and special education instructional strategies, or
  - research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

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Exemption for Educational Tests, Surveys, Interviews, Observations [38 CFR 16.101(b)(2)]

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - 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.

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Exemption for Educational Tests, Surveys, Interviews, Observations of Public Officials or When Identity is Protected by Law [38 CFR 16.101(b)(3)]

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - 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.

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Exemption for Research on Existing Data, Unlinked to Subjects [38 CFR 16.101(b)(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.

Exemption for Research on Public Benefit Programs [38 CFR 16.101(b)(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:
  - Public benefit or service programs;
  - 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.

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Exemption for Research on Taste and Food Quality [38 CFR 16.101(b)(6)]

- 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 or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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Drugs and Devices (Expedited Review Category Number 1)

- Clinical studies of drugs and medical devices if one of the following conditions are met:
  - The research is on drugs for which an IND application (21 CFR Part 312) is not required.
  - The research is on medical devices for which:
    - an investigational device exemption (IDE) application (21 CFR 812) is not required; or
    - the medical device is cleared or approved for marketing, and the medical device is being used in accordance with its cleared or approved labeling.

Blood Samples
(Expedited Review Category Number 2)

- Blood samples are collected by finger stick, heel stick, ear stick, or venipuncture as follows:
  - From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 milliliters (ml) in an 8-week period, and collection may not occur more frequently than two times per week.

Blood Samples
(Expedited Review Category Number 2)

- Blood samples are collected by finger stick, heel stick, ear stick, or venipuncture as follows:
  - 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 kilogram (kg) in an 8-week period, and collection may not occur more frequently than two times per week.

Noninvasive Collection of Biological Specimens (Expedited Review Category Number 3)

- Biological specimens for research purposes are to be collected prospectively by noninvasive means. Examples are as follows:
  - Hair and nail clippings in a non-disfiguring manner;
  - Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
  - Permanent teeth if routine patient care indicates a need for extraction;
  - Excreta and external secretions (including sweat.)

Noninvasive Collection of Biological Specimens (Expedited Review Category Number 3)

- Biological specimens for research purposes are to be collected prospectively by noninvasive means. Examples are as follows:
  - Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
  - Placenta removed at delivery;
  - Amniotic fluid obtained at the time of rupture of the membrane prior to, or during, labor.

Noninvasive Collection of Biological Specimens (Expedited Review Category Number 3)

- Biological specimens for research purposes are to be collected prospectively by noninvasive means. Examples are as follows:
  - Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
  - Sputum collected after saline mist nebulization.

Noninvasive Collection of Data (Expedited Review Category Number 4)

- Data must be collected through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared or approved for marketing.

NOTE: Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples of noninvasive collection of data are: (continued on next slides…)

Noninvasive Collection of Data (Expedited Review Category Number 4)

- ***Examples of noninvasive collection of data are:***
  - Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
  - Weighing the subject;
  - Testing sensory acuity;
  - Magnetic Resonance Imaging (MRI.)

Noninvasive Collection of Data (Expedited Review Category Number 4)

- ***Examples of noninvasive collection of data are:***
  - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
  - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual.

Collected Materials
(Expedited Review Category Number 5)

- Research involves:
  - Materials (data, documents, records, or specimens) that have been collected for any purpose, including previous research; or
  - Materials (data, documents, records, or specimens) that will be collected solely for nonresearch purposes (such as medical treatment or diagnosis.)

NOTE: Some research in this category may be exempt from the VA regulations for the protection of human subjects (38 CFR 16.101(b)(4)). This listing refers only to research that is not exempt

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Collection of Data From Voice, Video, or Photographs for Research Purposes (Expedited Review Category Number 6)

- Collection of data from voice, video, or photographs for research purposes

Note: See paragraph 55 of VHA Handbook 1200.05 for additional information

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Group Characteristics, Surveys, Interviews, and Quality Assurance (Expedited Review Category Number 7)

- Research must be 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 will employ survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

NOTE: Some research in this category may be exempt from the VA regulations for the protection of human subjects (38 CFR 16.101(b)(2) and (b)(3)). This listing refers only to research that is not exempt.

Previously-approved Research (Expedited Review Category Number 8)

- Research which has previously been approved by the convened IRB where:
  - No subjects have been enrolled and no additional risks have been identified; or
  - The research is permanently closed to the enrollment of new subjects; and
    - All subjects have completed all research-related interventions; and/or
    - The research remains active only for long-term follow-up of subjects; and/or
    - The remaining research activities are limited to data analysis.

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Minimal-risk Research (Expedited Review Category Number 9)

- Minimal-risk research is research not conducted under an IND application or IDE, and where the categories two (2) through eight (8) do not apply, and 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.