# CARILION CLINIC INSTITUTIONAL REVIEW BOARD
# Standard Operating Guidelines

| **Title:** 2.6: Review of Research: EXEMPT HUMAN SUBJECTS RESEARCH | |
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| **Original Date:** January 2006 | **Date of Last Revision:** 02-07, 01-08, 8-14, 8-23 |
| **Primary Sponsor:** Human Research Protections Office | **Approved By:** Director of the Human Research Protections Office |

## Objective:

To provide guidance on what qualifies a research submission as exempt research, and how to submit a research proposal that may be exempt to the Carilion Institutional Review Board (IRB).

## General Description:

One of the roles of the Carilion IRB is to determine whether or not a research proposal can be classified as exempt human subjects research. Research that may qualify as exempt is generally research involving educational, behavioral or social science studies that present little or no risk to the study subjects, or research involving existing data, medical records or pathological specimens, especially if subject identifiers are removed from the data.

## Procedure:

All proposed research, even if it is believed to be exempt research, is submitted to the IRB on the IRB Research Application, which can be found on the Carilion website by going to Departments, IRB and forms. Forms may also be obtained from the IRB office. All appropriate sections of the form must be filled out prior to submission.

If it is believed that research may be expedited (see attached pages), the following information must be uploaded with the PRIS3M submission:

- IRB Research Application*
- Consent form or research subject information sheet, if applicable
- Any additional literature or information
- Any surveys or data collection tools to be used with research, if applicable
- Principal Investigator's Curriculum Vitae received within 2 years from study submission
- All other study related materials, as applicable

**Note: Unless the study is sponsored or if the researcher will use a separate protocol to conduct his or her research, the IRB will consider the IRB Research Application to be the study protocol.*

Once all documentation is received, the IRB staff will review the research submission in PRISM. The IRB may request additional information as it determines to be appropriate.

The Human Protections Administrator (HPA) or his/her designee will then review the research

protocol. Upon exempt determination, a letter will be sent to the Principal Investigator stating that the research has been found to be exempt. Copies of this letter will be sent to the Research and Development Department, the Institutional Official, if appropriate, and another copy will be kept on file. If significant changes are made to the project the IRB should be notified to make sure that it still qualifies as exempt. For changes, a Research Change/Update Form with the pertinent information should be submitted.

To help you determine whether research may be exempt, 21 CFR 56.104 and 45 CFR 46.101 are listed below.

It is possible that some projects may not need IRB review. However, they should be submitted to the IRB so that it can be determined whether they need review or not.

## From the Code of Federal Regulations Title 21 Part 56.104

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations 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.

## From the Code of Federal Regulations Title 45 Part 46.101

(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, 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 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 cannot be identified, directly or through identifiers linked to the subjects; or(ii) any disclosure of the

human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, 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 §46.111(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 §46.111(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) & (8) Carilion Clinic does not currently use these Exempt categories.