

Conduct of Human Subjects Research

Policy Type: Administrative

Responsible Office: Office of Human Research Protection Program, Office of Research and Innovation

Initial Policy Approved: 02/05/2015

Current Revision Approved: 04/09/2018

Policy Statement and Purpose

Human subjects research at Virginia Commonwealth University and the Virginia Commonwealth University Health System Authority, hereafter collectively referred to as "VCU," must be carried out in accordance with applicable laws, regulations, and the highest ethical standards. As applicable, human subject research must be conducted in compliance with the following federal regulations: 45 CFR 46, 21 CFR 50, 21 CFR 312, 21 CFR 812, and 21 CFR 54.

VCU authority to conduct human subjects research is granted by a Federalwide Assurance (FWA) with the Department of Health and Human Services' Office for Human Research Protections (DHHS/OHRP). VCU's FWA number is FWA00005287.

The VCU FWA, as signed by the vice president for research and innovation of the university, requires prior Institutional Review Board (IRB) approval of all human subjects research, including research that may qualify as exempt, if the activity:

1. Is sponsored by VCU, or
2. Is conducted by or under the direction of any employee or agent of VCU in connection with their institutional responsibilities, or
3. Is conducted by or under the direction of any employee or agent of VCU using any property or facility of VCU.

Some non-research activities may require IRB approval, such as expanded access uses (FDA 21 CFR 312 Subpart I) and emergency use (FDA 21 CFR 56.102(d), 56.104, and 312.36) of investigational drugs or devices.

Noncompliance with this policy may result in disciplinary action up to and including termination. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

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Who Should Know This Policy

All individuals involved in human subjects research are responsible for knowing this policy and familiarizing themselves with its contents and provisions.

Definitions

Clinical Investigation

Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. [21 CFR 50.3]

Human Subject

The Code of Federal Regulations (Section 102(f) of 45 CFR 46) defines "human subject" as a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

Human Subjects Research

Only activities that meet the definition of both "human subjects" and "research" or "human subjects" and "clinical investigation" are considered human subjects research.

Interaction

Interaction includes communication or interpersonal contact between investigator and subject.

Intervention

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Minimal Risk

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [45 CFR 46.102(i)]

Private Information

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information). [45 CFR 46.102(f)]

Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. [45 CFR 46.102(d)]

Contacts

The Office of Human Research Protection Program officially interprets this policy. The Office of Human Research Protection Program is responsible for obtaining approval for any revisions as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Please direct policy questions to the Office of Human Research Protection Program.

Policy Specifics and Procedures

All human subjects research or clinical investigations must be submitted for review and approval by a VCU IRB or a VCU-approved external IRB before the research may begin. IRB approval is specific to the human subjects research or clinical investigation reviewed by the IRB. Protocols established by an IRB review may not be used to conduct a different human subjects research study or clinical investigation without the approval of VCU IRB.

All new research studies must be submitted for review through the RAMS-IRB electronic system. The following types of review are available:

1. Full IRB Review by the VCU IRB

Full IRB review and approval is conducted by the full board at a convened IRB panel meeting. Research that is greater than minimal risk to subjects and/or does not qualify for one of the other review types listed below must be reviewed by the convened IRB. Research approved by the convened IRB is subject to

continuing review by the IRB at least annually. Proposed changes to approved research must also be approved by the IRB prior to implementation.

2. Expedited IRB Review by the VCU IRB

An expedited review may be conducted by a single IRB member. Research is eligible for expedited review when there is no more than minimal risk to subjects and when the research activity falls into one of nine categories identified in the federal regulations. Research determined to not qualify for expedited review requires full IRB board review. Research approved by the expedited procedure is subject to continuing review by the IRB at least annually. Proposed changes to approved research must also be approved by the IRB prior to implementation.

3. Exempt Review by the VCU IRB

Research that qualifies for exempt review is no greater than minimal risk to subjects and the study procedures fall into one of six categories identified in the federal regulations. Exemption determinations are made by a single member of the VCU IRB. Once determined to be exempt, proposed modifications to the research that would change the type of review (e.g., research no longer qualifies for exemption), must be submitted for review and approval prior to implementation. Exempt research does not require continuing review.

Assistance with IRB submissions may be obtained from the VCU Office of Human Research Protection Program or at the [IRB webpage](#).

Forms

Submission of new studies for IRB review and approval must be done electronically in the RAMS-IRB system. Templates and remaining supplemental paper forms may be obtained on the Office of Research and Innovation website.

1. [Current IRB Forms](#)

Related Documents

1. Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46)
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>
2. [VCU IRB Written Policies and Procedures](#)
3. Title 21, Part 50 of the Code of Federal Regulations (50 CFR 50)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1>
4. Title 21, Part 56 of the Code of Federal Regulations (50 CFR 56)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56&showFR=1&subpartNode=21:1.0.1.1.21.3>

5. Title 21, Part 812 of the Code of Federal Regulations (21 CFR 812)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=812&showFR=1&subpartNode=21:8.0.1.1.9.2>
6. Title 21, Part 312 of the Code of Federal Regulations (21 CFR 312)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?cfrpart=312>
7. [VCU Human Research website](#)

Revision History

This policy supersedes the following archived policies:

Approval/Revision Date	Title
02/05/2015	<i>Conduct of Human Subjects Research</i>

FAQ

1. What categories of research may be exempt?

In accordance with the federal regulations, the following categories of research may be exempt:

CATEGORIES OF EXEMPTION [5 CFR 46.101(b)]

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. WPP# VIII-1
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 [Exemption category (2) (above)] 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. [a][b]WPP #VIII-1
5. Research and demonstration projects which are conducted by or subject to the approval of [federal] 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. WPP #VIII-1

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.

2. What kinds of research activities qualify for expedited review?

The following research activities are listed in the federal regulations as qualifying for expedited review:

Categories For Expedited Review:

[HHS 45 CFR § 46.110](#)

[FDA 21 CFR § 56.110](#)

1. **Clinical studies of drugs and medical devices only when condition (a) or (b) is met.**
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. **Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:** (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) 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 kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. **Prospective collection of biological specimens for research purposes by noninvasive means.** Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) 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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. **Collection of data 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/approved for marketing. (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: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
 5. **Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).** (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)
 6. **Collection of data from voice, video, digital, or image recordings made for research purposes.**
 7. **Research 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 research employing 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 HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\) and \(b\)\(3\)](#). This listing refers only to research that is not exempt.)
 8. **Continuing review of research previously approved by the convened IRB as follows:** (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
 9. **Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply** but 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.