



# VCU

## Conduct of Human Subjects Research

**Policy Type:** Administrative

**Responsible Office:** Office of Research Subjects Protection

**Initial Policy Approved:** 02/05/2015

**Current Revision Approved:** New

### Policy Statement and Purpose

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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 should 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 of the University, requires prior 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 his or her 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 good faith concerns, asks clarifying questions, or participating in an investigation is prohibited.

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## Who Should Know This Policy

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

## Definitions

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### 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.

### 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.

### Interaction

Interaction includes communication or interpersonal contact between investigator and subject.

### 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**

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The Office of Research Subjects Protection officially interprets this policy. The Office of Research Subjects Protection 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 Research Subjects Protection.

## **Procedures**

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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. 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 should 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 and/or does not qualify for one of the other review types 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 such as the Chairperson of an IRB Panel or an experienced member of the IRB. 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 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 Research Subjects Protection or at the [RAMS-IRB webpage](#).

## Forms

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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 website.

1. [Current IRB Forms](#)

## Related Documents

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1. [Title 45, Part 46, of the Code of Federal Regulations \(45 CFR 46\)](#)
2. [VCU IRB Written Policies and Procedures](#)
3. [Title 21, Part 50 of the Code of Federal Regulations \(50 CFR 50\)](#)
4. [Title 21, Part 56 of the Code of Federal Regulations \(50 CFR 56\)](#)
5. [Title 21, Part 812 of the Code of Federal Regulations \(21 CFR 812\)](#)
6. [Title 21, Part 312 of the Code of Federal Regulations \(21 CFR 312\)](#)
7. [VCU Human Research website](#)

## Revision History

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This policy supersedes the following archived policies:

None – New Policy

## FAQs

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There are no FAQs associated with this policy and procedures.