



**VCU**

Office of Research and Innovation

# Human Subjects Research: Getting Started

Virginia Commonwealth University  
Office of Research and Innovation  
800 East Leigh St.  
PO Box 980568  
Richmond, VA 23298

# **Table of Contents**

## **Introduction to the IRB**

**Step 1:** Determining Human Subjects Research

**Step 2:** Required Training for Conducting Research at VCU

**Step 3:** Determining Exempt, Expedited, or Full Board Review

**Step 4:** Submission Process

**Step 5:** Post-Approval

---

# INTRODUCTION TO THE IRB

---

VCU identifies on its Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) . As of July 1, 2016, VCU will have a single IRB panel that meets **weekly** to review full board studies. Weekly meetings will be held 1st and 3rd Wednesdays, and 2nd and 4th Tuesdays (with some changes due to holidays). Expedited and exempt studies will be reviewed by in-house IRB analysts.

## IRB Overview

VCU's IRB panels review and approve research studies that involve human subjects in research. This document will provide detailed information on the submission process. The IRB ensures the rights and welfare of human subjects are protected and in compliance with federal, state, and institutional regulation. IRB panels are comprised of a variety of members that have different backgrounds, training and experience.

## What Can You Do?

Our goal is to reduce time to approval as much as possible. There are a few things PIs can do to expedite this process.

- 1) Respond to IRB staff or reviewer notes/questions as quickly as possible
- 2) Be available the day before full board meetings, and during full board meetings (by phone or in person visit) to answer critical questions IRB members may have regarding your study.
- 3) Request an IRB staff consult, or contact the IRB office with questions, especially for complex studies.
- 4) Submit complete and consistent RAMS-IRB applications. Consult the guides (Getting Started, RAMS-IRB System, and RAMS-IRB Content), as well as other regulations or VCU WPPs prior to submission.

## VCU IRB Contacts

---

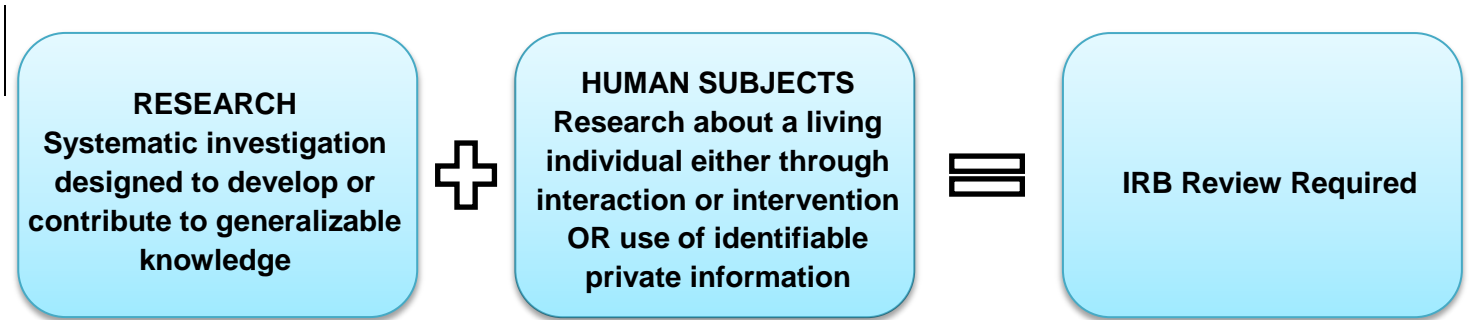
# DETERMINING HUMAN SUBJECTS RESEARCH

---

Step

1

The VCU IRB provides ethical oversight to all activities that meet the criteria of "research involving a human subject." IRB review is required if the activity involves research and/or involves human subjects.



Refer to a Decision Chart provided by the Office of Human Research Protections (OHRP) to help determine whether an activity requires IRB review in most situations.

[Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?](#)

There may be some instances where it appears an activity does not meet the definition of research with human subjects that do require IRB review, such as when VCU receives a direct federal award that involves human subjects research in some capacity (i.e., at subaward / collaborating institutions). See guidance on [Engagement in Research](#) from the Office of Human Research Protections (OHRP) for more information.

## Required Training

- Initial Requirement: **CITI (Collaborative IRB Training Initiative) Basic Course**
  - All **engaged** researchers are required to complete this training prior to submitting to the IRB.
    - An investigator becomes "engaged" in human subjects research when he/she (i) intervenes or interacts with living individuals for research purposes; or (ii) obtains individually identifiable private information for research purposes
  - All the modules listed for VCU must be completed. Most modules include a short quiz. An aggregate passing score of 80% is required. CME's and CEU's are available for CITI completion.
  - Complete CITI (Basic or Refresher) Human Subjects Protection online training in the type of research you are primarily conducting: Social and Behavioral Research **or** Biomedical Research
  - Directions:
    - Login to [www.citiprogram.org](http://www.citiprogram.org) to complete required training
    - [New Subscribers](#)
    - [Adding courses to your account](#)
    - [Associating your account with multiple institutions \(important if you've already taken CITI for another institution and don't want to take it again for VCU\)](#)
    - [Checking the expiration date for your training](#)
- Continuing Requirement: **CITI Refresher Course**
  - Every 2 years, researchers must take the CITI refresher course.
- GCP (Good Clinical Practice) Training – ONLY FOR SOME RESEARCH
  - As of January 1, 2017, all NIH funded researchers involved in the conduct, oversight, or management of clinical trials must be trained in Good Clinical Practice (GCP). NIH defines clinical trial as “a research study in which one or more humans are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” This applies to all new AND existing studies.
  - This GCP requirement can be met by completing one of the following trainings:
    - CITI's GCP training (for Biomedical Research) - Please see directions above for adding the GCP course
    - NIH's GCP Training (for Social Behavioral Research)

## Additional (Optional) Training

The Office of Research Subjects Protection offers periodic training (in person, online, etc.). We offer the following courses:

- IRB 101/ RAMS-IRB Training: This course introduces you to the process & requirements of the IRB, and how to do the online submission form
- IRB New Member Orientation: This is for new IRB panel members
- Hot Topics: Any topic where researchers may need updates or more guidance
  - [Suggest an educational topic here.](#)

---

# DETERMINING EXEMPT, EXPEDITED, OR FULL BOARD REVIEW

---

Step

3

## Types of Review

Studies will qualify for one of three types of review: Exempt, Expedited, or Full Board. The investigator initially determines the type of review, however the IRB makes the final determination.

### Exempt:

- Not greater than minimal risk
- Fall in at least one of the exempt categories found here: [View the OHRP Exempt Categories](#)

### Expedited:

- Reviewed by a single IRB member, not the entire board. If the single reviewer can't approve it, the study will move to the full board.
- Not greater than minimal risk
- Fall in at least one of the exempt categories found here: [View the Expedited Research Categories](#)

### Full Board:

- Reviewed at the monthly meeting by the full board (including at least one member who comes from a non-scientific background).
- Greater than minimal risk

OR

- Do not qualify for exempt or expedited review.

# SUBMISSION PROCESS

Step

4

## Prior to Submission

### COI Requirement

**Initial Reviews** - The COI review may occur concurrently with IRB review, but IRB approval cannot occur until it is determined that no conflicts exist or any conflicts have been acceptably managed.

1. Designate on the [IRB personnel roster](#) any research personnel who fulfill the definition of a COI Investigator. When designating 'COI Investigator,' independence and responsibility should be comparable/near comparable to PI.

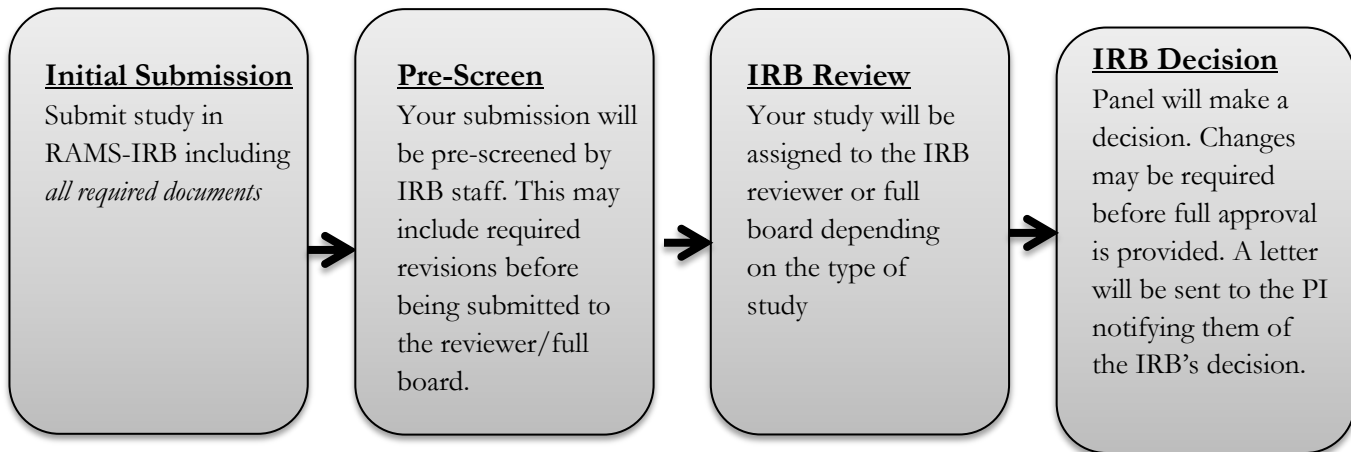
| Likely to be a COI Investigator  | Probably Not a COI Investigator   |
|--|---|
| <ul style="list-style-type: none"><li>• <b>PI on proposal/protocol **</b></li><li>• <b>Co-PI **</b></li><li>• Co-or Sub Investigators</li><li>• Key/Senior Personnel on Proposal</li><li>• Project Manager/Director</li><li>• Student (Usually graduate/trainee) who is a 'functional' PI on the protocol</li><li>• Medical Investigator</li><li>• Research staff authorized to make decisions without PI consultation</li><li>• Consultant who will make decisions about design, conduct, or analysis/reporting</li></ul> <p><b>**ALWAYS COI INVESTIGATOR</b></p> | <ul style="list-style-type: none"><li>• Students under direct supervision of PI/Co-PI/Co-I</li><li>• Research staff – including engaged community members, under direct supervision of PI (no decision making authority)</li><li>• Research-related personnel whose jobs support the research enterprise, eg. Investigational pharmacists, lab technicians, CRSU staff</li><li>• Anyone other than the PI on a training practice, resource grant.</li></ul> |

**\*COI Investigator** – Any individual, regardless of title, role or position, who is responsible for the design, conduct, or reporting of research. Individuals with such research responsibilities may be, but are not limited to, senior/key personnel, sub/co-investigator or subrecipient investigator, medical investigator, collaborator, consultant, student, trainee, or research coordinator. Exceptions include students or other personnel whose research activities are directly supervised. By considering an individual's degree of independence relative to the research, the PI on the protocol designates those who meet the definition of "COI Investigator".

2. All personnel designated as COI investigators must complete a Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS). See the [COI page](#) for more information about AIRS & other policies. [Click here to access AIRS.](#)
3. **Continuing Reviews** - IRB will check to ensure that all COI Investigators have updated their Financial Interest Report (FIR) within the past 12 months.
4. **Personnel Amendments** – a COI review will be completed for each prior issuing the IRB approval for the personnel addition. All new COI Investigators should complete a Financial Interest Report (FIR) in AIRS.

**External IRB COI Requirements** - Even though an external IRB will review the study, VCU will still conduct a conflict of interest review (COI) for each initial submission, which will occur concurrently with external IRB review.

# Initial Submission in RAMS-IRB



1. **All initial submissions will be submitted in the [RAMS-IRB smart form](#).** Please answer all questions in detail, consistently, and accurately.
2. **Upload Documents – [Many template versions of forms can be found here](#).**

Be sure all submitted documents include version numbers and/or dates in the footer. When documents are changed, a new version number and/or date should be applied. This helps the IRB track approved versions most efficiently.

  - a. **Exempt Reviews**
    - Information Sheet to inform participants about the research activity – Please include that the activity involves research, participation is voluntary, a brief description of what participants will be doing, who to contact with questions (generally the principal investigator), note any compensation to participants)
    - Recruitment materials
    - Survey instruments and interview questions
  - b. **Expedited Initial Submissions**
    - Informed consent form(s)
    - Recruitment materials
    - Survey instruments and interview questions
    - Grant proposal, if applicable
  - c. **Full Board Initial Submissions**
    - Informed consent form(s)
    - Recruitment materials
    - Survey instruments and interview questions
    - Multi-center study protocol
    - Grant proposal, if applicable
    - FDA regulatory documents, if applicable



# Special Requirements

If your study involves any of the following, please click to read the Written Policies and Procedures.

- Vulnerable Populations
  - [Pregnant Women, Fetuses, and Neonates](#)
  - [Prisoners](#)
  - Children
    - [Permissible Categories \(Children\)](#)
    - [Assent and Parental/Guardian Permission Considerations](#)
    - [Children in Court-Appointed or State Custody and Emancipated Minors](#)
- FDA Regulated Products
  - [Review of Devices - IDE Requirements \(SR vs. NSR Determination\)](#)
  - [Humanitarian Use Devices \(HUD\)](#)
  - [Emergency Use of a Investigational Drug, Device, or Biologic](#)
  - [Non-Research Uses \(Treatment Use, Single Pt. Use, Parallel Track\)](#)
  - [Review of Drugs - IND Requirements](#)
  - [Control of Investigational Drugs, Devices, and Biologics](#)
- Sponsors with Additional Requirements
  - [Department of Education \(DoEd\)](#)
  - [National Institute on Disability and Rehabilitation Research Requirements \(NIDRR\)](#)
  - [Department of Justice \(DoJ\)](#)
  - [Federal Bureau of Prisons](#)
  - [Department of Defense \(DoD\) - Department of the Navy \(DoN\)](#)
- Non-VCU Sites
  - [Non-VCU Institutions](#)
  - [Independent Investigators](#)
  - [Foreign Institutions/Sites](#)
- Subject Recruitment and Selection
  - [Subject Recruitment and Compensation](#)
  - [Evaluating Consent/Persons with Limited Decision-making Capacity](#)
  - [Equitable Subject Selection](#)
  - [Internet for Recruitment and Research Data Collection](#)
- Other Guidance
  - [Research Involving Data Registries and Specimen Banks](#)
  - [Genetic \(DNA\) Research](#)
  - [Research Participant Inquiries/Concerns](#)
  - [Planned Emergency Research, Exception from Informed Consent, and Waiver of Applicability of Informed Consent](#)

# Recruitment

[Please refer to the following page to learn more about recruitment.](#)

## HIPAA

Research involving *access or use of Protected Health Information (PHI)* is subject to compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations.

**Protected Health Information (PHI):** All individually identifiable health information that is obtained or maintained within the VCU Affiliated Covered Entity is considered protected health information.

[Click here for a complete list of identifiers.](#)

### **Step 1: Does HIPAA apply to my study?**

Use the [flow chart](#) to determine whether HIPAA applies to your study.

If YES, continue to step 2.

### **Step 2: Which pathway should I use?**

Use the [flow chart](#) to determine which of the following HIPAA pathway applies to your study.

[Once you have determined the pathway, click here to learn more.](#)

### **Commonly Used Pathways ([you can find for a complete list of pathways here](#))**

- **Signed, Written Authorization**
  - Standard mechanism, physically signed document, must contain specific elements and statements.
- **Waiver of the Authorization**
  - Mechanism to use PHI for research purposes when obtaining a signed Authorization is not feasible.
- **Partial Waiver of Authorization for Recruitment**
  - Used to allow researchers to access individual's PHI for *recruitment*.
  - If an individual decides to enroll in a study, full signed Authorization should be sought from the individual.
- **Review Preparatory to Research for Research Feasibility**
  - Allows for access PHI for the purpose of determining study feasibility (e.g., determining if an adequate number of patients exist to conduct the study) without obtaining signed authorization or waiver.
- **De-Identified Data**
  - Health information that has none of the 18 HIPAA identifiers associated with it is considered de-identified health information. A code link to identifiers may not be retained when utilizing the de-identified pathway. De-identified data is not subject to HIPAA regulations.

[Please use the link to learn more about Unauthorized Disclosures, Minimum Necessary PHI, Document Retention, and Breach of PHI.](#)

# Informed Consent

- Ensures respect for persons through provision of *thoughtful* consent for a *voluntary* act.
- Both an initial and ongoing process – allows people to decide whether or not to participate as a research subject, or to continue participation - Not just a form or document
- Must obtain informed consent from the subject or the subject's legally authorized representative PRIOR to participation AND
- Must appropriately document the informed consent process.
- The ORSP has written [Informed Consent Templates](#) that provide investigators with guidance in developing an informed consent document which includes all required elements of consent

## Basic Elements of Informed Consent

1. a statement that the study involves research, an explanation of the purposes & duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. a description of any reasonably foreseeable risks or discomforts to the subject;
3. a description of any benefits to the subject or to others which may reasonably be expected from the research;
4. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained (and that notes the possibility that the Food and Drug Administration may inspect the records - if the research is FDA-regulated);
6. for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

[For additional required elements of informed consent, click here.](#)

- Informed Consent should be designed to educate the subject population in terms that they can understand. (Ex. Written using “lay language” and in a language that subjects understand)
  - [Limited English Proficiency Subjects: Consent Short Forms for LEP subjects, click here.](#)
- Documentation of Informed Consent
  - A written informed consent document should be developed including all required (and applicable additional) elements of informed consent. This document is provided to the research subject. This may be:
    - (1) full written consent document OR
    - (2) “short form” document to be used in conjunction with full consent document, and summary of an oral presentation of the informed consent process.
      - Needs to be justified & witness must be present for oral presentation- will sign short form consent AND a copy of the summary
  - Note: See next section for how to request a waiver of documentation of consent.

# Waivers

- Waivers may be granted for some elements of consent. The VCU IRB cannot waive documentation of informed consent under 45 CFR 46.117(c)(1) for **FDA-regulated research\***.
  - \*NOTE: For research that involves an FDA-regulated product, the IRB may waive the requirement for informed consent only in emergency situations (for details see VCU IRB WPP XVII-6)

## Types of Waivers

- Waivers of Some or All Elements of Consent – can request to waive some required elements of consent, or can request to waive consent entirely.
  - An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
    1. The research involves no more than minimal risk to the subjects;
    2. The waiver or alteration will not adversely affect the rights and welfare of the subjects’;
    3. The research could not practicably be carried out without the waiver or alteration; and
    4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
  - [For more information, please click here.](#)
- Waiver of Documentation of Consent – may not be required to get a signature from a subject (ex. Conducting a minimal risk survey over the phone)
  - The IRB may waive the requirement for the investigator to obtain a signed consent form for subjects if:
    - That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; OR
    - No more than minimal risk and involves no procedures for which written consent is normally required.
  - [For more information, please click here.](#)
- Waiver of Assent – Do not get assent from child (most likely still get parental permission)
- Waiver of Documentation of Assent – Do not get child’s signature, but still get assent
- Waiver of Parental Permission – Do not get parental permission
- Waiver of Documentation of Parental Permission – Do not get parents’ signature, but still get parental permission

You may use the following charts to determine what type of waiver (if any) you should request.

|                 | Includes All Elements of   | Includes Some Elements of  | Includes No Elements of |
|-----------------|----------------------------|----------------------------|-------------------------|
| The participant |                            | Waiver of Some Elements of | Full Waiver             |
| The participant | Waiver of Documentation of | Waiver of Documentation of | Full Waiver             |

### Research Involving Children:

#### ASSENT FORM

|           | Includes All Elements of   | Includes Some Elements of | Includes No Elements of |
|-----------|----------------------------|---------------------------|-------------------------|
| The child | No Waiver                  | N/A                       | Full Waiver of Assent   |
| The child | Waiver of Documentation of | N/A                       | Full Waiver of Assent   |

#### PARENTAL PERMISSION

|            | All Elements of Parental      |                            | Includes No Elements of         |
|------------|-------------------------------|----------------------------|---------------------------------|
| The parent | Waiver of Parental Permission | Waiver of Some Elements of | Full Waiver Parental Permission |
| The parent | Waiver of Documentation of    | Waiver of Documentation of | Full Waiver of Parental         |

**IF YOUR STUDY INVOLVES PARENTS & CHILDREN, YOU WILL NEED ALL 3 DOCUMENTS: CONSENT, ASSENT, PARENTAL PERMISSION.**

## Amending an Approved IRB Study

Modifications to expedited and full board studies must be submitted for IRB approval prior to implementing changes of any kind. Many modifications to exempt studies may be done without prior approval, but be sure to review the specific criteria to ensure a change is permissible.

Changes to studies in RAMS-IRB can be initiated by starting an Amendment activity in the system. Modify the research plan accordingly and upload revised documents to the study workspace.

- [Exempt Research](#)
- [Expedited Research](#)
- [Full Board Research](#)
- [WIRB Approved Research](#)

## Continuing Review

Expedited and full board research must be re-reviewed by the IRB at least **annually** through a continuing review process. Exempt research does not require continuing review. Well in advance of an expiration date, reminders are sent to investigators prompting preparation and submission of a continuing review package.

## Electronic RAMS-IRB Continuing Review

- Login to RAMS-IRB and open the workspace for the study needing continuing review
- Complete a continuing review activity and upload relevant documentation such as DSMB reports.

**Paper Submissions:** [Please refer to the following directions.](#)

## Problem Reporting

The following events need to be reported to the IRB:

- Unanticipated problems – within 5 days of learning of the event
  - Event is unexpected, related/possibly related to participation in research, and research places subjects or others at greater risk than was previously recognized
- Protocol deviations or violations
- New Information or complaint that increases risk
- Sponsor-imposed Protocol suspension
- Changes in labeling or withdrawal from marketing
- Breach of confidentiality
- Noncompliance

**RAMS-IRB Studies:** Submit reports in RAMS-IRB using the Reporting submission type within an approved study workspace.

**Paper Studies:** Submit Prompt or Non-Prompt reports in paper at the ORSP office, 3rd Floor of BioTech One Building.

Read more about identifying unanticipated problems in the [OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events](#).

## Other Reporting

Most other events occurring in a research study do not need to be reported to the IRB unless they are unanticipated problems. However, there may be times when a sponsor requires reporting to the IRB or there is other information the investigator feels the IRB should know, in which case a report may be submitted on a Non-Prompt paper form or using the reporting function in RAMS-IRB.

## Post Approval Monitoring

The purpose of the program is to assist the university and investigators in conducting human research that is of the highest ethical quality and is compliant with federal, state, and local requirements. The PAMQuIP staff works towards this goal by improving investigator/IRB performance through monitoring, education and measurement of the overall quality, effectiveness, and efficiency. In addition, the PAMQuIP staff acts as a resource for the VCU/HS research community by offering help through problem-solving tips, templates, focused educational services, external/internal audit preparation and referrals.

- [Types of Visits](#)
- [Overview of the Visit Process](#)
- [Preparing for a Visit](#)
- [Quality Improvement Education, Consultation & Assistance](#)
- [Resources](#)
- [Study Conduct Toolkit](#)

## Study Close Out

VCU IRB oversight may end (following a request for closure) only under the following circumstances and conditions:

1. The research is permanently closed to enrollment at the site(s) under the VCU IRB approval; and
2. All interactions/interventions with subjects, or access to a subject's personally identifiable information, (including identifiable biological specimens) for the purpose of research data collection is complete; and
3. (a) All use, study, and/or analysis of identifiable private information at the research site(s) under the VCU IRB approval is complete.

**Electronic (RAMS-IRB) Studies:** Open the study workspace for the study you wish to close and initiate the close study activity, or a study can be closed at the time of continuing review by selecting the close study option.