

VCU's Return to Research (R2R): What Are My Responsibilities to the IRB?

The purpose of this document is to provide guidance to researchers seeking to resume on-campus or in-person research activities with human subjects. It outlines the steps that must be taken prior to resuming on-campus/in-person human research activities, as well as when and how the IRB must be notified of an investigator's intention to resume on-campus/in-person human research activities.

This guidance applies only after the Governor lifts his [executive order](#) **AND** VCU OVPRI initiates Phase II in the [Phased R2R plan](#) (6/12/2020).

Specific guidance is outlined below, but an overview of this process is also outlined in a flowchart, available on the [OVPRI R2R Website](#).

STEP 1: Obtain Institutional Approvals

You must wait until you have **all relevant approvals** before resuming on-campus/in-person human research activities. This includes:

- Obtaining relevant facility approvals from your department according to VCU's Return to Campus plan, including approval from the [Building Manager and the Return to Campus Coordinator](#)
- In addition, if research occurs off campus, additional approvals may be needed:
 - If research occurs at an off-campus site, that location must approve your return
 - If research occurs in a participant's home, the participant must freely give permission for researchers to enter
- Employees complete the required "Reboarding at VCU" training, and HR Representatives report employee returns to Central Administration
- You have obtained any/all required supplies and resources to support a return to campus

Studies that were already approved for on-campus/in-person research by receiving a Tier 1 or Tier 2 approval from OVPRI are anticipated to still have approval to continue. However, investigators should consult with their department chair/dean about if any additional approvals are needed at this time.

Information and additional guidance regarding obtaining these approvals can be found on the [OVPRI R2R website](#) or consult your department chair.

STEP 2: Notify the IRB of Your Return

Studies Reviewed by the VCU IRB:

You must notify the IRB of your intention to resume on-campus/in-person human research activities. This may occur in one of two ways: (1) Logging a Public Comment in RAMS-IRB; or (2) Submitting an Amendment in RAMS-IRB. Both options, and when they should be utilized, are described below:

1. Log a Public Comment in RAMS-IRB.
 - a. **This option should be utilized ONLY if the study will resume all activities exactly as written in the RAMS-IRB smartform protocol OR Contingency Protocol (if one is currently approved).** If ANY changes are necessary to support the resumption of the research, Option #2 (Submit an Amendment) must be utilized
 - b. The Public Comment should include:
 - i. Anticipated date of resuming in-person activities
 - ii. Confirmation that all necessary institutional approvals have been obtained
 - iii. Confirmation that the research will be conducted as outlined in the RAMS-IRB smartform protocol or the Contingency Protocol (if one has been approved). If the Contingency Protocol is being retired and research will be conducted exactly as outlined in the RAMS-IRB smartform, then communicate that to the IRB.
 - c. **Given that all research activities that can be conducted remotely should be conducted remotely (per the OVPRI Phased Return to Research Plan), this Public Comment option will likely be less frequently utilized**
2. Submit an Amendment
 - a. This option should be utilized if changes are required to support the resumption of your research project
 - b. **OVPRI Guidance for Phase II, III, and IV of the R2R plan requires that all research activities that can be conducted remotely should be conducted remotely. When subjects are on-campus for other purposes, investigators should still consider whether certain activities can be conducted remotely, in order to minimize the time spent in-person/on-campus.** For example:
 - i. Studies designated as Tier 4 because they involved no in-person contact should remain remote.
 - ii. Recruitment is remote **whenever possible** (as opposed to whenever convenient)
 - iii. Consent-only visits should continue to be remote (i.e.: phone or Zoom conversations. [Guidance on how to obtain consent remotely can be found here](#))
 - iv. Interactions (survey completion, interviews, assessments, etc.) continue to be conducted remotely
 - v. Interventions (distributing study materials, telemedicine visits, computerized tests, etc.) are converted to remote or contactless delivery wherever possible

- vi. Only interventions that truly require in-person contact (i.e.: blood/sample collection, imaging, tests requiring special equipment, etc.) should be conducted in-person and then with physical distancing

Studies Reviewed by External IRBs (i.e.: WIRB, NCI CIRB, etc.):

You must comply with any requirements from the external IRB regarding your intention to resume on-campus/in-person human research activities and submission of amendments for any modifications.

In addition, you must comply with all institutional policies about the return to research, such as those outlined by the OVPRI Phased Return to Research Plan and any other VCU, VCU Health or departmental requirements. **This includes compliance with the institutional requirement that all research activities that can be conducted remotely should be conducted remotely (per the OVPRI Phased Return to Research Plan).**

When your study returns to on-campus/in-person human research activities:

1. Log a Public Comment in RAMS-IRB to notify the VCU HRPP of your plans.
 - a. The Public Comment should include:
 - i. Anticipated date of resuming in-person activities
 - Studies that already had approval as a Tier 1 or Tier 2 study may have previously logged this date. If not, you should log it at this time.
 - ii. Confirmation that all necessary institutional (local) approvals have been obtained

PLEASE NOTE: If your study is reviewed by an external IRB and changes include revisions to how HIPAA Authorization will be obtained for example, if your changes necessitate a Waiver of the signature element, this change MAY require institutional approval.

- iii. Confirmation that any changes to the protocol, such as changes to make previously in-person research activities remote, have been approved by the reviewing IRB.

How Do I Know if I Need to Amend?

The guidance below is intended to help investigators determine if and when an amendment is required to their study in order to support the resumption of on-campus/in-person human research activities.

1. First, evaluate the **entire** RAMS-IRB smartform AND the COVID-19 Contingency Protocol (if one is currently in place)
2. Anywhere you plan to do something different than what is written (*no matter how minor*), an amendment is necessary for expedited and full board studies.
 - a. Exempt studies should refer to [WPP VIII-5](#) for a list of all changes that must be submitted to the IRB.
 - b. Studies that already submitted a COVID-19 Contingency Protocol and that will continue to follow those approved remote procedures exactly as approved do not

need to amend again. An amendment is only needed when a change is being made. If no changes are being made, Option #1 (Log Public Comment) may be utilized.

3. Examples of changes that may be necessary:
 - a. Changing in-person interactions to remote interactions (see Step 2 above)
 - b. Halting or altering recruitment procedures, or adding new ones
 - c. Additions/changes to research measures/procedures (i.e.: adding COVID-19 related questions that will be included in the research data, changing screening procedures, etc.)
 - d. When a study implements additional COVID-19 risk minimization procedures as a research activity (e.g. requiring activities to be done remotely, new/altered communications to participants about risks or risk minimization above baseline measures required by the University, etc.)
 - e. Alterations to data security or privacy protections (i.e.: changes in data storage locations; new/different locations for participant interaction; etc.)

The IRB does not need to approve changes made to address the baseline VCU Phased Return to Research Plan - the basic health and safety requirements outlined by the University and VCU Health (e.g. wearing a mask, physical distancing, etc.) for on campus activities. The IRB also does not require review and approval of an amendment to direct participants to view the [IRB's video for participants about returning to campus](#).

If you have questions about what modifications need to be submitted to the IRB to support resuming your study, [contact your IRB coordinator](#). For questions about how to minimize COVID-19 risks of infection or transmission, consult the [VCU Office of Environmental Health and Safety](#).

What Process Should I Use to Amend My Study?

Studies can be amended in one of two ways: through the [COVID-19 Contingency Protocol Form and Process](#), or through the usual amendment process in RAMS-IRB. Which one should be used depends on the nature of the changes.

1. COVID-19 Contingency Protocol Form and Process
 - a. This process should be used to make **temporary changes**. That is, changes that are in response to COVID-19, which will not be utilized after the situation resolves.
 - b. Investigators should utilize the form and process for COVID-19 Contingency Protocol Amendments. [Instructions for this process can be found on the HRPP blog](#).
 - i. If a COVID-19 Contingency Protocol is already in place, but requires changes, add the changes to the existing COVID-19 Contingency Protocol Form Document and submit the updated version of the document in an amendment using the instructions outlined in the blog post linked above.
2. Usual Amendment Process in RAMS-IRB

- a. This process should be used to make **permanent changes**. That is, changes that may or may not be in response to COVID-19, but which regardless are anticipated to continue to be utilized after the situation resolves.
- b. Investigators should utilize the [usual amendment process in RAMS-IRB](#) (i.e.: make edits directly to the smartform/documents).

If you have questions about which process to use for changes to your study, [contact your IRB coordinator](#).