### STEP 1: OBTAIN INSTITUTIONAL APPROVALS

**ALL STUDIES**

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

1. 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
2. In addition, if research occurs off campus, additional approvals may be needed:
   a. If research occurs at an off-campus site, that location must approve your return
   b. If research occurs in a participant’s home, the participant must freely give permission for researchers to enter
3. Employees complete the required “Reboarding at VCU” training, and HR Representatives report employee returns to Central Administration
4. You have obtained any/all required supplies and resources to support a return to campus

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 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 used 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 MUST be conducted remotely. This applies to all research activities, regardless of whether the subject is already present on-campus for other purposes. For example:
      i. Consent-only visits should continue to be 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

**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 MUST be conducted remotely. This applies to all research activities, regardless of whether the subject is already present on-campus for other purposes. 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

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 MUST 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.
2. The Public Comment should include:
   a. Anticipated date of resuming in-person activities
   b. Confirmation that all necessary institutional (local) approvals have been obtained
   c. 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.

### Per OVPRI R2R:

- **Step 1**, Obtain Institutional Approvals
  - **All Studies**
    - You must wait until you have all relevant approvals before resuming on-campus/in-person human research activities. This includes:
      1. 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.
      2. In addition, if research occurs off campus, additional approvals may be needed:
        a. If research occurs at an off-campus site, that location must approve your return.
        b. If research occurs in a participant’s home, the participant must freely give permission for researchers to enter.
      3. Employees complete the required “Reboarding at VCU” training, and HR Representatives report employee returns to Central Administration.
      4. You have obtained any/all required supplies and resources to support a return to campus.

- **Step 2**, Notify the IRB of Your Return
  - **Studies Reviewed by 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. **Log a Public Comment in RAMS-IRB**:
        a. This option should be utilized if the study will resume all activities exactly as written in the RAMS-IRB smartform protocol or Contingency Protocol (if one is currently approved).
        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).
      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 MUST be conducted remotely. This applies to all research activities, regardless of whether the subject is already present on-campus for other purposes.
           i. Consent-only visits should continue to be 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**
    - 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 MUST 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.
      2. The Public Comment should include:
         a. Anticipated date of resuming in-person activities.
         b. Confirmation that all necessary institutional (local) approvals have been obtained.
         c. 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.
**VCU’s Return to Research (R2R): What Are My Responsibilities to the IRB?**

Follow this flowchart to determine the appropriate action to take in order to resume on-campus/in-person human research activities for studies reviewed by the VCU IRB. For external studies, follow the written guidance above, or on the [OVPRI R2R Website](#).

**BEGIN HERE**

Do you have all applicable approvals to return to campus? Including:
1. OVPRI Notification of beginning Phase II in the R2R plan
2. Obtaining relevant facilities approvals
3. Employees completed training and HR Reps report returns to Central Admin
4. I have any/all required supplies and resources

- **Yes**
  - Are changes necessary to support the resumption of your study* (including converting all procedures that can be done remotely to be remote)?
    - **Yes**
      - Log Public Comment in RAMS-IRB to document intent to resume research. Include in the comment:
        1. Anticipated date of resuming in-person activities
        2. Confirmation that all necessary approvals have been obtained
        3. Confirmation that the research will be conducted as outlined in the smartform/Contingency Protocol (or if the Contingency Protocol is being retired, specify this)
    - **No**
      - Submit temporary changes utilizing the COVID-19 Contingency Protocol Form. If changes are needed to the existing approved Contingency Protocol Form, edit the existing Form and upload the revised form when prompted.

- **No**
  - PERMANENT CHANGES
    - Submit an amendment in RAMS-IRB and utilize the usual process for making changes (i.e.: make changes to smartform directly)

  **TEMPORARY CHANGES**

- **Yes**
  - Submit changes utilizing the COVID-19 Contingency Protocol Form. If changes are needed to the existing approved Contingency Protocol Form, edit the existing Form and upload the revised form when prompted.

*How to determine if changes are necessary to your study:*

Evaluate the ENTIRE smartform/Contingency Protocol. Anywhere you plan to do something different than what is written (no matter how minor), submit that change in an amendment. If the smartform/protocol will continue to be followed exactly as written, no amendment is necessary.

**Note:** some flexibility may be available for exempt studies. For guidance, consult the Terms of Approval in your approval letter or call your IRB Coordinator.