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

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 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

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.

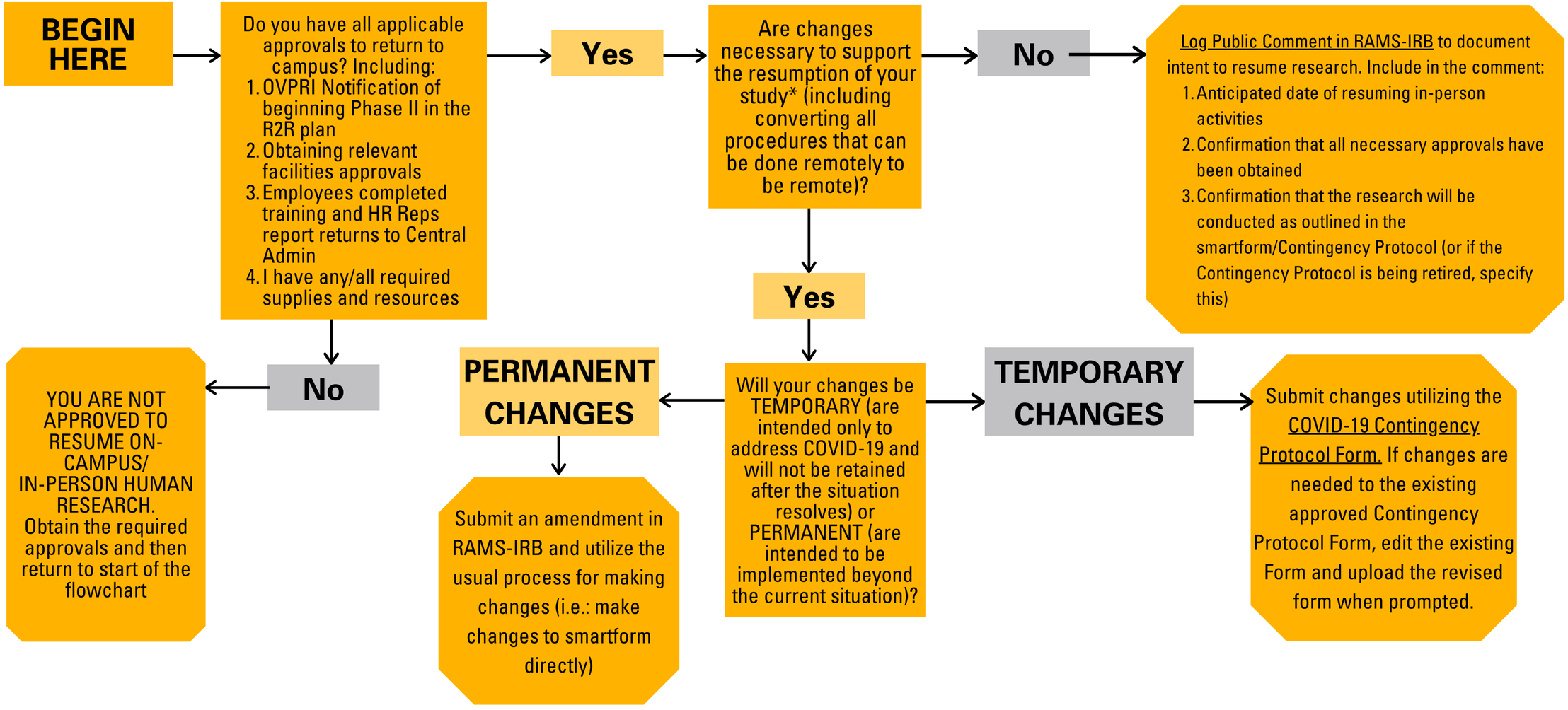
In addition, you must comply with all institutional policies about the return to research, such as those outlined by the OVPRI Phased Return to Research Plan and any other VCU, VCU Health or departmental requirements. This includes compliance with the institutional requirement that all research activities 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.
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
        i. 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 o the signature element, this change MAY require institutional approval.
    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.



***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.