Dear colleagues,

Following consultation with VCU's research leaders and advisors, I am writing to provide research teams with important guidance supporting the continued safety of our human research participants, patients, and our community (regardless of IRB-of-record).

Out of an abundance of caution, it is important that research teams take the following actions as cases of COVID-19 rise in the greater Richmond area:

1. Review study activities to reduce risk of exposure to COVID-19 and consider whether virtual visits are possible.
2. Discuss the resources available to support your study and how you will respond if those resources become limited.
3. Ensure that your human research study has a VCU HRPP Tier Assignment. If it does not, please communicate your study's Tier assignment in accordance with the instructions below. Note that this will help us to communicate changes that might impact you in the future. The VCU HRPP COVID-19 Continuation Planning process, including the Tiering Process is described below.

As you know, this is an evolving situation, so please keep in mind that these guidelines may change. We are reviewing the landscape daily, including the VCUHS vaccination process, and will continue to update you as information becomes available.

VCU HRPP COVID-19 Continuation Tiering Process

Communication of your study's Tier assignment to the HRPP is done by either: the VCU COVID-19 Human Research Continuation Request Portal (Tiers 1 and 2) or by logging a public comment in RAMS-IRB (Tiers 3 and 4). We ask that Principal Investigators complete designation of a tier for each of your studies at this time. If your research was previously approved as Tier 1-4, there is no need to resubmit. If the University finds it necessary to implement limitations due to COVID-19 infections, notification will be sent out via e-mail and blogs. Again, the requirements listed for each Tier below are NOT mandatory at this time; they are provided for informational purposes only. We are only asking that Principal Investigators designate a Tier for each of your studies now.

Specific instructions for each Tier are given below:

Tier 1: High potential direct health benefit to research participants due to life-saving or life-sustaining interventions or treatment:

How to get a Tier 1 determination to continue in-person activities:

- If your research was previously approved as Tier 1 via the portal, you do not need to submit to the Continuation Request Portal again. COVID-19 related trials are Tier 1 trials.

- To seek a Tier 1 approval at this time, the PI must submit a brief justification to continue in-person visits for Tier 1 research using the VCU COVID-19 Human Research Tier 1 & 2 Continuation Request Portal.

Requirements:

- All in-person visits must be converted to virtual visits where possible.
- Reminder: In-person study participant visits must be in the best interest of the participant and should be evaluated daily, as the public health conditions evolve.
- Risk and resources must be evaluated daily and additional adjustments may be needed to ensure safety.

Actions to take for the VCU HRPP:

- The IRB of record must approve any changes supporting continuation of participants and new enrollment (for VCU IRB see COVID-19 amendment process).
- If a study is going to revert to following a previously approved COVID-19 Contingency Protocol (and other COVID-19 documents), that intention should be communicated to the IRB in a public comment in RAMS-IRB.
- For studies that will voluntarily pause some or all in-person visits: Log-in to RAMS IRB and submit a public comment to document that you have paused in-person visits. The study team should notify all active study participants that study activity is paused. This notification may be done via telehealth, phone, or other personal means and may provide an opportunity to reassure participants that their safety is our priority.

Tier 2: Moderate potential health benefit to research participants due to the therapeutic nature of the intervention or treatment, which is not directly life-saving or life-sustaining.

How to get a Tier 2 determination to continue in-person activities:

- If your research was previously approved as Tier 2 via the portal, you do not need to submit to the Continuation Request Portal again.
- If your research was previously submitted but not approved as Tier 2 and you wish to be reconsidered, the PI must re-submit a brief justification to continue in-person visits for Tier 2 research using the VCU COVID-19 Human Research Continuation Request Portal.
- If your research was not previously submitted in the Continuation Request Portal and you would like to seek a Tier 2 approval at this time, the PI must submit a brief justification to continue in-person visits for Tier 2 research using the VCU COVID-19 Human Research Tier 1 and Tier 2 Continuation Request Portal.

Requirements:

- All in-person visits must be converted to virtual visits where possible.
- Reminder: In-person study participant visits must be in the best interest of the participant and should be evaluated daily, as the public health conditions evolve.
- Risk and resources must be evaluated daily and additional adjustments may be needed to ensure safety.

Actions to take for the VCU HRPP:

- The IRB of record must approve any changes supporting continuation of participants and new enrollment (for VCU IRB see COVID-19 amendment process).
- If a study is going to revert to following a previously approved COVID-19 Contingency Protocol (and other COVID-19 documents), that intention should be communicated to the IRB in a public comment in RAMS-IRB.
- For studies that will voluntarily pause some or all in-person visits: Log-in to RAMS IRB and submit a public comment to document that you have paused in-person visits. The study team should notify all active study participants that study activity is paused. This notification may be done via telehealth, phone, or other personal means and may provide an opportunity to reassure participants that their safety is our priority.

Tier 3: Limited or no direct health benefit to research participants (including studies that were disapproved as Tier 2).

Requirements:

- All in-person visits must be converted to virtual visits where possible; if not possible, consider the risks of in person visits and be ready to pause those visits should additional information come from OVPRI or VCU Health System. If it is not possible to convert the visit to virtual, clinical research teams should verify clinical research space access with VCU Health System clinic management.
- The study team should notify all active study participants that in-person study activities are paused. This notification may be done via telehealth, phone, or other personal means and may provide an opportunity to reassure participants that their safety is our priority.
- New studies may be proposed and enroll participants for remote activities only

Actions to take for the VCU HRPP:

- **As soon as possible and before _____**, the PI should log a public comment in RAMS-IRB informing the VCU HRPP of the following things: 1) the PI's determination that their study is Tier 3, and 2) confirmation that all in-person research activities have paused.

- The IRB of record must approve any changes supporting continuation of participants and new enrollment (for VCU IRB see COVID-19 amendment process).

- If a study is going to revert to following a previously approved COVID-19 Contingency Protocol (and other COVID-19 documents), that intention should be communicated to the IRB in a public comment in RAMS-IRB.

Tier 4: Studies involving no in-person interaction with human research subjects.

Actions to take for the VCU HRPP:

- **As soon as possible and before _____**,the PI should log a public comment in RAMS-IRB informing the VCU HRPP of the PI's Tier 4 determination. If this was previously done, it does not need to be done again.
- The PI should evaluate whether any changes to the approved study protocol are needed and submit an amendment for any modifications (for VCU IRB see COVID-19 amendment process).
- If a study is going to revert to following a previously approved COVID-19 Contingency Protocol (and other COVID-19 documents), that should be communicated to the IRB in a public comment in RAMS-IRB.
- New studies may be proposed and enroll participants for remote activities only

The VCU COVID-19 Human Research Tier 1 and Tier 2 Continuation Portal is designed to assist PIs with obtaining a Tier 1 or 2 determination and routing justification for continuation. This submission will be routed to your chairperson for approval and then to the associate dean for research. Submissions for cancer-related trials managed by Massey Cancer Center will be routed through Massey. Upon school/center/college approval, documentation will be provided to the PI and automatically submitted to the VCU Human Research Protection Program (HRPP).

QUESTIONS

Please refer participants, their families and community partners with questions about COVID-19 to the VCU Health COVID-19 website.

Researchers with questions regarding the tiering process, their clinical trials and the appropriate tier or available resources should contact Mary Harmon, Director of Clinical

Research, VCU Health; or Lisa Ballance, Executive Director for Clinical Research and Compliance.

Questions regarding any IRB submission, converting to remote procedures, and the appropriate tier should be directed to Sue Robb, Interim Director, Human Research Protections Program, or to your assigned VCU IRB Coordinator (assigned in RAMS-IRB).