



# VCU

## Office of the Vice President for Research and Innovation

June 11, 2020

Dear colleagues,

Over the past several months, the Human Subjects Research Program and the IRB have continued regular operations to support the research occurring at VCU and VCU Health. We have been impressed with the creativity, cross-disciplinary collaboration, and innovation our researchers have shown, and we have celebrated with you whenever a VCU study was mentioned in the news.

Here are a few of the ways that our office has been working to support researchers during this time:

- We have added up to two additional full board panel meetings per week specifically dedicated to the review of new COVID-19 studies and amendments, which enabled faster reviews.
- We have made the expedited and exempt reviews of new COVID-19 studies and amendments of COVID-19 Contingency protocols a top priority over all other submissions.
- HRPP staff have had phone and zoom consultations with numerous researchers to discuss ways studies can adapt.
- HRPP staff have participated in daily Rapid Activation calls to facilitate quick start-up of COVID-19 clinical protocols.
- Our office has worked with departments across the University to make available a new DocuSign platform for FDA-regulated studies that accommodates the FDA's requirements for electronic signatures.

We look forward to building on these successes and continuing our collaboration with investigators as human research studies return to campus and return to having in-person contact with participants.

As we look towards the re-opening of research (currently scheduled for Monday June 15, 2020 when Phase II of the OVPRI Phased Return to Research Plan takes effect), we want to take a moment to outline the VCU IRB's approach to reviewing research in the context of COVID-19.

- 1. COVID-19 Risk Identification:** The IRB considers the risks of COVID-19 infection and transmission to be environmental risks that are experienced across all spaces, people (employees and subjects), and research types. These risks will be considered a "new normal." Therefore, they do not need to be identified as study-specific risks in IRB submissions.
- 2. Baseline COVID-19 Risk Minimization:** As VCU and other institutions across the state and country begin to re-open, guidelines for health and safety are being laid out by VCU, VCU Health, the Commonwealth of Virginia, and by other off-site facilities. These guidelines (e.g. physical distancing, face coverings, cleaning, etc.) are not research-specific, yet they are expected to be equally implemented across all human research studies, regardless of the type of research, the location where

the research occurs, and people involved. The federal, state and institutional public health guidelines are also a “new normal”.

The IRB considers the public health guidelines laid out by VCU, VCU Health, the Commonwealth of Virginia, and by other off-site facilities to be the baseline risk minimization procedures for COVID-19. We expect that all researchers will be knowledgeable about and will follow the most restrictive policy for the location where their research will occur. Therefore, these baseline health and safety precautions do not need to be detailed or acknowledged to the IRB as study-specific risk minimization procedures. The IRB will assume they are being implemented across all studies.

Off-site locations and research participants may have differing levels of comfort about allowing researchers into their spaces/homes. We advise researchers to carefully gauge the willingness of off-site locations to allow research in their facilities, the guidelines they’ve put in place, as well as subject willingness to enter the research location. For home visits, researchers should inquire about and respect any participant requests regarding the use of source control (e.g. cloth face masks) and physical distancing while in their home in addition to adhering to basic state guidelines.

- 3. Additional Study-Specific COVID-19 Risk Minimizations:** The IRB recognizes that individual studies may involve special activities, equipment, or testing procedures that warrant the implementation of additional risk minimization procedures above and beyond the baseline precautions. Investigators are advised to place the health and safety of their participants as a top priority and take whatever steps are appropriate to best protect subjects from COVID-19 transmission and infection during their participation in in-person research activities.

Investigators who have questions about their study’s specific implementation of the University’s Return to Campus guidelines should work with the [VCU Office of Environmental Health and Safety](#) to determine what additional precautions for physical distancing, cleaning, and protective equipment should be taken. Then, those study-specific risk minimization procedures should be added in an amendment to the study’s IRB submission/protocol.

- 4. Scope of the IRB’s Review:** The VCU IRB is responsible for evaluating risks and benefits to participants, but other location/space, access, resource and personnel considerations are determined by deans and department chairs. This is not within the scope of the IRB’s review. Therefore, we will notify and advise investigators (and/or other University officials if necessary) when concerns are identified about a study’s implementation of institutional policies, but we will not hold up IRB approval if they do not otherwise impact the IRB’s review considerations.

However, the IRB does have an ethical responsibility to protect subjects, and the poor conduct of in-person research activities may place participants at greater risk. The IRB expects that all investigators will proactively work to minimize COVID-19 risks, but if questions arise, the IRB has the purview to inquire about and require additional risk minimization procedures (e.g. requiring activities to be done remotely, communications to participants about risks, etc.).

- 5. On-Campus Research Activities:** IRB approval by the VCU IRB or any external IRB does not necessarily mean that research may proceed on campus.

Per the University's reopening plan, investigators must work with their Department Chairs, Deans, Building Managers, Return-to-Campus Coordinators, and Human Resource Representatives to obtain all necessary approvals and permissions for building access and the return of research staff to campus.

Studies reviewed by external IRBs are still subject to VCU's institutional requirements, including health and safety requirements related to staffing and building safety, and those studies must also follow their reviewing IRB's policies and procedures for risk identification and minimization.

As research participants come to VCU and VCU Health facilities, they will also be expected to follow all institutional guidelines. Therefore, the IRB has prepared a brief [1-minute video to educate research participants about how to safely return to campus](#). Investigators are strongly encouraged to direct participants to watch this video before their visit.

- 6. In-Person Research Activities:** The OVPRI [Phased Return to Research Plan](#) states that in re-opening phases II, III, and IV, "All research that is possible to be done remotely should continue remotely." This requirement's reference to "all research" means that this requirement also applies to activities that, before COVID-19, would have taken place within the context of another non-research interaction or intervention (e.g. a routine visit). It applies to both VCU IRB and external IRB studies.

The IRB interprets this statement to mean that each separate study activity that could be done remotely, will be done remotely. Therefore, the IRB expects that investigators will be engaging in only the minimum necessary in-person research activities (i.e. those activities that cannot be done any other way except through in-person contact, such as blood draws, imaging, physical testing, etc.) and other interactions will continue to occur remotely (i.e. recruitment, consent, survey completion, interviews, etc.) until the University enters Phase IV of the OVPRI Phased Return to Research Plan.

To demonstrate inclusion and justice, the IRB expects that all investigators, when engaging in in-person research activities, will be prepared to offer face coverings and hand sanitization supplies to participants who need them. Not all participants will have access to or be able to afford such protective supplies, and research participation should be open to all individuals. Contact the [VCU Office of Environmental Health and Safety](#) for questions about ordering supplies.

- 7. Notifying the IRB of Return to On-Campus/In-Person Activities:** Both VCU and external IRB studies must provide notification in RAMS-IRB of their intention to resume on-campus/in-person human research activities. Complete instructions for this are described in instructions on [the HRPP website](#).

The purpose of communicating a study's return to the IRB is twofold: 1) to keep the IRB up-to-date about what the study is doing and 2) to facilitate the study team's own documentation about how the research was conducted. This information enables the HRPP to have context for the review of submissions and to assist when participants have questions or in case of an audit. Investigators that do not communicate this information could be asked more questions during reviews, which could extend the review timeline.

- 8. Amendments:** IRB policies require that investigators prospectively submit amendments for any changes to research. Therefore, as investigators assess which study activities are possible to do remotely, they should plan ahead for the potential need to submit an amendment for IRB review if making any changes to their IRB-approved study. Instructions about whether an amendment is necessary and how to submit a COVID-19 Contingency Amendment can be [found at the HRPP blog](#).

Guidance on when to submit an amendment can be found in the [HRPP's COVID-19 FAQs](#) and on the [OVPRI Phased Return to Research webpage](#).

For expedited and full board research, federal regulations require that modifications to research activities not be initiated without prior IRB review and approval, except when necessary to eliminate apparent immediate hazards to subjects (in which case the investigator must promptly report the modification to the IRB) ([WPP VIII-5](#)).

Exempt studies are required to submit amendments only in certain circumstances, so investigators should refer to [WPP VIII-5](#) for a list of all changes that must be submitted. Questions about whether an amendment is needed should be directed to the [assigned IRB Coordinator](#) for the study.

Studies reviewed by an external IRB should ensure that proposed changes to accommodate these institutional requirements are approved by the reviewing IRB prior to the implementation of any changes. For example, if changes necessitate a Waiver of the signature element, this change MAY require institutional approval. Studies must also comply with any requirements from the external IRB regarding an intention to resume on-campus/in-person human research activities and submission of amendments for any modifications.

- 9. Notifying the IRB whenever a COVID-19 Contingency Protocol is retired:** At such time that a study returns to following their approved smartform as written, with COVID-19 Contingency procedures no longer being needed, investigators must notify the IRB using a public comment on the main study page (not in an amendment or continuation). Instructions about when and how to retire a study's contingency procedures can be found at [the HRPP website](#). The IRB will notify investigators at some future date of when all contingency protocols institution-wide will be retired.

The IRB would like to thank all investigators for their patience during the past several months and as we move forward with re-opening. Your willingness to let COVID-19 submissions be reviewed first demonstrates how VCU and VCU Health are united in supporting research that will benefit our patients, students, and the community. The IRB will continue to prioritize COVID-19 submissions and contingency amendments. However, we receive a volume of up to 300 submissions per week, so we ask for your continued patience as we work to serve the entire institution.

The IRB remains committed to collaborating with you and helping you satisfy the regulatory and ethical requirements for human research. We encourage investigators to contact us and draw upon the regulatory expertise of the HRPP staff as questions arise about your studies, such as questions about modified consent processes and signatures, privacy protections, or equitable recruitment.

As we have seen over the past months, information can change rapidly, so to stay up-to-date on the latest information and current requirements, watch the [OVPRI Phased Return to Research webpage](#). You can also subscribe to the [IRB's blog](#), which is the IRB's primary method of communicating important updates to the research community.

Sincerely,

*Your IRB Colleagues and HRPP staff*