Vancouver CoastalHealth Research Institute

PROVIDENCE HEALTH CARE Research Institute

To: PHC Research Community

June 10, 2020

Re: Resumption of Human Subject Research

I know you have been anxiously awaiting communication from PHCRI regarding the resumption of human subject research at PHC. As I informed you all last week, the process for resuming human subject research is complex and requires significant coordination with operations teams at PHC, in addition to departments responsible for research oversight at UBC. A thoughtful and measured approach is needed in determining the scope of Stage 1 research resumption for human subject research at PHC.

In accordance with PHCRI's previous communication of June 3, 2020, there will be a phased-in approach to resumption of on-site human subject research activity at PHC. This phasing is needed to responsibly restore clinical services and other patient and public spaces across PHC's facilities and is aligned with the VCH/PHC COVID-19 Recovery Planning Framework. This will enable VCH/PHC's ability to maintain acute care capacity for COVID-19 cases, while simultaneously minimizing impact to non-COVID cases.

PRIORITIES

During Stage 1, the following human subject research will be prioritized based on:

1. COVID-19 research[1]
2. Current research activity exemptions, as previously approved by PHCRI
3. Ongoing[2] clinical trials concurrent with clinical care

The resumption of human subject research activities at PHC is dependent on:

(i) alignment of research study requirements with VCH/PHC's COVID-19 recovery plan;
(ii) the type and extent of clinical or diagnostic services required;
(iii) the ability of a clinical department/area to support a research study; and
(iv) an approved safety plan.[3]

[1] It is now a requirement of PHCRI that COVID-19 related clinical research (e.g., clinical trials, registries, biobanks) be submitted to the COVID-19 Clinical Research Coordination Initiative (CRCI) for review. PHC operational research approval may be withheld until confirmation of CRCI review is provided to PHCRI. Additional details regarding the CRCI initiative may be found here: https://www.med.ubc.ca/research/covid-19-clinical-research-coordination-initiative/

[2] The focus during Stage 1 will be on the resumption of clinical trials that, prior to the curtailment, had *both* UBC REB approval and PHC operational research approval in place. This includes clinical trials that were either ready to enroll the first patient, or had already enrolled the first patient and enrollment was continuing. By clinical trial we mean any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.

[3] Where research program/unit operations occur within a PHC clinical area, the safety plan developed by PHC will apply and must be adhered to. Where there is no overlap with a PHC clinical area, the research program/unit will be required to develop a safety plan.

SUBMISSION REQUIREMENTS

When a research program/unit is ready to consider resumption of onsite human subject research at PHC, the head of the research program/unit[4] will need to collect and collate investigator-level information (including previously exempted research), populate the PHCRI required documentation, and submit the required documentation to PHCRI for review. The documentation that must be submitted to PHCRI is as follows:

1. The "***PHCRI Unit Level Research Access Summary for Human Subject Research***" spreadsheet, which defines the processes that will be implemented to manage overall occupancy; and
2. A copy of the PHC clinical program safety plan (as applicable). Where research space is not managed by PHC, a copy of the research program/unit's safety plan, which amalgamates investigator-level plans and takes occupancy limits into account[5] must be submitted. WorkSafe BC has a safety plan template, which may be used to guide the development of a research program/unit safety plan.

All forms may be found on the PHCRI website.

REVIEW PROCESS

1. Investigators must submit research resumption requests for onsite human subject research to their research program/unit heads.

2. The research program/unit head will send the unit level submission to PHCRI at vpresearchsupport@providencehealth.bc.ca for review and approval. Researchers belonging to the UBC Department of Medicine should cc: dom.research@ubc.ca on their submission to PHCRI.

Submissions for Stage 1 resumption of human subject research will be reviewed on a rolling basis upon receipt and should be provided to PHCRI no later than **FRIDAY, JUNE 26, 2020**.

3. PHCRI will review the submission, taking into consideration the criteria for Stage 1 prioritization of human subject research, appropriate safety plans and building occupancy. PHCRI will engage the applicable PHC operational leads, as well as additional PHC stakeholders (e.g., PHC facilities personnel) for input and guidance. If the research program/unit has already engaged with PHC operational leads, please provide the name and contact information of such operational leads on Tab 1 of the ***PHCRI Unit Level Research Access Summary for Human Subject Research***" spreadsheet. The guiding principles developed by UBC and Health Authority Guidelines (included below for reference) will guide decision-making and processes related to the resumption of onsite human subject research activities. It is important to note that:

[4] PHCRI is asking that research resumption requests be coordinated within research programs/units to expedite the review process. We are strongly discouraging individual submissions (i.e. at the investigator-level). We are flexible as to how these submissions are organized (e.g., may be submitted by the Research Centre Head, Clinical Trials Unit Medical Lead, Research Program Head, as appropriate).

[5] Each research program/unit must include a safety plan for all on-site research, which must be read and acknowledged by all researchers and research staff requiring access to the space. Special emphasis must be included to address cleaning and sanitation and PPE availability. Research program/unit heads together with Principal investigators are responsible for monitoring and ensuring compliance with safety measures. Personnel violating the plan or regulations will have their access to the site revoked.

a. Due to the complexity of these reviews, including the need for PHCRI to consult with various PHC operations and department level personnel, PHCRI cannot guarantee a timeframe within which these reviews may be conducted. We will, however, do our best to facilitate timely reviews;
b. PHC space that is utilized by research and managed by PHC requires approval from PHC operations for increased research activity;
c. Research program/unit level plans that do not align with the VCH/PHC COVID-19 recovery plan, priorities for clinical research and occupancy guidelines, may be required to make adjustments to their plans and re-submit to PHCRI for approval.

4. Once all appropriate levels of PHC review have been obtained, PHCRI will issue a notification letter to the research program/unit level head, who will then notify individual researchers. The notification letter will list the human subject research projects that have been approved for resumption in Stage 1, which are then authorized to proceed.

5. Changes to unit-level information (i.e. new projects) must be added to the "***PHCRI Unit Level Research Access Summary for Human Subject Research***" spreadsheet and submitted to PHCRI for review.

UBC and Health Authority Guiding Principles

- The health and well-being of faculty, health professionals, trainees, staff, patients and the public is paramount.
- The orders, notices and guidance of the Provincial Health Officer, Health Authorities and WorkSafeBC will be followed.
- Approval for on-site activities (including research, education and administration) will only be granted to those who require on-site resources and cannot conduct this work remotely.
- **All activities that can continue remote work must do so.**
- There will be a staged and coordinated approach across each building and site (includes university, health authority and clinical research spaces).
- Staged resumption of activity may need to be reversed and stricter curtailment conditions imposed in response to public health guidance or changes to the situation at any particular site.
- Equity and personal circumstances will be considered in evaluating how to plan and conduct resumption of on-site activities.

SAFETY CONSIDERATIONS

1. VCH/PHC has developed COVID-19 resources that are specific to the acute, administrative, ambulatory, community and long-term care settings: http://ipac.vch.ca/Pages/Emerging-Issues.aspx. Under the *recovery resources* tab, researchers will find key principles for safety, recovery checklists and scripts for each of the above-noted health care settings. The following factors are addressed for each of the health care settings:
    a. virtual and in-person visits;
    b. family, visitors, and support;
    c. considerations for staff providing direct patient care and for those who are not;
    d. environment (e.g., physical distancing, lay out and flow), cleaning and disinfection, and supplies (e.g., PPE recommendations).

PHCRI strongly encourages research program/unit heads to review these resources to ensure that the elements noted above have been adequately addressed in the safety plans submitted for review.

2. VCH has developed resources for educating staff on appropriate use of PPE. Refer to the section on *personal protective equipment and hand hygiene* on the following website: http://ipac.vch.ca/Pages/Emerging-Issues.aspx.

3. Research must not introduce additional risk of COVID-19 transmission to staff, patients or families who are working in, or receiving services at VCH/PHC.

4. All activities that can be performed remotely must continue to do so. If a researcher or research team member must come to work, they need to assess their own health using the daily self-screening assessment tool or other applicable screening checklist. If a researcher or research team member is experiencing any COVID-19 symptoms, they should inform their supervisor and not come to work.

5. Researchers and research staff must maintain a distance of two meters between persons at all times, must comply with the maximum occupancy of each office or open workstation, and disinfect shared workspaces, as per their approved research program/unit safety plan.

6. Researchers, research team members and research participants must follow the PHC Visitation Changes guidelines while on site. Sponsor/industry representatives are not currently considered "essential visitors" and are not permitted on site during Stage 1 of human subject research resumption without PHC operational approval.

7. As part of the safety plan, research participants must be pre-screened for COVID-19 exposure and symptoms, as per VCH/PHC guidelines, prior to attending PHC facilities for procedures or tests. Alternatively, where possible, amendments to the original study application should be made to conduct remote/virtual visits.

These measures are in place to ensure the health and safety of all research personnel.

We fully understand that the research curtailment has significantly impacted your research programs and research personnel. Our goal is to manage this next phase competently to allow for increased occupancy in the very near future.

We thank you for your continuing cooperation and as always, if there are any questions or comments, please reach out to me.

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