Vancouver CoastalHealth Research Institute

PROVIDENCE HEALTH CARE Research Institute

To: VCH Research Community

June 11, 2020

Re: Resumption of Human Subject Research

We know you have been anxiously awaiting communication from VCHRI regarding the resumption of human subject research at VCH and we acknowledge that over the last few days, you may have received conflicting messaging regarding next steps. As noted in our Memo dated June 2nd, the process for resuming human subject research is complex and requires significant coordination with operations teams at VCH, 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 VCH.

In accordance with VCHRI's previous communication, a phased-in approach to resumption of on-site human subject research activity is being planned at VCH. This is needed to slowly and responsibly restore clinical services and other patient and public spaces across VCH's facilities and communities 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 preventing undue harm to non-COVID cases. Prioritization and restoration of healthcare services are being determined by VCH/PHC and VCHRI's phased-in resumption plan.

PRIORITIES

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

1. COVID-19 research[1]
2. Current research activity exemptions, as previously approved by VCHRI
3. Ongoing[2] clinical trials concurrent with clinical care (including new enrollment)

The resumption of human subject research activities at VCH 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 VCHRI 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. VCH operational research approval may be withheld until confirmation of CRCI review is provided to VCHRI. 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, prior to the curtailment, had *both* UBC REB approval and VCH 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 is integrated with a VCH clinical area, the safety plan developed by VCH will apply and must be adhered to. Where there is no integration with a VCH clinical area, the research program/unit will need to develop its own safety plan.

SUBMISSION REQUIREMENTS

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

1. The "***VCHRI 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 VCH clinical ***safety*** plan (as applicable). Where research space is not managed by VCH, a copy of the research program/unit's safety plan, which amalgamates investigator-level plans and takes occupancy limits into account, must be provided to VCHRI.[5] 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 VCHRI 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 VCHRI at research@vch.ca for review and approval. Researchers belonging to the UBC Department of Medicine should cc: dom.research@ubc.ca on their submission to VCHRI.

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

3. VCHRI will review the submission taking into consideration the criteria for Stage 1 prioritization of human subject research, safety plans and building occupancy. VCHRI will engage the applicable VCH operational leads, as well as additional VCH stakeholders (e.g., VCH facilities personnel) for input and guidance. If the research program/unit has already engaged with VCH operational leads, please provide the name and contact information of such operational leads on Tab 1 of the ***VCHRI 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:
    a. Due to the complexity of these reviews, including the need for VCHRI to consult with various VCH operations and department level personnel, VCHRI cannot guarantee a timeframe within which these reviews may be conducted. We will, however, do our best to facilitate timely reviews;

[4] VCHRI is requesting 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 in 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/signed 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.

b. VCH space that is utilized by research and managed by VCH requires approval from VCH 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 VCHRI for approval.

4. Once all appropriate levels of VCH review have been obtained, VCHRI 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 "***VCHRI Unit Level Research Access Summary for Human Subject Research***" spreadsheet and submitted by the research program/head to VCHRI 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 has developed COVID-19 *recovery 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).

    VCHRI strongly encourages research program/unit heads to review the resources provided by VCH to ensure that the elements noted above have been adequately addressed in their safety plans.

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 VCH Essential Visitor 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 VCH operational approval.

7. As part of the safety plan, research participants must be pre-screened for COVID-19 exposure and symptoms, as per VCH guidelines, prior to attending VCH 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.

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