Post-COVID Interdisciplinary Clinical Care Network (PC-ICCN) Research Intake Form

Post-COVID-19
Interdisciplinary Clinical Care Network
Recovery | Care | Research | Education

Instructions & guidelines for form

1. **Definitions**. In this document:
    - PC-ICCN is the network that oversees the integration of clinical care, research and education offered through the Post-Covid Recovery Clinics (PCRC)
    - The 'Biobank' means the biospecimen collection agency, BC Covid-19 Biobank Network (BCCBN), that collaborates with PC-ICCN to support research activities
    - 'Proposed research' means that body of work outlined in this application and described and supported by the letter of REB approval attached, or to be attached, to this application.
    - PI means Principal Investigator
2. **Incomplete forms.** Incomplete forms will be returned to the applicant. Unless explicitly instructed to skip a section (as restricted to the 'Requested Materials' section only), please include a brief explanatory statement for any questions you believe are not applicable to your study.

Policies

1. **REB approval policy.** A letter of REB approval for the research must be submitted to the PC-ICCN before final approval can be provided. Applicants who have already obtained REB approval may attach their letter to this application.
2. **Peer review policy.** It is expected that all proposals have undergone and been approved by an external peer review. Applicants without peer review support for their study will be asked for evidence of this before requested materials are released and/or access to patients is granted.
3. **Open science policy.** PC-ICCN has an open science policy and it is therefore expected that researchers using PC-ICCN and Health Authorities' resources will contribute data, likely to be of interest to other researchers and to the collective research dataset.

Applicant's proposing studies that do not include data sharing opportunities must demonstrate why data sharing is not reasonable and how this limitation is outweighed by the potential benefits of the work.

4. **Data and biospecimen direct sharing policy.** PC-ICCN's data and biospecimens cannot be directly shared with researchers whose work is not described in your approved ethics application. All secondary and subsequent uses of PC-ICCN/PCRC data and biospecimens 1by your team or others must be first approved by relevant REBs and by the PC-ICCN's scientific committee.

5. **Publication policy.** It is expected that all contributions made by PC-ICCN, its Biobank and associated data registry, as well as its Principal Investigators (PIs), will be acknowledged as appropriate in publications, posters, and presentations resulting from the work described herein. Authorship will be determined according to standard ICMJE criteria.

6. **Biospecimen Availability.** Applicants should note that biospecimens cannot be held for applicants and will be distributed chronologically, with chronological order based on the date that the application is 'approved', having met all policy and other requirements.

7. **Access to data.** In signing this form, the applicant(s) acknowledge(s) that further applications may be required for data access, as necessitated by adherence to privacy and ethical compliance requirements.

8. **Cost recovery policy.** Sustainability of the PC-ICCN/PCRC Research activities relies, in part, on recovering costs associated with research support activities. A budget will be provided to the contact PI based on the requirements of the work proposed. This budget will be agreed upon by both parties (i.e., the applicant and a designated representative of PC-ICCN) prior to data sharing, releasing biospecimens and/or providing services supporting access to PCRC patients.

Title of proposed research

Biospecimens required in proposed research?

Yes _____ No _____

Research involving biospecimens will need approval from the BC Covid-19 Biobank Network. To access the COVID-19 Clinical Research Coordination Request Form, please go to the following site:

https://rc.med.ubc.ca/redcap/surveys/?s=WM7X3WHAAP

Principal Investigators (PIs)

Indicate the names and contact information for each of the PIs for the proposed research (add rows as needed). Note that requested data/material will be sent to the person identified as the 'Contact PI'.

Name	Institution	Email Address	Phone Number
Contact PI			
Additional PIs			

Overview of proposed research

Summary of Research (< 300 words)

Objectives

Questions & Hypotheses

Population addressed

Please describe the patient group of focus including inclusion and exclusion criteria.

Analysis plan (< 300 words)

Please provide a summary of the data analysis plan for the study (< 300 words).

End of Study

Please indicate the total number of patients and/or biospecimens requested, and/or the timeline for the studies completion.

Power / Sample size justification

Please provide a summary of your calculations supporting the requested data / samples as both reasonable and necessary to address your research question(s).

Justification/rationale for proposed research

Explain how the proposed research meets an urgent public health need (< 300 words).

How will the proposed research impact clinical care of COVID-19 patients? (< 300 words).

Publication plan

Please list any publication you expect to result from the body of work associated with this application. Denote as To Be Decided (TBD), as needed. Note that a PC-ICCN representative may contact you, periodically, for the purpose of updating this list.

Publication type [1]	Interim title	Publication forum [2]	Target date (YY/MM)

[1] Including (but not limited to) papers, book chapters, posters and presentations
[2] Such as name of journal or conference

Support for Proposed Research

Peer review

Has the proposed research undergone peer review (YES/NO)? _____

If you replied **YES**, please include a list of documents demonstrating peer support for the work. If you replied **NO**, please describe your plan for having the study peer reviewed, as per policy statement (above). Note that a representative of PC-ICCN may request a copy of one or more of these documents during the application review process.

Financial support

Please list any current financial support for the proposed work.

Name of Award	Granting Agency	Award ID	Date funding begins (YY/MM)

Research Ethics Board approval

What is the status of REB approval? Please indicate as 'received' or 'pending'. _____

Is/was peer review part of your REB process? _____

Name and ID number of REB

Name of institution issuing REB

Requested Data/Material

Section 1 - Data elements being requested

Please skip this section if your request is limited to accessing patients and you are not requesting access to data from the PCRC's patient data registry.

Indicate the data requested. Note that this may be data associated with the request for biospecimens (see below) or it may be 'standalone' data (i.e., without a request for biospecimens).

Data	Description (fill as needed)

Section 2 – Biobank samples being requested

Please skip this section if no biospecimens are/will be requested from the biobank network (BCCBN).

Request list

Please provide information for each type biospecimen being requested. Note that the Biobank Manager will contact the PI to provide information on the Biobank Holdings and to gather additional information.

Sample type	Number of Samples [1]	Aliquot size

[1] Please indicate the total number of samples needed for each given sample type

Section 3 - Additions to patient protocols

Please skip this section if your proposed research will not include access to patients and/or additions to current patient protocols.

Direct access to patients

Are you requesting direct access to patients that present to the PCRC (YES/NO)? _____

If you answered **YES**, please provide a description of what is being requested and justification for this request. Please be sure to include information on where the patient visit will be held, how long the full visit will take and what will be asked of the patient.

If you answered **YES**, provide your plan for minimizing the burden placed on patients as a result of your research activities.

Additions to standard PCRC clinical procedures.

Are you asking for the PCRC clinical team to schedule/conduct additional tests, add items to physician assessment protocols and/or administer additional questionnaires and/or consenting processes on your behalf (YES/NO)? Note that 'additional' items are those that are not part of the standard PCRC clinical procedures. _____

If you answered **YES**, please provide a list of the additions requested to PCRC patient procedures. Skip this section if all proposed PSR data collection and test activities are part of your 'access to patients' plan, as described above.

Name/ID	Description/Justification	Specify what support is needed from the PCRC clinical team

Signatures

Please complete this section for each of the PIs that are part of this application. By signing this form, the applicants agree to the policy statements described in this document.

PI name	Signature [1]	Date (YY/MM/DD)
Contact PI		
Additional PIs		

[1] Electronic signatures will be accepted.

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Application form is complete and ready for review (YES/NO)? _____

Clinical and other metadata requested (data) (YES/NO)? _____

Biospecimens requested (YES/NO)? _____

Additions to PCRC patient protocols requested (YES/NO)? _____

Includes requests to contact patients (YES/NO)? _____