UBC Pharmacy Residents Residency Project Guide

Resident Research Guide

How to start your research and receive support

1. Take the TCPS2 Core Tutorial

- Go to https://tcps2core.ca/
- This is a mandatory training requirement for all researchers at Island Health.
- The course is self-paced and takes approximately 4 hours. On completion, you will receive a certificate for your records.

2. Determine if your project is classified as research or quality improvement

- Visit this link to submit to the QI Ethics Screening Tool and Registry.
- This tool will ask you some questions, classify your project as either research or quality improvement (QI). and assign you a risk score. Your results will be automatically forwarded to our QI Ethics Team.
- A member of the Research Ethics & Compliance office or a member of the QI Ethics Team will contact you to schedule a **30 minute** consult to answer questions about your project and to provide you with support for your applications.
- Reminder: **You will require an official exemption from research ethics before proceedng, even if your project is classified as QI.**

3. Register for an account in ROMEO, our Research Services Portal.

4. Register for an account in RISe

5. Want to work with Patient Partners?

- Send an e-mail to the **Leader of Patient and Public Research Engagement at Island Health by going to their website: https://www.islandhealth.ca/research-capacity-building/patient-oriented-research/out-team-services . It's best to start this process as early as possible.**

6. Acquaint yourself with the Research Ethics & Compliance Website

- Access study protocol and consent templates.
- Understand our policies and procedures.
- Our website can be found at https://www.islandhealth.ca/research-capacity-building/research-ethics-compliance-office

6. Submit an ethics application in RISe

7. Submit an operational application in Romeo

Research Services Portal, aka **ROMEO**

To register for an account in the Research Services Portal, email ResearchEthics@islandhealth.ca

- Ask for a Research Account
- Provide, First & Last Name, Island Health Email Address

Forgot your password?

To reset your password, visit https://viha.researchservicesoffice.com/Romeo.Researcher and click on the Reset Password button

Research Information Systems, aka **RISe**

To register for an account in RISe, you will need a UBC CWL (Campus Wide Login). To set one up, visit https://activate.id.ubc.ca/iamweb/ and follow the steps provided.

Have questions?

Please reach out to schedule a consult with a member of our team by reaching out to **ResearchEthics@islandhealth.ca**. Be sure to include "UBC Pharmacy Resident" in your subject line.

Operational review runs concurrently and takes minimum of 6 weeks.

An institutional Approval certificate must be issued before you start your research project and is required for all studies,

Have ethics application questions? **ResearchEthics@islandhealth.ca**
Have operational application issues? **ResearchOperations@islandhealth.ca**
Have ROMEO account issues? **ResearchEthics@islandhealth.ca**

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Ethics Application Guide

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Protocol

- Save time and use a Protocol template.
- Ensure there are sections on study objectives, inclusion & exclusion criteria, study design and procedures, statistical considerations, data collection & management, publication of results, references, and appendices.
- Please ensure all study team members and their contact information are consistent between the study protocol and the ethics and operational applications.

Data Management Plans & Privacy

- Please outline all types of data that will be accessed, analyzed, or collected during the course of the research activities.
- Please include a table that outlines the data source, how it will be destroyed, and when it will be destroyed.
- If there is any intent to preserve research data for future, secondary use, please consult TCPS2 Article 3.13 on the requirements to separately consent research participants for this data retention and use.
- If the research team wishes to send Island Health data outside of Island Health (e.g., to an academic institution or NGO), they must use **KiteWorks Secure File Transfer Protocol** to transfer this data.

General Tips & Closure Forms

- Be sure to use Island Health and/or UBC email addresses. In order to prevent a privacy breach, only institutional email addresses can be used.
- If recruiting from Island Health employees or patients, or using recruitment channels at any of our sites or online dissemination tools, please ensure a site-specific recruitment plan is described in detail under the Study Procedures.
- TCPS2 Article 4.7 items a, b, and c stipulate that it is unacceptable to not communicate the results of the research with study participants in a timely manner. Please develop a plan that includes sharing results in plain language with participants and how they will access them.
- **Closures:** Please be mindful that when your study concludes, you are obliged to submit a post-approval activity (PAA) to the REB in the form of a **closure form** confirming the fate of the research data and the cessation of research activities.

Consent Forms

- Save time and use an Informed Consent Form template.
- Include UBC and Island Health logos in the header.
- Depending on whether Island Health or UBC is the Board of Record, please include one of their telephone lines and e-mail addresses for participants to contact in case of complaints. Our stock writing is as follows:

For complaints about your rights as a research participant, please contact the Island Health Research Ethics and Compliance Office in Victoria at (250) 519-6726 or email: ResearchEthics@islandhealth.ca

Retrospective Chart Reviews

- Just because a chart review may be considered minimal risk does not mean that consent is not required.
- When requesting a waiver of consent, the REB requires that five conditions are satisfied. Please justify each condition separately for the REB as per **Article 3.7A**.
- If the retrospective chart review is seeking to retain personal identifiers and/or retain data for prospective future use and/or sharing with other researchers or institutions, participant consent is likely required.

Incidental Findings Plan

- It can happen over the course of clinical research that researchers notice important information that was not noticed during the course of clinical care. When these findings are deemed **material** researchers are ethically obliged to have a plan to communicate these findings with either the patient or one of their care providers.
- To determine the materiality of incidental findings, TCPS2 suggests they have three of the following elements:
    - Analytic validity
    - Potential significance
    - Actionability
- Please consult TCPS2 Article 3.4 in depth for more information.
- Please consult this article for assistance in how to develop a management plan to present to the REB to manage these findings should they occur: https://ethics.gc.ca/eng/incidental_findings.html

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