How to Obtain Approval to Conduct Research at Island Health

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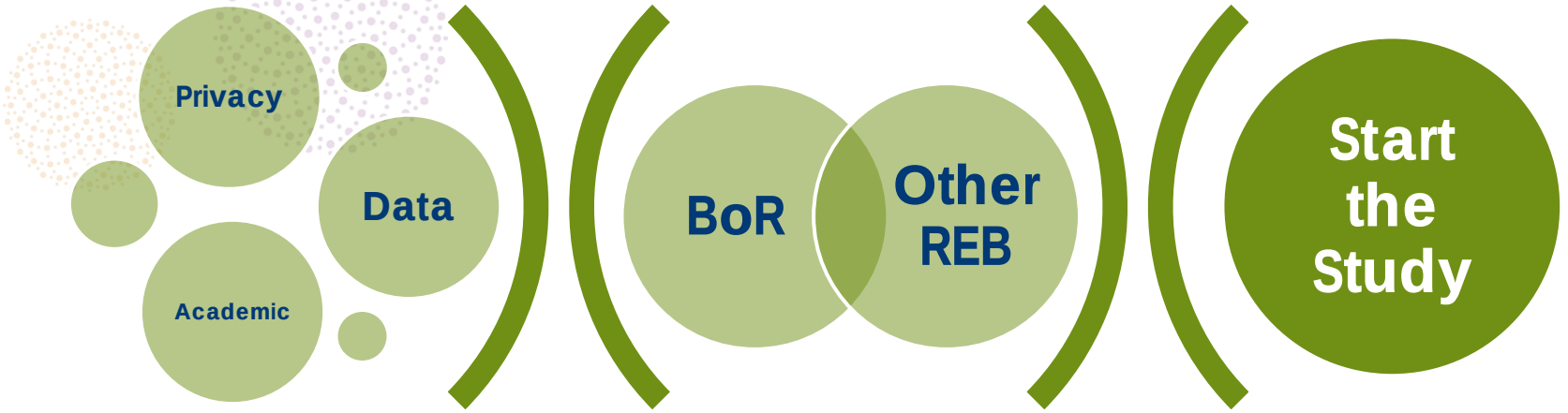
Purpose for Today

- What approvals are required to conduct research
- Data from Island Health
- Research Ethics review
- Ethical principles and common pitfalls
- How to start the process

Separate but Concurrent



Operational Ethical Institutional

Operational (as applicable)

- Departments affected by conduct of research
- Academic supervisor
- Data – including Stewards
- Contracts
- Privacy

Integrated Operational Review

- Research Portal
- Ethics application contains operational questions
- REO communicates with approvers
- Data is separate

Data from Island Health and process

Health Authority Data – there is lots of it!

- Many areas of care
- Many activities
- Many people involved

Transfusion Medicine

BC Trauma Registry

Patient Encounters

Emergency

Laboratory

Medical Imaging

Mental Health &
Substance Use

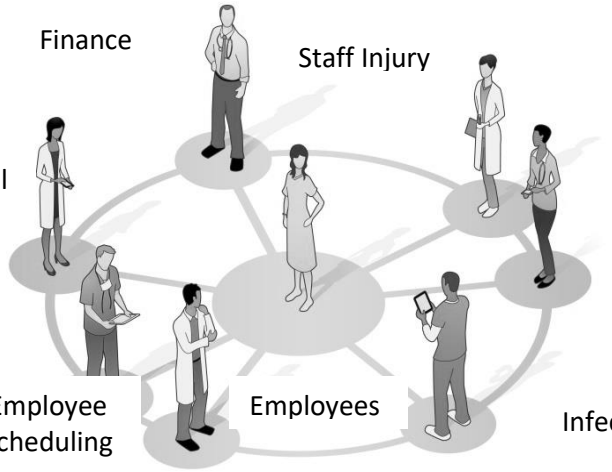
Pediatric
Intensive Care
Database

BC Perinatal Database Registry

Finance

Staff Injury

Payroll



Employee
Scheduling

Employees

Hospital Care

Clinical Orders

Surgical Waitlist

Surgery

Infection Prevention
& Control

End of Life

Residential Care

National Ambulatory Care Reporting System

Community Health Services

Pharmacy

Statistics:
Services
Capacity
Utilization
Cost

So how do I get started obtaining data?

- How do I know what data to ask for?
- Is there a list I can choose from?

Unfortunately there isn't (yet).

Requirements:

1) Be clear on the question you want to answer (hypothesis)
2) Be clear on how you are going to go about answering it (protocol)
3) E-mail a brief description of your project and the kind of data you think you need to

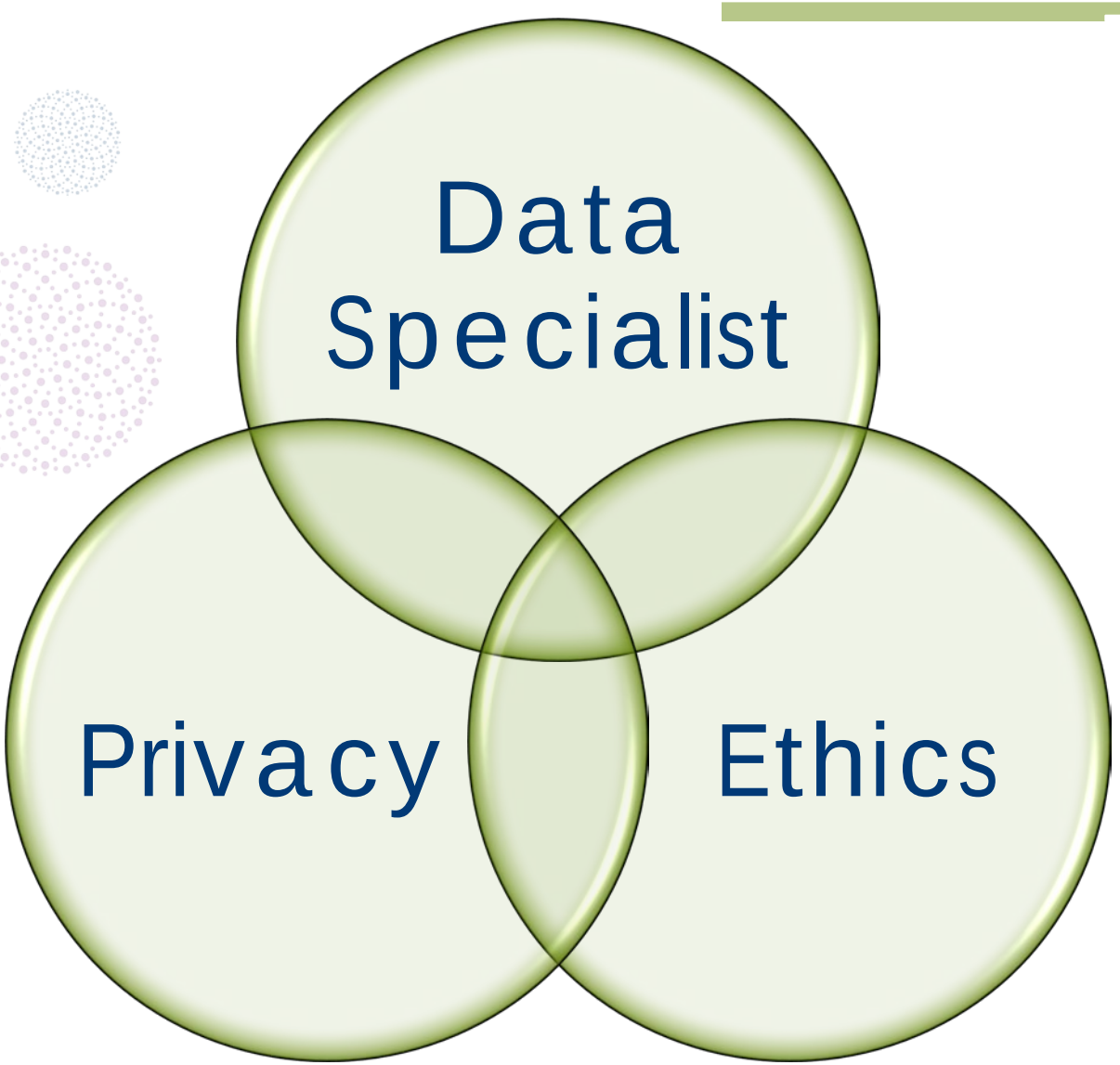
DataRequest@viha.ca

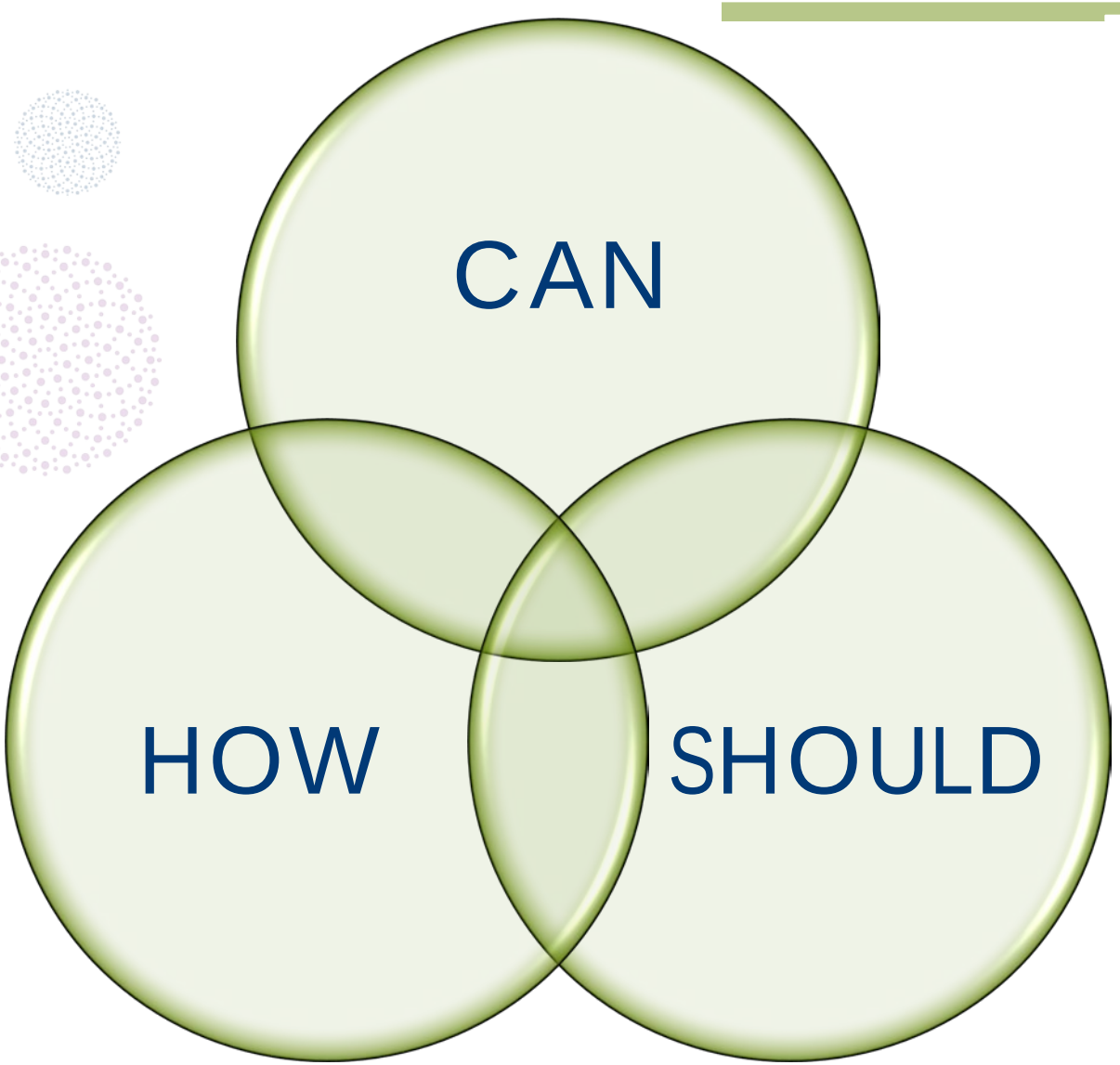
The Conversation

- You will be put in touch with someone at Island Health who knows the data
- They will be able to advise you on availability of the data
- They will advise you on the completion of the DAR

Data Access Request Form

- **Who:** the research team
- **Why:** why do you need data (protocol)
- **What:** what data do you need (in detail)
- **When:** when do you need the data, and at what intervals (if more than once)
- **How:** how will the data be provided to the research team
- **Where:** where will analysis be carried out
  i.e. restrictions on accessing data from outside Canada


Data Specialist
Privacy
Ethics


CAN
HOW
SHOULD

COMING SOON:

- An on-line Data Access Request (DAR) form is being developed but not yet available.
- You will require the assistance of an Island Health data specialist to identify the data you require, and to tell you if it is available.

DataRequest@viha.ca

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Research Ethics Review

Research Ethics

- Both a **legal** and **ethical** responsibility to ensure that research carried out meets appropriate research ethical standards
- Standard: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCSP2 2014)

Research Ethics Purview:

- Our people (patients and staff / physicians)
- Our resources (places and equipment / services)
- Our data

Scope of review

- REBs *do not* conduct scholarly review
- REBs *do* review scientific quality and methods to assess the risks and benefits and use of resources
- Research that is badly designed is unethical for people and resources

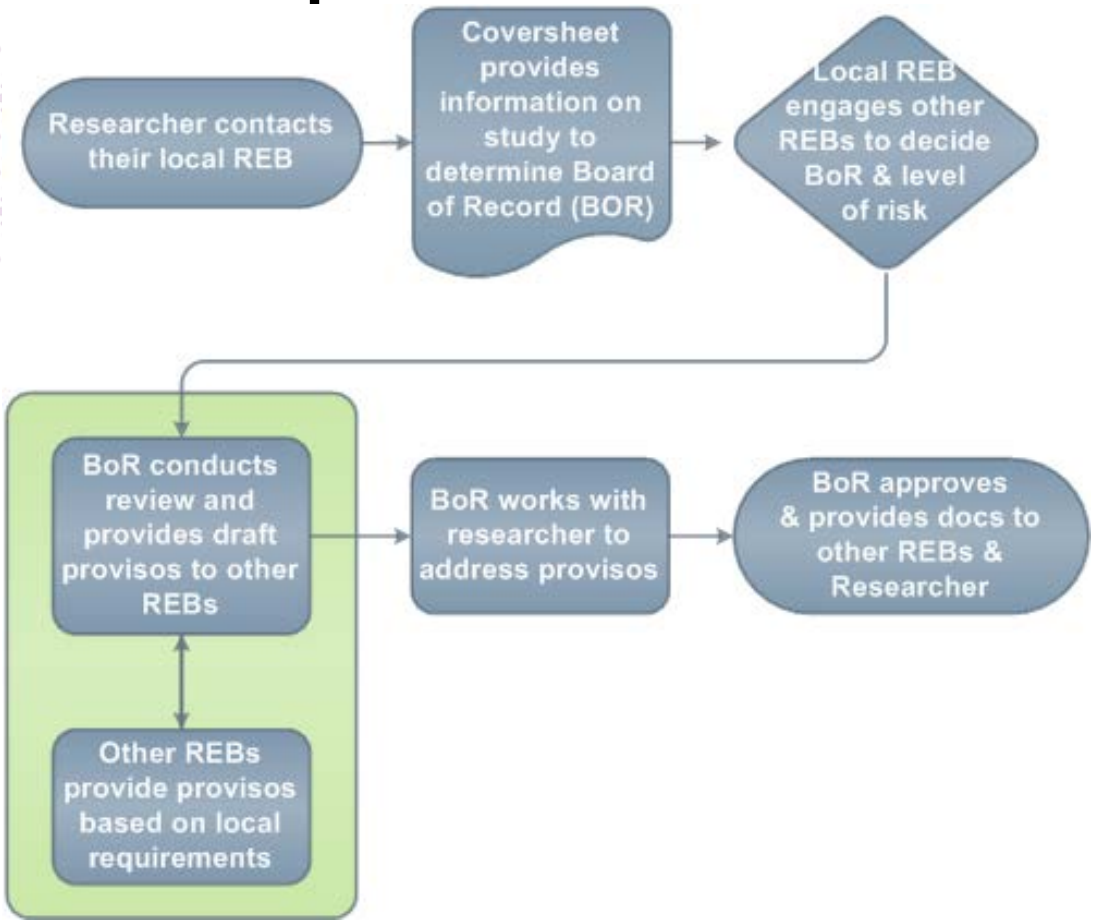
Scope of review

- The office of Research Ethics only reviews research…
- According to TCPS2, REBs are not required to review:
  - quality improvement;
  - quality assurance; or
  - program evaluation

Checklist[1]

1. Is the project **being presented** to the public, colleagues, the institution, your department or others (including students) as a "research" project (do you consider the project research)?	☐ Yes ☐ No
2. Is the project **funded** by (or being submitted to) a grant/award competition from a funding agency that *requires* research ethics review?	☐ Yes ☐ No
3. Is this a post-secondary **student research project** (whether for a class or a thesis) being conducted with the support of a College or University?	☐ Yes ☐ No
4. Does the project involve a **comparison of interventions or processes** where there is division of participants into different **groups**?	☐ Yes ☐ No
5. Does the project involve a **comparison of interventions or processes** either to **test** a new intervention or to **assess** the effectiveness of a process change?	☐ Yes ☐ No
6. Does the project involve **pilot testing or evaluation** of a new intervention, treatment or program, for which it would be **difficult to estimate the risk and benefit in advance**?	☐ Yes ☐ No
7. Will the project **results be statistically supported to enhance future** individuals, treatments or interventions beyond the project's participant population?	☐ Yes ☐ No

Relationship to Uvic & others



Why go through Research Ethics?

- Researchers require intellectual freedom / scientific inquiry
  - Freedom of inquiry
  - Freedom to challenge conventional thought
  - Freedom from censure

- With great freedoms comes great responsibilities...

(TCPS-2, Chapter 1, Article A)

"**Research is a step into the unknown**. Because it seeks to understand something not yet revealed, research often ***entails risks*** to participants and others..."

(TCPS-2, Chapter 1, Article A)

- All risk relating to ethics of the study needs to be assessed…
- All risks:
  - Risk to participants
  - Risk to researchers
  - Risk to the data
  - Risk to the integrity of the research

Risk of harm could be…

- Inherent to participation in the research activity;
- Due to vulnerability: Individuals whose circumstances may make them vulnerable in the context of research;
- External/contextual risk

We review risk by…

- Provide opportunity for consultation at design stage for ethically soundness (i.e. aligns with TCPS-2 ethical principles and FoIPPA);
- Conduct review of your research to see if it will be conducted ethically;

- Provide continuing review when your study changes;
- Investigate if a complaint is filed about a study;
- Hold a record of your study once closed.

Proportionate Review

- Minimal Risk Studies: The probability and magnitude of **possible harms** implied by participation in the research is ***no greater than those encountered by participants in their everyday life***

(TCPS-2; Article 2.8, B)

Proportionate Review

- Ethical review based on principle that the ***more invasive the research***, the greater should be the ***care in assessing the research***.

(Island Health, SOP 502, Research Ethics Review Policy)

Above minimal risk studies

- Any study involving an intervention or vulnerable population, deception, or novel procedure

- Goes to the “Full-Board” for review

The REB….

The Research Ethics Board (REB) is a group of people who oversee the ethical conduct of research studies

2 REBs within Island Health

HREB (*Health* REB)

- 17 members
- Coordinator: *Dawn Pollon*
- Reviews primarily minimal risk studies
- Behavioural studies
- 70+ studies per yr
- 30+ amendments per yr
- Harmonized studies
- Delegated reviews (no full board required) usually

2 REBs within Island Health

CREB (*Clinical* REB)

- 13 members
- Coordinator: *Karen Medler*
- All clinical trials and studies with clinical/medical interventions
- Generally above minimal risk
- 50+ new studies per year
- 170+ amendments per year
- Monthly full board reviews

REB

Good Science + Rigorous Methods = Ethical Research

Ethical Principles & Other Common Pitfalls

When in doubt... (*the* source)

- Read/search the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2014)

http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

Differentiate between:

Patient & Participant

and

Patient Health Information/Record
& Participant Data

2 Hats Issue

(Hint: you only have 1 head):

- What you have access to as a clinician is not what you can use for research
- As a researcher you must go through the proper channels **to access patient information**
- Audits are conducted on electronic health records

If you want to use (already collected) data without consent

- **Article 3.7a** Alteration to consent requirements
- **Article 5.5a** Secondary use of Health Care Records without consent
- You must successfully argue for and meet all the items listed under the articles

Other Common Pitfalls

- Confusion over “de-identified” vs “anonymized” vs “anonymous” data
- Start date: Research may not commence until ethics is received
- Spell-check…Use it! Spell erros impacts your credbilty

Other Common Pitfalls

- Protocol; Informed Consent Forms (ICFs) – use the approved templates from Island Health
- All public facing documents must have REB contact information and Island Health logos on them – this is our "stamp" that we have reviewed

ISAP: Information, Security and Privacy may be consulted

- Linkage of patient data to another source/data set)
- Identifiable data (including PHNs and MRNs and full postal codes)
- Indirectly identifiable data
- Data moving or being transferred to another site

ISAP – Information and Privacy may be consulted if your study…

- Use and security of portable devices (laptops, **USBs**, smart phones)
  - Portable devices should only be used as **a last resort** per the Privacy Commissioner
  - If they must be used, must be from the list of approved devices

- Keep data study codes separate from data
- De-identifying of data (third party best)
- Questions? contact island Health Privacy specialist Shannon.May@viha.ca

Electronic Devices and Security

- Non-standard/non-Island Health issued device to be connected to our network (e.g. **tablets**)
- Study requires software be installed on a Island Health computer
- Likely requires IM/IT input and possibly a Privacy Impact Assessment (PIA) which can take time

Tips for the wise…

- Avoid inconsistency (= time delay in us processing and you revising your application)

- Big Pitfall: Inconsistency between…

  REB Application ⟺ Proposal/Protocol

**Tip: Copy and Paste so that the documents align!*

How to Submit on the Online Research Portal

...you are not just submitting an ethics application...

- Submitting both:

  1) Ethics application

  2) Operational application

  but it's all in the same application

Changes to Approved Study

- Use portal to submit an Amendment Application if you need to **change** something in your **study** (you need approval before you institute any change)

Mandatory Reporting

- Report Protocol Deviation or other unanticipated event;
- Annual Renewal
- Closure report

Submission process – The Island Health Research Portal

- https://viha.researchservicesoffice.com/romeo.researcher/login.aspx

Timelines

- An application goes through many hands - plan for this when submitting
- Expect the review to take a minimum of ***4*** weeks before you hear back from Research Ethics
- …time can be extended depending on the queue…

Submitting your Application

- **Start early:** We can't anticipate issues until we have seen the full application & protocol
- Submit the application, protocol, and all study materials
- Use the templates
- Include data flow diagram

After submission

- Once it has been reviewed you will receive a “Notice of Review” via email
- Respond to the Notice of Review including addressing each point in the Notice

After submission

- Justify any changes that REB requests but you do not feel are necessary….this is a conversation
- Provide ‘track-changes’ version of documents to speed up the finalization

Submit an Ethics Applicati

www.viha.ca/rnd/research_ethics/ethicsapp.htm

http--www.viha.ca-r | BC Ethics Harmonizati | Cultural Safety Trainin | RISe | Home page - Universi | Information Security F | REO Team Document | F

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Ethics Application

Submit an Ethics Appl

Welcome to the Research Services Portal for online subm operational review, and continuing review forms.

Please refer to the videos, FAQs, and help documents on have questions about using the Portal, please consult the

When you are ready to begin your submission, please log PORTAL.

REQUIREMENTS FOR SUBMISSION

This Checklist Prior to Submission (.doc) describes all re ethics application, including important information on wh Board (REB).

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- FAQs for Reviewers

Submit an Ethics Application

Welcome to the Research Services Portal for online submission of research ethics approval, operational review, and continuing review forms.

Please refer to the videos, FAQs, and help documents on the right hand side of this page. If you have questions about using the Portal, please consult these materials before contacting our office.

When you are ready to begin your submission, please login through the RESEARCH SERVICES PORTAL.

REQUIREMENTS FOR SUBMISSION

This Checklist Prior to Submission (.doc) describes all required documents and standards for every ethics application, including important information on what will be required by the Research Ethics Board (REB).

Prior to uploading your documents to the Portal, please ensure that you have followed the guidance in the checklist.

If the documents submitted with your application are incomplete or do not meet the standards described in the checklist, our office will contact you to let you know that changes are

Any questions should be directed to researchethics@viha.ca.

Annual Renewal

Ongoing studies must be reviewed at least annually to ensure they continue to be conducted as described in the initial approval. The annual renewal process can be completed within the Research Services Portal and must be 'submitted' by the Principal Investigator.

The Principal Investigator or other identified study main contact will receive a reminder approximately six (6) weeks in advance of the expiry of the study through the Research Services Portal.

If the study is not renewed prior to the expiry of the current Research Ethics approval, it will be considered as lapsed and you will be unable to conduct research activities until such time as the renewal is in place. In addition, the lapse will be reported to the department head(s) where the research is taking place and not further funds will be released. We may also be required to notify the funding agency, study sponsor, and/or regulatory authorities of the lapse of approval.

Notification of Study Closure

The Principal Investigator is required to submit a notificatPDF)ion to the REB when the study is ready to be closed (i.e. there are no active study activities with participants, and the study can be archived for the requisite period of time indicated in the application). Please submit the Study Closure form in the Research Services Portal.

forms

Templates

- Data Flow Diagram Sample (PDF)
- Health Research Informed Consent Template (.doc)
- HREB protocol template (.doc)
- ICF Checklist (PDF)

Reporting Problems to the REB

See Safety Information and Unanticipated Problems Reporting Guidelines (PDF) for details on:

- What, how, and when to report
- A list of NON-reportable events
- Definitions of terms
- Examples of document types

Related questions?