vancouver island health authority
Research and Capacity Building
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OPERATIONAL REVIEW AND APPROVAL OF RESEARCH

Frequently Asked Questions

How is research reviewed and approved at VIHA?

- There are two streams of review and approval for research at VIHA that flow concurrently. **BOTH** must be satisfied before the research can commence:
  1. **Research Ethics Review and Approval**: All studies must be reviewed and approved by either the Clinical Research Ethics Board (CREB) or Health Research Ethics Board (HREB; including the Joint UVic-VIHA Subcommittee of Health Research). This is a completely separate process from Operational Review.
  2. **Operational Review and Approval**: All studies must undergo Operational Review, where researchers submit relevant study information to the Director of each impacted department, facility, service or support at VIHA required to conduct the research. This is a completely separate process from Research Ethics review.
- Once both approvals are obtained, a final Institutional Approval Certificate (which will include the date of Research Ethics approval) will be provided.

Why does VIHA require operational impact review and approval for research studies?

- To enable the tracking of metrics and the provision of oversight related to who is conducting research, where and in what areas.
- To ensure departments impacted by the research have an opportunity to determine if they can support the study and what the impact will be on their staff, facilities, equipment and space.
- To ensure that any significant costs for services or other resources that result from the research within a department are assessed and covered.
- To assist departments in determining whether their staff requires training (e.g., in-service training by the Researcher or training by a Sponsor, if applicable).
- To determine if there are any other concerns or issues regarding the conduct of the research that need to be addressed with the researcher before the research can start.

What comes first, Research Ethics review or Operational Review?

- The processes are conducted concurrently.
- The Research and Capacity Building will provide final **Institutional Approval to Conduct a Research Project** to the Researcher only after all required departmental approvals AND research ethics approval have been obtained.

What kinds of studies require Operational Review?

- Operational Review (and research ethics review) are required when research projects involve (but are not limited to):
  - VIHA patients or employees and/or their families;
  - Access to any health records held by VIHA;

- Impact on clinical or other VIHA services or resources (such as pharmacy, lab or medical imaging);
  or
- Being conducted at a VIHA-operated facility.

Whose responsibility is it to obtain operational approval for a research project?

- It is the responsibility of the Researcher to obtain Operational Review approval(s) from each department.

What do I have to submit?

- Please complete a **"Operational Review Application for a New Research Project' Form,** accessible from the Research and Capacity Building Department's web site.
- Additional documents relevant to how the study will affect the department or program (e.g., protocol synopsis, lab manual, pharmacy manual, informed consent) should be completed as needed by each department.
- The Operational Review Application Form (section 11, page 4) contains a list of specific documents required by some of the major providers of research support services at VIHA such as the lab, pharmacy, imaging, medical records and Heart Health.

Who do I submit the form to?

- For most studies, a completed copy should be forwarded to the Director of each department impacted by the research unless another contact is indicated in section 11 of the form (for example for laboratory support).
- If a department or program has a Medical Director in addition to an Administrative Director, the **Administrative Director** should receive the form.
- Some studies may be broad enough in scope that they require review and approval by an Executive Director or a member of VIHA's Executive Leadership team.
- If the Principal Investigator is a Director, the Executive Director should be provided with a copy of the completed application form.
- A list of Directors is provided on the Research and Capacity Building Department's web site.
- If you are unclear who needs to review your study, please contact VIHA's Research Administrative Coordinator at -370-8046 (18046).

What is the expected turnaround time for a departmental Operational Review?

- The turnaround time is normally two **weeks** from the date that all necessary information has been submitted to the department.
- In some cases (for example complex clinical trials involving laboratory services), it may take longer to assess the specific requirements of the protocol.

How is an approved departmental Operational Review communicated back to me?

- Once approved within a department, the signed Operational Review form is returned **to you** (NOT to the Research and Capacity Building Department).

What do I do with a department approval when I receive it?

- You forward it (or *them* if more than one department is involved) to the Research Administrative Coordinator at the Research and Capacity Building Department.
- Some departments (such as pharmacy, medical imaging or laboratory services) may also provide a formal letter to a Researcher outlining any specific terms, conditions, services and costs. These should also be submitted to Research and Capacity Building.

Does having an Operational Review approval mean I have approval to conduct my study?

- No. You must have both operational approval(s) **and** Research Ethics approval before you can conduct your study.
- When the Research and Capacity Building Department has all of the above, you will be issued an Institutional Approval Certificate to conduct your study.

What if I cannot get the Operational Approval(s) I have requested?

- If **not approved**, the department is requested to provide you with written notification that the research cannot be accommodated, including the rationale.

What is an "Internal" Research Project?

- One in which the Principal Investigator is an **employee of VIHA** and the study is **being conducted at VIHA**.

What is an External Research Project?

- An external research project can be either:
  - A research project conducted at VIHA by **a Principal Investigator with no VIHA affiliation**; or
  - A research project conducted by a **Principal Investigator with VIHA affiliation, at a non-VIHA location** but using VIHA's support services or facilities in some way to enable conduct the study.

Is there a difference in the operational review process for Internal and External Research Projects?

- No.

Do Quality Improvement (QI) or Program Evaluation projects have to go through the same operational review process as research studies do?

- No.
- Please refer to the QI and Program Evaluation checklist online at: www.viha.ca/rnd/operational_review

Who is an external researcher?

- An external researcher is a Principal Investigator who has no formal affiliation with VIHA.
- A student Principal Investigator meeting a curriculum requirement to conduct a study (who is not a VIHA employee or does not have a contract with VIHA)

How will I know when a research project has received final approval and I can start my study?

- The **VIHA Institutional Approval to Conduct a Research Project** will be sent via email to the Principal Investigator and the Primary Contact for the study.

Questions? Concerns? Feedback?

Please contact Lorraine Trischuk, Research Administrative Coordinator at 250-370-8046 (18046 from VIHA locations) or: Lorraine.Trischuk@viha.ca