
Frequently Asked Questions (FAQ's)

For the **Health Research Ethics Board (HREB)** and the **Joint UVic/VIHA Research Ethics Subcommittee**

If you don't see the answer to your question here, please contact the Research Ethics Office and we would be happy to help you ([link](#)).

Do I need to apply for research ethics approval for my study?

How do I know if my project is “research” or not?

How do I know if I should submit my study to the Clinical Research Ethics Board (CREB), to the Health Research Ethics Board (HREB), or to the Joint UVic/VIHA Research Ethics Subcommittee?

How do I know if my study is above minimal risk?

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I have submitted my application to the HREB or to the Joint Subcommittee. When will I receive a response?

I received a letter from the HREB or the Joint UVic/VIHA Subcommittee in response to my application for ethical approval, now what?

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I wish to make an amendment to a study that was approved by the HREB or the Joint UVic/VIHA Research Ethics Subcommittee. How do I go about this?

How long do I need to keep the study records?

How long does ethics approval last? How often do I need to renew my ethics approval?

What do I need to do when my study is finished?

Do I need to apply for research ethics approval for my study?

All human research that is conducted by members of the VIHA or that involves VIHA facilities, patients, residents, clients, staff or resources, or human tissue or biological material requires research and ethical approval from a VIHA research ethics board prior to commencement.

How do I know if my project is “research” or not?

Research is defined as any systemic investigation (including pilot studies, exploratory studies, and course based assignments) to establish facts, principles or generalizable knowledge. If you are not sure whether it is “research” or not, please contact the Research Ethics Office and we would be happy to help you ([link](#)).

How do I know if I should submit my study to the Clinical Research Ethics Board (CREB), to the Health Research Ethics Board (HREB), or to the Joint UVic/VIHA Research Ethics Subcommittee?

Studies should be submitted to the Clinical Research Ethics Board (CREB) if they involve a clinical intervention as part of the study, including clinical trial applications evaluating drugs, devices and natural health products. For example, if a study involves administering medication or a medical device, providing alternate medical treatment that is not standard of care, etc.

Studies that do not involve clinical interventions should be submitted to the Health Research Ethics Board (HREB). Studies that are below minimal risk and involve UVic faculty, staff or students who wish to conduct research within VIHA should be submitted to the Joint UVic/VIHA Research Ethics Subcommittee.

Studies that are above minimal risk and involve UVic faculty, staff or students who wish to conduct research within VIHA will need to be submitted to the UVic HREB and a VIHA REB separately – either the VIHA CREB or the VIHA HREB depending on the nature of the study.

How do I know if my study is above minimal risk?

The *Tri-Council Policy Statement* (TCPS) definition of “minimal risk” is as follows: “The research can be regarded as within the range of minimal risk if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research. The designation of minimal or non-minimal risk affects the way the application is reviewed not the substance of the ethical review.”¹

For example, if a study involves administering medication or a medical device, or providing alternate medical treatment that is not standard of care, etc. then this would be a study that is above minimal risk (and should be submitted to the Clinical Research Ethics Board [CREB]). A study that involves gathering highly sensitive or stigmatizing information, or research that could result in emotional or psychological harm, are other examples of studies would be considered above minimal risk.

¹ For more information see: Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. 1998 (with 2000, 2002 and 2005 amendments). Click here for the definition of “[minimal risk](#)”.

What are the requirements for submitting a study to the HREB or to the Joint UVic/VIHA Subcommittee?

The requirements for the HREB and the Joint UVic/VIHA Subcommittee are listed on the Research Ethics website ([link](#)).

What are the consent form requirements for the HREB or to the Joint UVic/VIHA Subcommittee?

The consent form requirements for the HREB and the Joint UVic/VIHA Subcommittee are listed on the Research Ethics website ([link](#)). Note that there is also consent form templates available on the website to assist researchers; researchers are not obligated to use these templates but they are recommended since they facilitate the review process.

Is there a deadline or meeting date to submit an application to the HREB or to the Joint UVic/VIHA Subcommittee? (When do I need to submit my application to the HREB or to the Joint UVic/VIHA Subcommittee by?)

Reviews of minimal risk studies submitted to the HREB or to the Joint UVic/VIHA Subcommittee are sent for review as they are received; therefore there are no meeting dates or deadlines that applications need to be received by. HREB studies that are above minimal risk will be reviewed either at the next HREB meeting or by special arrangement of an ad hoc meeting outside of the regular schedule. Note that the Joint UVic/VIHA Subcommittee only reviews studies that are minimal risk. For studies above minimal risk an application must be made to the UVic HREB and the VIHA HREB separately.

I have submitted my application to the HREB or to the Joint Subcommittee. When will I receive a response?

For minimal risk studies, you will receive a response from the HREB or to the Joint UVic/VIHA Subcommittee within two weeks to a month from the time your application is received. Studies that are above minimal risk that are submitted to the HREB may take longer to receive a response.

I received a letter from the HREB or the Joint UVic/VIHA Subcommittee in response to my application for ethical approval, now what?

If your letter outlined points that required clarification or revision then you will need to respond to this letter and address these points. The most straight forward way to do this is to write a formal letter addressing each point the letter makes in turn. Include a copy of any revised materials, i.e. the consent form, with marked changes (track changes or highlighted changes) along with a “clean” or unmarked revised copy. Include a version date on all revised materials. This information can either be mailed to the address where you sent your original ethics application or can be emailed to the address of the person who sent you your letter (if you received your letter via email). Note that only one copy of this information is needed.

Once I have submitted my response and revisions to the letter from the HREB or the Joint UVic/VIHA Subcommittee, when will I receive a response?

You will usually hear from the ethics office within a week from when your response is received. If there are further issues requiring clarification or revisions a response may take a bit longer, and you will receive either another email or a letter outlining the concerns, depending on the nature of the issues. Once all of the concerns from the HREB or the Joint UVic/VIHA Subcommittee have been satisfactorily addressed, you will receive an email

stating that your study has been approved and you may begin your research. A formal certificate of this approval will be emailed to you shortly after that.

I wish to make an amendment to a study that was approved by the HREB or the Joint UVic/VIHA Research Ethics Subcommittee. How do I go about this?

Prior to amending your study, complete and submit a HREB amendment application form or a Joint UVic/VIHA Subcommittee amendment application form available on the VIHA Research Ethics website ([link](#)). You will usually hear from the ethics office within one week from when your application is received. If there are issues requiring clarification or revisions you will receive either an email or a letter outlining the concerns, depending on the nature of the issues. If there are significant concerns, for example with participant safety, then a response may take longer. Once any outstanding issues have been satisfactorily addressed, you will receive a letter via email stating that your amendment has been approved and you may proceed with your study as amended.

How long do I need to keep the study records?

There is no VIHA policy on how long to keep study records for studies that do not involve a clinical intervention as part of the study (i.e. studies that are not governed by Health Canada) though 5 years is the average. Note that for Joint UVic/VIHA Subcommittee submissions UVic requires researchers to keep study records for 5 years. It is important to specify to research participants in the consent form how long you plan to keep study records, and when and how you will destroy them.

How long does ethics approval last? How often do I need to renew my ethics approval?

Ethics approval lasts for one year. Therefore to keep your ethics approval up to date, and to remain in compliance, it is necessary to submit an Annual Renewal Application every year prior to the anniversary of your original study approval (as stated on your certificate of approval). For example if your study was approved on January 5, 2010, you would need to complete and submit an annual renewal application before January 4, 2011. You should send your annual renewal application in about a month prior to the anniversary of your study, and not less than one week prior, to ensure sufficient time for processing so that your ethics approval status remains continuous. Annual renewal application forms for the different Boards are available on the Research Ethics website ([link](#)).

What do I need to do when my study is finished?

When your study is complete, submit a Study Closure Report. Study Closure Report forms for the different Boards are available on the Research Ethics website ([link](#)). You will receive acknowledgment that the form was received by the ethics office and your file will be closed.