



# **GUIDEBOOK**

## **General Guidelines for Investigators**

Prepared by: Vitalité Health Network Research  
Centre and Research Ethics Office

## TABLE OF CONTENTS

<b>TABLE OF CONTENTS</b> .....	2
<b>LIST OF APPENDICES</b> .....	3
<b>PART 1- INTRODUCTION</b> .....	4
1.1    Goal.....	4
1.2    Responsibility of Vitalité Health Network as regards research activities .....	4
1.3    Responsibility of Vitalité Health Network as regards the activities of the Research Ethics Board .....	4
1.4    Organizational Structure of Vitalité Health Network .....	5
1.5    Eligibility of a research project.....	6
1.6    Support in preparing a research proposal.....	6
<b>PART 2 - THE EVALUATION PROCESS</b> .....	7
2.1    The evaluation process .....	7
2.1.1    Submitting a research proposal to the Research Centre .....	8
2.1.2    Administrative feasibility .....	8
evaluation .....	8
2.1.3    Scientific evaluation.....	9
2.2    Decision process .....	9
<b>PART 3 - THE RESEARCH ETHICS BOARD</b> .....	11
3.1    Goal.....	11
3.2    Terms of reference .....	11
3.3    Authority.....	11
3.4    Power and decision-making.....	12
3.5    Membership and operations.....	12
3.6    REB meeting schedule .....	14
3.7    Project evaluation.....	14
3.7.1    Delegated evaluation .....	14
<b>PART 4 - THE INVESTIGATOR'S RESPONSIBILITIES</b> .....	16
4.1    Continuous Ethics Evaluation .....	16
4.2    Request for Amendment.....	16
4.3    End of Research Project .....	17
4.4    Correspondence .....	17
<b>PART 5 - CONTACT INFORMATION</b> .....	18

## LIST OF APPENDICES

- APPENDIX I** Checklist
- APPENDIX II** Guide to Writing a Research Proposal
- APPENDIX III** Example of a Research Proposal Title Page
- APPENDIX IV** Guide to Writing a Consent Form
- APPENDIX V** Example of a Consent Form
- APPENDIX VI** Administrative Feasibility Evaluation Grid
- APPENDIX VII** **Template for Letter of Support**
- APPENDIX VIII** Scientific Evaluation Grid
- APPENDIX IX** Request for Continuous Research Progress Evaluation for Research Projects
- APPENDIX X** Request for Amendment
- APPENDIX XI** End of Research Project Notice

## **PART 1**

### **INTRODUCTION**

#### **1.1 Goal**

The primary goal of this guidebook is to inform investigators of the process for submitting and evaluating research projects at Vitalité Health Network. This document also provides information pertaining to the Research Ethics Board and the investigators' responsibilities with respect to project management.

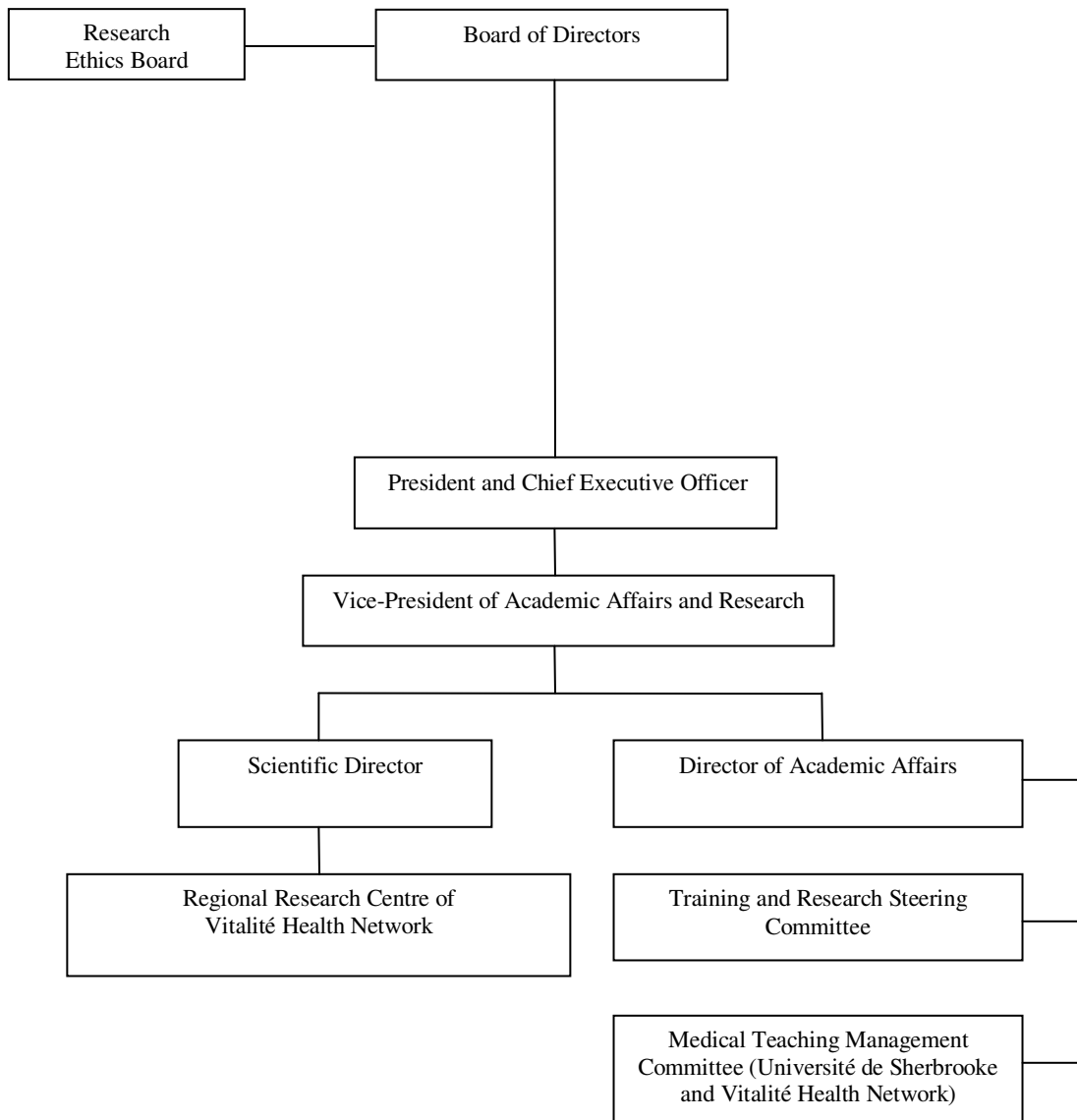
#### **1.2 Responsibility of Vitalité Health Network as regards research activities**

The Board of Directors of Vitalité Health Network is ultimately responsible for the quality of the research conducted within its facilities. For this purpose, the Board has designated the Research Centre of Vitalité Health Network as responsible for evaluating the administrative feasibility of a proposed research project. This evaluation is based on the principle that the Network is responsible for ensuring that the research activities conducted within its facilities do not adversely affect the quality of the care provided there. In parallel, the Research Centre also evaluates the scientific content, validity and relevance of the research project. Furthermore, the Research Centre plays a key role in facilitating and promoting research within the facilities of Vitalité Health Network.

#### **1.3 Responsibility of Vitalité Health Network as regards the activities of the Research Ethics Board**

The Research Ethics Board (REB) is tasked with evaluating the ethical acceptability of all research involving human subjects and human biological materials conducted under the authority or auspices of the Network's facilities, i.e. by their employees and students, wherever this research takes place. The REB reports directly to Vitalité Health Network Board of Directors.

## 1.4 Organizational Structure of Vitalité Health Network



## **1.5 Eligibility of a research project**

For a research project to be eligible for approval within Vitalité Health Network, it must be submitted by employees of the Network, professionals in the health care system, investigators in academic institutions or public research centres, or students working under the supervision of investigators. Some exceptions may apply. The eligibility of a research project can be confirmed by contacting the Research Centre.

## **1.6 Support in preparing a research proposal**

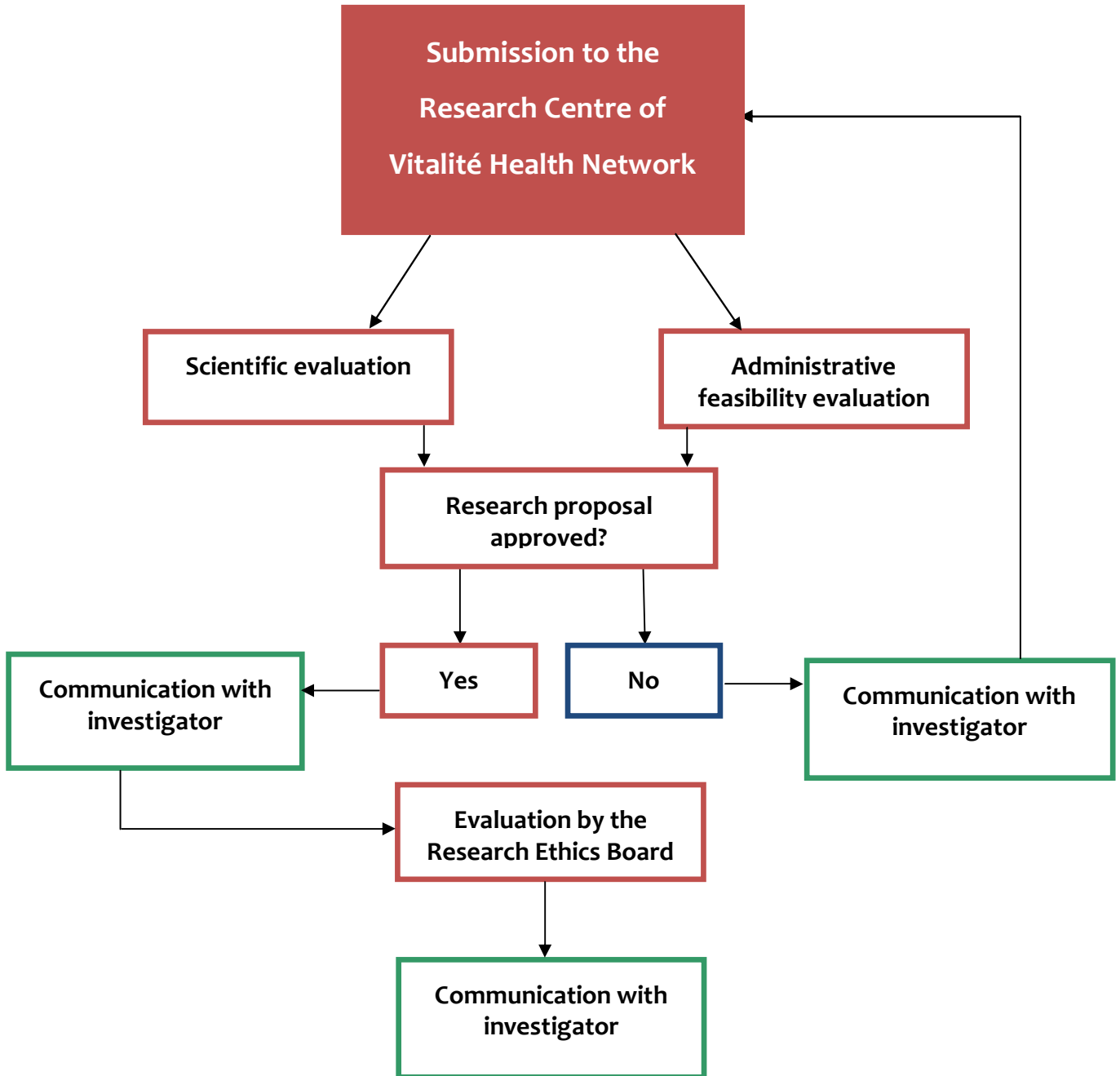
The Research Centre can assist employees of Vitalité Health Network in the preparation of a research proposal and other related documents. Indeed, the Research Centre offers support ranging from the initiation of projects to the publication of findings. Please contact the Research Centre for further information.

## PART 2

### THE EVALUATION PROCESS

#### 2.1 The evaluation process

The following figure depicts the complete evaluation process of a research proposal.



### 2.1.1 Submitting a research proposal to the Research Centre

For a research proposal to be evaluated, it must be submitted to the Research Centre before the Research Ethics Board (REB) submission. A submission must include the following:

- Completed checklist, indicating that the required documentation is found in the research proposal (appendix I);
- Proposed research protocol (appendices II and III);
- Information and consent form(s) (appendices IV and V);
- A detailed budget (including funding sources);
- Support letters from the Network department(s) or outside organization(s) involved in the project confirming their support (where applicable);
- Materials used to recruit participants (where applicable): advertisements, posters, etc.;
- Other documents (where applicable): questionnaires, interview tools, forms, observation notebooks;
- Approval letters from any other REB (where applicable).

**Incomplete submissions will be returned.** A complete submission is forwarded for both scientific and administrative feasibility evaluations. If the proposal is accepted without modifications (for its scientific content **and** administrative feasibility), it is forwarded directly to the Ethics Office where further evaluations will occur. Research proposals which require modifications will be returned to the principal investigator to make the necessary modifications before submitting the proposal to the Ethics Office.

### 2.1.2 Administrative feasibility evaluation

The purpose of the administrative feasibility evaluation is to provide the Research Centre with the following information:

- Where the research project will take place and where the study population is located;
- What departments or sectors from Vitality Health Network establishments are required to be involved in the research and are outside collaborations (e.g. universities) needed; **Letters of support from all involved parties in are required. These letters must indicate that the involved parties have been informed of their implications and the resources they must supply for the project. A Letter of Support template can be found in the appendices (Appendix VI).**
- What needs exist in the areas of financial, human and physical resources.

This evaluation is completed within a maximum of 10 business days.

The administrative feasibility evaluation is performed using the administrative feasibility evaluation grid for research proposals (appendix VI).

This evaluation in combination with the scientific evaluation allows the Research Centre to make an informed decision with respect to a research project's relevance and feasibility.

### 2.1.3 Scientific evaluation

The purpose of the scientific evaluation is to look at the scientific aspects of a research project. It determines the scientific validity and relevance of the proposed research project.

The evaluators are selected such that, together, they possess the expertise needed to perform an accurate assessment of the scientific protocol of the proposed project. The group responsible for performing scientific evaluations is typically, but not exclusively, made up of Research Centre staff. As needed, the opinions of outside experts may be sought (which can delay the evaluation process).

The scientific evaluation of a research proposal is completed within a maximum of 10 business days.

The scientific evaluation is performed using the scientific evaluation grid for research proposals (appendix VII).

A research proposal that has already been peer-reviewed (CIHR, NSERC, SSHRC, NBHRF, Health Canada, etc.) is not required to undergo scientific evaluation by the Research Centre. In such cases, the submission process nevertheless remains the same for the investigator, since the project must be submitted to the Research Centre for administrative feasibility evaluation.

## 2.2 Decision process

For the aforementioned evaluations, one of the three following decisions may be rendered:

Type of decision	Meaning of the decision
<b>Final approval</b>	The research proposal is approved without modifications. Suggestions could nevertheless be made for the investigator to improve the project.
<b>Initial conditional approval</b>	The research proposal is approved conditionally. The proposal requires modifications, clarifications or justifications. The reviewed documents must be resubmitted and approved by the Research Centre before the project is forwarded to the Ethics Office.

**Refusal**

The research proposal is refused and not forwarded to the Ethics Office. The proposal can be resubmitted for evaluation once modified according to comments from evaluators.

## PART 3

### THE RESEARCH ETHICS BOARD<sup>1,2</sup>

#### 3.1 Goal

The Research Ethics Board (REB) of Vitalité Health Network is responsible for protecting research participants who serve as human subjects by safeguarding their rights, and ensuring their safety, wellness and dignity. It evaluates research projects and ensures their ethical compliance before authorizing them to be implemented or continued. The REB is guided by the principles set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (which sets the standard for REB in Canada) and any other national or international standard considered relevant. In addition, it ensures compliance with the provincial *Personal Health Information Privacy and Access Act* and the federal *Personal Information Protection and Electronic Documents Act*.

#### 3.2 Terms of reference

The REB's terms of reference contain two essential components:

- Evaluating research proposals;
- Monitoring research projects.

The REB evaluates and monitors all research projects conducted in whole or in part within one or more facilities of Vitalité Health Network. Any research involving human participants or human biological material must be examined and approved by the REB before the research activities are undertaken.

#### 3.3 Authority

By virtue of its authority, the REB has the right and duty to make decisions on research projects involving human subjects and human biological material. The REB examines all such research projects featuring at least one of the following characteristics related to one or multiple facilities of Vitalité Health Network:

- The project will be at least partially conducted within one or multiple facilities;
- Some subjects will be recruited among the clients or staff of the facility or from records retained by the facility;
- The project will use human remains, cadavers, tissues, body fluids, embryos or foetuses;
- The researchers state that one or multiple facilities are participating;
- The researchers state that they are affiliated with one or multiple facilities;
- The project will use human, physical or financial resources belonging to one or multiple facilities.

### 3.4 Power and decision-making

The REB of Vitalité Health Network has the power to approve, reject, propose changes to, or terminate any research that is submitted or that is already under way.

The decision it renders may be one of the following:

Types of decision	Meaning of the decision
<b>Final approval</b>	The research proposal is approved without modifications. A final approval letter must be obtained before the recruitment phase is initiated.
<b>Initial conditional approval (with modifications)</b>	After evaluating the documents, the REB may ask for some modifications. An initial conditional approval letter will be sent. <b>Note:</b> When the required modifications are completed, reviewed documents must be resubmitted to the Ethics Office for review. If the modifications are satisfactory, a final approval letter will be sent and the recruitment phase will begin. <i>A <b><u>final approval letter</u></b> must be obtained before the recruitment phase can begin.</i>
<b>Refusal</b>	After evaluating the documents, the REB can refuse the research proposal. A refusal letter will be sent explaining the reasons for this decision.

### 3.5 Membership and operations

The REB is structured and operates based on the principles set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

#### REB membership

- **Chair:** Ensures that the REB operates in accordance with the policies and procedures of Vitalité Health Network with respect to the research ethics evaluation process. The chair monitors the decisions made by the REB for consistency, and ensures they are adequately recorded and communicated to investigators in writing or electronically;
- **Vice-Chair:** Assumes the role of chair when the latter is absent;

- **Quantitative research expert\***: Possesses expertise relevant to understanding the methodological impact of quantitative research proposed or under way;
- **Qualitative research expert\***: Possesses expertise relevant to understanding the methodological impact of qualitative research proposed or under way;
- **Ethics expert\***: Possesses formal training in ethics and has experience pertaining to the types of research conducted within the Network;
- **Person with experience in research methods and fields**: Possesses extensive knowledge of the research methods or disciplines falling under the authority of the REB;
- **Person with a legal background\***: Alerts the REB to legal issues and their repercussions but does not give formal legal opinions and does not act as a legal counsel for the REB;
- **Physician**: Possesses experience and expertise in a medical discipline;
- **Nurse**: Is registered with the Nurses Association of New Brunswick;
- **Community member\***: Primarily reflects the research participants' perspective; the community member enriches the REB's vision and core values and furthers the dialogue by empowering local communities.

## **REB operations**

The quorum is set at 50% plus one of the appointed members. However, board members that are identified with an asterisk (\*) in the previous list must be present for the quorum to be valid.

All members of the REB can participate during the deliberation process. All members, excluding the chair, have voting power. A decision is made by a consensus vote.

In certain circumstances, the principal investigator **could be required** to attend the REB meeting:

- If a new project submitted to the REB for evaluation is deemed “high risk”;
- In the incidence of a protocol deviation;
- If major side effects associated with a given study have arisen.

\* Please note that the REB has the right to request the presence of the principal investigator at any time and for any other reasons deemed necessary.

The REB can appoint *ad hoc* consultants in situations where the knowledge or expertise required for the complete evaluation of a research project are lacking. These special consultants are not included in the quorum and have no voting power.

### **3.6 REB meeting schedule**

REB members meet regularly to discharge their duties. The REB meets once a month throughout the year, generally on the third Wednesday of the month. The meeting schedule is made available so that researchers can prepare their proposals accordingly. You can obtain this schedule by contacting the Research Centre (see Section 5). The meeting schedule is approved at the April meeting every year.

**NOTE: TO PROVIDE SUFFICIENT TIME FOR THE SCIENTIFIC CONTENT AND ADMINISTRATIVE FEASIBILITY OF A PROJECT TO BE EVALUATED, IT IS SUGGESTED THAT RESEARCH PROPOSALS MUST BE SUBMITTED TO THE RESEARCH CENTRE ONE MONTH BEFORE THE TARGETED REB MEETING.**

### **3.7 Project evaluation**

The REB of Vitalité Health Network has adopted a proportional ethical evaluation method based on the general principle that the more invasive the proposed research, the more carefully it must be evaluated.

The REB has two levels of evaluation:

- Full evaluation of projects by the REB (full committee);
- Delegated evaluation of projects performed by the chair and two members of the REB.

#### **3.7.1 Delegated evaluation**

The Ethics Office determines the circumstances under which delegated evaluation of a research project is appropriate and determines who is responsible for conducting it. The decision is based on the minimal risk threshold: whereby prospective participants, by participating in a research project, will incur no more inconveniences than they would normally face during daily life activities.

### 3.8 Research projects not requiring REB evaluation

The following research projects do not need to be examined by the REB:

- Research exclusively based on information in the public domain, with no reasonable expectation of privacy;
- Observation of people in public places, provided the research does not involve staging by the investigator, direct interaction with people or groups, or the collection of personal information to be disseminated in photo, film or video format, and the targeted people or groups have no expectation of invasion of privacy;
- Program evaluations, quality assurance or quality/performance improvement studies, or review and evaluation of a program or service. Any project designed to ensure that a product or service meets specific requirements.

**If in doubt, please contact the Research Centre of Vitalité Health Network.**

<sup>1</sup> The Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, the Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 1998 (with 2000, 2002 et 2005 updates).

<sup>2</sup> Centre for Interdisciplinary Research in Rehabilitation in Greater Montreal. (2010). *Research Ethics Board*. Montréal, Canada. Consulted on August 20th, 2010 at : [www.crir.ca](http://www.crir.ca)

## PART 4

### THE INVESTIGATOR'S RESPONSIBILITIES

The principal investigator oversees all research activities related to the project. He or she is also responsible for submitting the following documents to the Research Centre and the REB:

- Request for Annual Research Progress and Ethics Evaluation;
- Request for Amendment;
- End of Research Project Notice.

#### 4.1 Continuous Ethics Evaluation

All active research projects must undergo continuous ethical monitoring. Through such evaluations, research projects being conducted within the Network can be monitored to ensure they are progressing and to identify any problems. The REB asks all principal investigators to submit a brief annual report at least once every 12 months from the anniversary date of the initial project approval. Based on the risk associated with the research project, the REB reserves the right to request more frequent annual evaluations. To submit a request for annual evaluation, the *Request for Continuous Research Progress Evaluation* form (appendix IX) must be completed. The Ethics Office is responsible for informing the principal investigator of the expiry date of the research project approval by sending a letter 60 days and 30 days beforehand. If the request for annual evaluation is not received before the expiry date, the REB may suspend the research activities until the request is received and the ongoing approval of the project is granted.

#### 4.2 Request for Amendment

The REB approves specific versions of the documents submitted for a research project. In the course of a research project, some modifications to the documents may be required. However, **ANY** modifications to the previously approved documents be they major or minor, must be submitted to, and approved by, the REB of Vitalité Health Network. To submit a request for amendment (modification), the *Request for Amendment* form must be completed (Appendix X).

Major modifications to the research protocol will require the research project to be resubmitted to the Research Centre's evaluation process as described in section 2 of this document. Some examples of major modifications include:

- Modifications to the methodology or experimental protocol;
- Modifications related to the sampling;

- Significant modifications related to the budget.

### **4.3 End of Research Project**

When a research project ends, the principal investigator is responsible for informing the Research Centre and the REB by completing the *End of Research Project Notice* form found in appendix XI.

### **4.4 Correspondence**

To ensure the correspondence emanating from the Research Centre, the Ethics Office and the REB is well managed, it is strongly recommended to have a binder for this purpose.

## **PART 5**

### **CONTACT INFORMATION**

#### **MAILING ADDRESS:**

Research Centre of Vitalité Health Network  
330 Université Avenue  
Moncton NB E1C 2Z3

**TELEPHONE:** 506-862-4492

**FAX:** 506-862-4373

**E-MAIL:** [recherche.research@vitalitenb.ca](mailto:recherche.research@vitalitenb.ca)

# Appendix I Checklist

Before submitting your research proposal, ensure you have all the required documentation.

- Proposed research protocol
- Consent forms\*
- Other documents: Questionnaires, interview tools, forms, observation notebooks, etc.\*
- Material used to recruit participants (advertisements, posters, etc.)\*
- Approval letters from any other Research Ethics Boards (where applicable)
- Support letters from the departments/sectors of Vitalité Health Network that are involved confirming their participation in the research project
- Budget (if applicable)

*\*These documents must be submitted in French and English, where applicable.*

**All research involving human subjects or human biological materials conducted at Vitalité Health Network must be evaluated and approved by the Research Ethics Board. Final written approval must be obtained before research activities begin.**

**Please submit your documentation in electronic format (*preferred*) or hard copy format to:**

Research Centre of Vitalité Health Network  
 330 Université Avenue  
 Moncton NB E1C 2Z3  
 Telephone: 506-862-4492      E-mail: recherche.research@vitalitenb.ca

## Appendix II

# Guide to Writing a Research Proposal

## THE RESEARCH PROPOSAL

All research projects must have a duly written research proposal in French or English. At this stage, diligent efforts must be made to determine all aspects of a research project. A research proposal must contain between **10 and 15 pages**, excluding the title page, list of references, tables and figures, consent forms, questionnaires, advertising material and budget proposal.

**Note:** A professional approach requires that a research proposal as well as all attached documents be well written (spelling, grammar and sentence construction). The same applies to documentation in French. Translations must be professional and respect the principle of equivalence. Otherwise, the Research Centre will return the proposal to the investigator.

Each page of the research proposal must have a heading in the upper right corner indicating the name of the principal investigator, and page numbering at the bottom of each page. The font used as well as the layout of the information must be such that these documents can be easily read and understood. The use of “Arial” or “Times New Roman” 12 point font is therefore recommended, along with clear headings (in bold) and ample space within the text.

### TITLE PAGE

A title page is required when submitting a research proposal. This constitutes the document’s cover page and must include the:

- Title of the proposal;
- Name of the principal investigator, along with his or her title and contact information (address and telephone number);
- Names of the co-investigators working on the research project, along with their titles and contact information (addresses and telephone numbers);
- Name and contact information (address and telephone number) of the resource person for the research project, should questions arise from the Research Centre or the Research Ethics Board (if the resource person is either the principal investigator or one of the co-investigators, write this name in **bold**);
- Version number and date of the proposal (must be updated if more than one version has been submitted).

## SUMMARY OF THE RESEARCH PROPOSAL

This section must not exceed one page and must be written in layman's terms. The summary must contain the following sections:

1. A paragraph that introduces and underlines the importance of the field of research in question. This paragraph should also summarize in a few sentences what is not known within the field and relate it to the proposed research project;
2. A paragraph that presents the general goal for the research and sets out the specific research objectives or questions. These should be underlined. Example: Objective 1: To determine the incidence of X in populations Y and Z. For each objective, provide a brief description of the methodology to be used;
3. A paragraph that describes the expected findings, discusses the positive contribution of these findings to Vitalité Health Network, and proposes a timeline for the whole research project.

## RESEARCH PROPOSAL

The research proposal must present a clear and concise description of the research plan and discuss the following, in this order:

- **Review of literature and relevance of the proposed research**  
Present a review of the literature related to the proposed research field. This section should provide an overview of the current knowledge while identifying major issues and what remains unknown in the field. Demonstrate the scientific reasoning behind the research and explain how the proposed project could contribute to the advancement of the field;
- **The goal of the research and the objectives and/or research questions**  
Present in detail the goal of the proposed research and the specific objectives or research questions that will allow this goal to be reached;
- **Methodology**  
Include the target population and a justification of the sample size, study type, data collection method (conduct of the study), and data analysis method;
- **Expected findings**  
Describe the expected findings, the anticipated difficulties, and the proposed timeline. Complete with a short paragraph that describes the importance of the proposed research and explains **how the project will make a positive contribution to Vitalité Health Network**;
- **Project timeline**
- **References**

- **Tables and figures (if applicable)**
- **Consent forms**
- **Questionnaires and any other tools used (if applicable)**
- **Advertising material (if applicable)**
- **Detailed budget**

Appendix III  
Example of a Research Proposal Title Page

**Title of the Proposal**

**Principal Investigator**

Given Name and Surname, Title

Address

Telephone Number

**Co-Investigators**

Given Names and Surnames, Titles

Addresses

Telephone Numbers

**Resource Person for the Research Project**

Given Name and Surname

Address

Telephone Number

Version Number and Date

## Appendix IV

# Guide to Writing a Consent Form

## THE CONSENT FORM

Free and informed consent is a process in itself and not simply a form to be signed. It is at the heart of the ethics governing research involving human subjects and implies dialogue and information sharing, with the entire process allowing potential participants to agree or refuse to participate in research projects.

The consent form is a tool that protects and promotes human dignity. A copy of the consent form must be given to the participants for them to retain and to serve as the basis for future discussions with the research team.

This guide is designed to assist in the development of consent forms for research projects. **However, some sections may not apply to your research project.** If this is the case, please omit these sections on your form. Explanations are provided under each section to help the investigator write the form.

### GENERAL INSTRUCTIONS

As many forms as necessary must be written, i.e. a consent form is required for each target group **for which participation differs within a given protocol** (e.g. control group, treatment group).

A form must be **easy to read and simple to understand**. Avoid language that is too scientific or complex.

#### Font

The font used as well as the layout of the information must be such that these documents can be easily read and understood. The use of “Arial” or “Times New Roman” 12 point font is therefore recommended, along with clear headings (in bold) and ample space within the text. Furthermore, all text must be aligned to the left to facilitate reading of the documents.

#### Letterhead

The first page of a consent form must be printed on the letterhead of the organization responsible for the study (e.g. *Université de Moncton*).

#### Form identifier

The dated version must be indicated at the bottom left of each page.

The page numbering must appear at the bottom right, with the total number of pages also being indicated (e.g. page 1 of 7)

A section at the bottom left must be reserved for participants to initial each page. This procedure allows them to ask questions and to assimilate information as each page is read.

### Use of the pronoun “you”

It is recommended that the word “you” (second person) be used throughout the text, except for the section of the form where the participant must give his or her consent.

## **SECTIONS OF A CONSENT FORM**

### **PROJECT TEAM AND SPONSOR**

- **Title of the research project**
- **Principal investigator**
- **Co-investigators**
- **Project sponsor**

Prospective participants should know who is asking them to participate in a study and why.

The consent form should identify the principal investigator and the other members of the research team that the participants will be dealing with. The names of all these people should be provided along with their affiliations (professional titles). In addition, the organization that is sponsoring the project and all the other organizations involved should be identified.

### **DECLARATION OF RESPONSIBILITY**

After the section with information on the research team members, a statement of responsibility for the project must be signed by the investigator in charge. Copies of the consent form must be signed ahead of time.

### **A. INTRODUCTION**

The investigator must indicate the reasons for recruiting a participant into the study, i.e. the specific reasons for asking him or her to participate rather than someone else.

## **B. OBJECTIVE OF THE RESEARCH PROJECT**

The information given to prospective participants should explain, in layman's terms: the **goal of the research, the subject being studied, and hypothesis and/or objectives of the proposed research.**

## **C. NATURE OF MY PARTICIPATION**

This section must be very clear and detailed and provide enough information for participants to be able to understand and visualize what they will have to do. Rather than providing a scientific description of the procedures, this section must explain the practical implications for participants. If needed, use a table. It is necessary to:

- Describe everything that participants will have to do in simple terms, illustrating with examples if necessary;
- Indicate whether participants must change or cease a current treatment or medication in order to be included in the study, and explain how this change or cessation will affect their health status;
- Explain the specific restrictions associated with the treatment, such as diets or exercises;
- Indicate the routine examinations and tests that participants will have to undergo in order to be included and participate in the study (physical examinations, vital signs, medical history, blood tests [with the amounts of blood drawn each time indicated, if applicable], urinalysis, X-rays, frequency of tests, etc.);
- Indicate the specialized examinations that participants will have to undergo in order to be included and participate in the study, and provide clear explanations;
- Indicate the questionnaires or logbooks that participants will have to complete and specify the amount of time they will have to devote to doing so and at what frequency;
- Specify the number of sessions, the length of each session, and the planned breaks;
- Specify the follow-up (if applicable), especially in the case of longitudinal studies;
- Indicate where the experimentation will take place;
- Specify whether the sessions will be recorded on audio or video tape;
- Make a distinction between the standard treatment and the treatments or interventions related to the research project.

## **D. POSSIBLE BENEFITS OF MY PARTICIPATION**

Describe the benefits that participants are entitled to expect, even if these cannot be guaranteed. If no benefits are expected to accrue to the participants themselves, indicate this also. If there are no direct benefits, it is appropriate to indicate the contribution that participants will make to the advancement of scientific knowledge or to the understanding of a condition or illness, etc.

“Closer follow-up” (medical, nursing, dietary or other) is not to be mentioned among the benefits, since this would amount to saying that regular patients do not receive good services, and may have the effect of inciting, not to say coercing, potential participants in their decision-making process. As well, this “closer follow-up” is determined by the research protocol and could, in some cases, even constitute a genuine inconvenience, depending on the number and length of the visits.

The reimbursement of expenses incurred during visits is not a benefit, since it is quite normal to reimburse expenses that participants would not have incurred had they not been participating in the study.

## **E. RISKS AND INCONVENIENCES POTENTIALLY RESULTING FROM MY PARTICIPATION**

Prospective participants must understand the risks to which they will be exposed and must, in particular, be informed about the possible harm they might suffer from their participation in the study.

The information supplied to prospective participants seeking their consent should describe all foreseeable harm, including physical, emotional or psychological harm as well as any other potential inconveniences.

Some examples could include:

- Loss of self-confidence after receiving a poor result on a memory test;
- Regret at revealing personal information to an interviewer;
- Interruption of family routines;
- Long waits;
- Boredom;
- Disclosure of personal information;
- Fatigue;
- Stress related to the experimentation;
- Pain related to the type of samples taken;
- Transportation;
- Emotional reactions;
- Other.

If a risk exists, it must be accurately described by explaining the possible consequences and related probabilities. All known risks must be disclosed, even when they are rare, if knowledge of them may make a reasonable person hesitate to participate in the study. The possibility of unexpected risks, where a study involves a new intervention whose dangers are not all yet known, must be mentioned. If there are risks, mention the corresponding preventive measures that will be taken.

## **F. ALTERNATIVES TO PARTICIPATION**

Some projects may involve treating participants who are suffering from a particular illness, syndrome or condition. In such cases, it is especially important for prospective participants to know whether other treatments or therapeutic options are available, where these exist. Where there are no other alternatives (e.g. no other possible therapies), this should be mentioned.

As well, prospective participants should be informed about the care they can expect to receive if they decline to participate in the study. If a research project is not examining a medical treatment, it must be made clear to participants that, from the medical perspective, they will obtain no benefit from the research.

## **G. COMPENSATION IN CASE OF HARM**

The following paragraph must appear in consent forms:

*If you were to suffer any harm resulting from any procedure related to the study, you will receive all necessary medical care. By agreeing to participate in this study, you waive none of your rights and do not release the investigators (where applicable: organizations, companies) or institutions involved from their legal and professional responsibilities.*

## **H. VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW**

It is important to carefully explain to participants that their participation is voluntary and that they can terminate it at any time, for any reason and without prejudice, by giving a verbal notice.

It must be determined what will happen to the data collected from participants who withdraw. The investigator must clarify whether, in such cases, this data will be retained or destroyed.

## **I. HALTING OF THE PROJECT OR OF A PARTICIPANT'S INVOLVEMENT**

Participants must know that certain grounds could lead to the halting of the project by the investigators, e.g. new data rendering the project unethical or a participant no longer meeting the selection criteria.

## **J. ACCESS TO MEDICAL OR OTHER RECORDS**

Indicate whether the investigator, or anyone else involved in the project, will have access to certain data in participants' medical records. Clearly indicate what information will be obtained from the records and for what reason. All access to medical records must be approved by the Research Ethics Board (REB).

## **K. FINANCIAL COMPENSATION**

The monetary, moral or material contribution offered to participants must retain a symbolic value and must at no time constitute an incentive for participants to participate in the research where it could reasonably be assumed they would have refused without the offer. The investigators and REB are responsible for evaluating the symbolic or unduly motivating nature of the compensation offered, depending on the participants involved in a research project. Financial compensation in no way signifies that participants are to be paid. The money is given on a "complimentary" basis, and the investigator will justify doing so in the consent form. **If no financial compensation is to be provided for participation, this must also be mentioned.**

## **L. INFORMATION DISSEMINATION PLAN**

Investigators must inform participants whether they plan to use the information collected for the purposes of scientific and professional communications (publications). Please ensure to mention that no information identifying participants will be disclosed in these communications.

## **M. CONFIDENTIALITY**

The measures that will be taken to protect the confidentiality of data must be specified, namely the:

- Codification of nominal data;
- Location where research data will be stored and related procedures;
- Storage methods;
- Access to the data.

Specify the period during which the data will be retained. If this period is greater than **five years**, the investigator must justify this choice to the REB, which will be required to evaluate the relevance of the time period.

Explain that the data, including audiovisual materials, will be destroyed when this time period expires.

Investigators must inform research participants that the information collected will only be used in relation to the current research.

## N. CONTACT PERSONS

In addition to questions resulting from emergency situations that may arise, study participants may wish to receive more information on the study itself, some terms and conditions, or their rights as research participants. For this purpose, the contact information of the resource person (principal investigator and/or one of the co-investigators) who will be able to address these issues must be provided to research participants.

### **The following paragraph is required:**

**If you have questions about your rights as a research participant, or if you wish to discuss the study with someone who has no ties to the research, you may contact Isabelle Dugas, Regional Ethics Office Manager of Vitalité Health Network, 1750, Sunset Drive, Office B-226E, Bathurst, NB E2A 4L7, 506-544-2506; e-mail address: [isabelle.dugas@vitalitenb.ca](mailto:isabelle.dugas@vitalitenb.ca).**

## DECLARATION BY THE PARTICIPANT

Except in some special cases, consent is given by the participants themselves, which means this section must be written in the first person singular, must be kept as simple as possible, and must not repeat information previously stated in the form.

Insert a sentence stating that participants have read and understood the terms of the consent form and have been satisfactorily informed about the nature of, and reasons for, their participation in the project.

Members of the REB encourage investigators to allow participants a period of reflection between the first contact, when the investigator explains the expected participation, and the second contact, when the participants sign the consent form. A copy of the form must be given to participants (two copies of the form are therefore required at the first meeting, with participants signing and dating both copies and keeping one).

For each signature, the name must also be printed. A witness must also sign.

## DECLARATION BY THE PERSONS RESPONSIBLE FOR OBTAINING THE CONSENT

For research ethics follow-up, it is important to have the name of the person who obtained the participants' consent. **This person may be the principal investigator.** Indeed, some participants subsequently complain that the person did not inform them well about some elements of the research.

Furthermore, by signing, the person responsible for obtaining the consent declares having fulfilled all the conditions required to obtain free and informed consent from participants. A witness must also sign.

#### **DECLARATION BY THE LEGAL REPRESENTATIVE OR PROXY**

Signature by the proxy or legal representative will only be requested in cases of incompetency, of a participant who is a minor, of a reading or writing difficulty, or of a need for an interpreter. A witness must also sign. This section must be contained within **one separate page**.

Appendix V  
Example of a Consent Form

## CONSENT FORM

### **PROJECT TEAM AND SPONSOR**

PROJECT TITLE:

PRINCIPAL INVESTIGATOR: (Name and professional title)

CO-INVESTIGATOR(S) (research director): (Names and titles)

PROJECT SPONSOR: (Name of organization, e.g. *Université de Moncton*)

### **DECLARATION OF RESPONSIBILITY**

The principal investigator is responsible for the conduct of this project and agrees to fulfill the commitments contained herein.

Signature of investigator responsible for the project: \_\_\_\_\_

### **A. INTRODUCTION**

*Sample wording:*

*We are inviting you to participate in a research project involving people who, like you, suffer from rheumatoid arthritis and who have never taken anti-inflammatory drugs...*

*You have just undergone chemotherapy for cancer of the prostate. We are inviting you to...*

### **B. OBJECTIVE OF THE RESEARCH PROJECT**

*Sample wording:*

*This project is designed to document... or... The goal of this study is to...*

### **C. NATURE OF MY PARTICIPATION**

*Sample wording:*

*Your participation in the study requires one (or more) meetings that will last... at most and take place at... (location). You will be asked to answer questions on... You will also have to attend sessions ....*

*Provide enough information for subjects to be able to understand and visualize what they will have to do.*

Initials: \_\_\_\_\_

## **D. POSSIBLE BENEFITS OF MY PARTICIPATION**

### **Sample wording:**

*There are no direct benefits resulting from your participation in this study. However, your participation will allow research to be conducted that will advance knowledge of...*

## **E. RISKS AND INCONVENIENCES POTENTIALLY RESULTING FROM MY PARTICIPATION**

### **Sample wording:**

*The primary drawback associated with your participation is the time you will be required to devote to this research. You could also feel concern about... In this case, you can express your concern and expect to receive all necessary explanations.*

*It is understood that, from a medical perspective, your participation in this research project poses no risk to you whatsoever. However, from a psychological perspective, it is possible that discussions occurring during the project may cause you to relive difficult memories. If you feel the need, psychological support will be at your disposal at any time and completely free of charge. It is also understood that your participation will have no effect on any treatment you will eventually receive.*

## **F. ALTERNATIVES TO PARTICIPATION**

### **Sample wording:**

*You do not have to participate in this research project to obtain the necessary health care for your condition. There are other therapeutic options or interventions for the treatment of arthritic pain. We encourage you to discuss all possible options with the principal investigator. He or she will discuss all the benefits and risks associated with other treatments or interventions.*

## **G. COMPENSATION IN CASE OF HARM**

### **The following paragraph must appear in consent forms:**

*If you were to suffer any harm resulting from any procedure related to the study, you will receive all necessary medical care. By agreeing to participate in this study, you waive none of your rights and do not release the investigators (where applicable: organizations, companies) or institutions involved from their legal and professional responsibilities.*

## **H. VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW**

Initials: \_\_\_\_\_

Sample wording:

*It is agreed that your participation in the aforementioned research project is entirely voluntary and that you remain free to terminate your participation at any time, without having to justify your decision or suffer any loss whatsoever.*

**I. HALTING OF THE PROJECT OR OF A PARTICIPANT'S INVOLVEMENT**

Sample wording:

*The researchers might have to withdraw you from the research project if you do not follow the project guidelines (e.g. no smoking or drinking) or if the researchers deem it better for your health and well-being.*

**J. ACCESS TO MEDICAL OR OTHER RECORDS**

Sample wording:

*The research team will consult your medical record in order to obtain the following information: (provide a list of the information required and the reason for its requirement).*

**K. FINANCIAL COMPENSATION**

Sample wording:

*As compensation for potential expenses incurred in the course of your participation, you will receive a lump sum of \$X for the session (or each session if there are several).*

OR

*You will receive no compensation for your participation in this research. However, you will be reimbursed for parking and meal expenses you incur during your visits for this research project. Please supply us with the receipts.*

**L. INFORMATION DISSEMINATION PLAN**

Sample wording:

*The data collected will be used for scientific and professional communication purposes.*

Initials: \_\_\_\_\_

## M. CONFIDENTIALITY AND ANONYMITY

### Sample wording:

*The data collected will remain confidential. Personal data will be stored in a locked filing cabinet. Only those people responsible for the project will have access. The data will be retained for a maximum of five years and will then be destroyed.*

**You may also explain in this section that additional precautions will be taken to keep the data confidential, such as assigning a numeric code to all documents so that no names appear.**

## N. CONTACT PERSONS

### Sample wording:

*For any questions or information requests about the project, I can contact either of the following persons:*

- *Principal investigator: (telephone number)*
- *Co-investigator: (telephone number)*

### Required text:

***If you have questions about your rights as a research participant, or if you wish to discuss the study with someone who has no ties to the research, you may contact Isabelle Dugas, Regional Ethics Office Manager of Vitalité Health Network, 1750, Sunset Drive, Office B-226E, Bathurst NB E2A 4L7, 506-544-2506; e-mail address: [isabelle.dugas@vitalitenb.ca](mailto:isabelle.dugas@vitalitenb.ca).***

Initials: \_\_\_\_\_

**DECLARATION BY THE PARTICIPANT**

The entire “Declaration” section must be contained within one separate page.

**Sample wording:**

*I declare having received sufficient explanations on the nature and conduct of this research project. I have read and understood the terms of this consent form and have received a copy. I acknowledge having been sufficiently informed about the nature and reasons for my participation in the project. I have had the opportunity to ask questions, which were answered to my satisfaction.*

\_\_\_\_\_  
*Signature of participant*

\_\_\_\_\_  
*Date*

Name printed: \_\_\_\_\_

\_\_\_\_\_  
*Signature of witness:*

\_\_\_\_\_  
*Date*

Name printed: \_\_\_\_\_

**DECLARATION BY THE PERSON RESPONSIBLE FOR OBTAINING THE CONSENT**

*I, \_\_\_\_\_, undersigned, attest having explained the terms of this form to the prospective participant, having answered the prospective participant’s questions, and having clearly indicated that the prospective participant is free to terminate participation in the above project at any time.*

\_\_\_\_\_  
*Signature of person responsible for obtaining consent*

\_\_\_\_\_  
*Date*

Name printed: \_\_\_\_\_

\_\_\_\_\_  
*Signature of witness*

\_\_\_\_\_  
*Date*

Name printed: \_\_\_\_\_

Signed in Moncton, on \_\_\_\_\_

**DECLARATION BY THE LEGAL REPRESENTATIVE OR PROXY**

This section must be contained within one separate page.

Sample wording:

\_\_\_\_\_  
Signature of the legal representative

\_\_\_\_\_  
Date

Name printed: \_\_\_\_\_

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
Date

Name printed: \_\_\_\_\_

Appendix VI  
Administrative Feasibility  
Evaluation Grid

**ADMINISTRATIVE FEASIBILITY EVALUATION GRID**

<b>DATE OF THE FEASIBILITY EVALUATION:</b>	
<b>TITLE OF THE PROJECT:</b>	
<b>PRINCIPAL INVESTIGATOR:</b>	
<b>CO-INVESTIGATORS/CONTRIBUTORS:</b>	
<b>TARGET GROUP:</b>	
<b>NO. OF SUBJECTS TARGETED FOR RECRUITMENT:</b>	
<b>PROJECT START DATE:</b>	
<b>PROJECT END DATE:</b>	

	A*	AC	NA	N/A
<b>1. The study population is accessible and not excessively solicited.</b>				
<b>2. The need to target outside groups (or not) has been considered, as necessary.</b>				
<b>3. Subject samples are available during the established recruitment period.</b>				
<b>4. There is a sufficient number of qualified employees available throughout the duration of the project.</b>				
<b>5. The required space and physical resources needed for the project are available.</b>				
<b>6. The required technology is available (e.g. phlebotomy, radiology, etc.).</b>				
<b>7. The sectors involved and the contributors have sent letters of support.</b>				
<b>8. The study budget has been evaluated, and it financially supports the project activities.</b>				
<b>9. The costs related to the involvement of support staff and professionals have been factored in the budget.</b>				
<b>10. The project is financially viable over the long term.</b>				
	A*	AC	NA	
<b>OVERALL RECOMMENDATION</b>				

\* A = Acceptable  
 AC = Accepted conditionally, see Comments  
 NA = Not acceptable  
 N/A = Not applicable

<b>GENERAL COMMENTS:</b>
Approval of administrative feasibility for your facility
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Conditional
Comments:
Request for modifications:
Approval date: _____
_____ Signature of the person responsible for the administrative feasibility evaluation

Appendix VII  
Template for Letter of Support

---

## Letter of Support

Research Project	
Title of project	

Principal Investigator			
Name			
Phone No.		Fax No.	
Email			

Establishment where the project will take place	
Establishment	
Service/Department	

### Chef of service/Director/Manager of the service/department

- I confirm that the aforementioned service/department has been informed of its implication in the present research project.
- I understand that the logistics required for the project's realization has been taken care of by the Principal Investigator, in collaboration with the Vitalité Health Network Research Centre.

If the project requires resources from the involved service/department, please specify:

- The goals of the research project, the personnel's roles, and the expectations pertaining to the project have been explained to me by the Principal Investigator.
- I agree to explain to the personnel in my service/department the role they will play in the present research project.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (printed)

\_\_\_\_\_  
Position

# Appendix VIII

## Scientific Evaluation Grid

**SCIENTIFIC EVALUATION GRID**

<b>DATE OF THE SCIENTIFIC EVALUATION:</b>	
<b>TITLE OF THE PROJECT:</b>	
<b>PRINCIPAL INVESTIGATOR:</b>	
<b>CO-INVESTIGATORS/CONTRIBUTORS:</b>	
<b>TARGET GROUP:</b>	
<b>NO. OF SUBJECTS TARGETED FOR RECRUITMENT:</b>	
<b>PROJECT START DATE:</b>	
<b>PROJECT END DATE:</b>	

	A*	AC	NA	N/A
<b>1. The title is representative of the research.</b>				
<b>2. Literature on the various aspects of the problem is clearly established.</b>				
<b>3. The goals and objectives of the research are clearly defined and are attainable.</b>				
<b>4. The population and sampling size (No. of participants) are well specified.</b>				
<b>5. The research methodology is appropriate.</b>				
<b>6. The tools are described (validity and reliability).</b>				
<b>7. The data analysis method is well specified and appropriate.</b>				
<b>8. The findings will meet the research objectives.</b>				
<b>9. A plan for disseminating the findings has been envisioned.</b>				
<b>10. The budget and funding sources are mentioned and reasonable.</b>				
<b>11. The timeline proposed is attainable.</b>				
<b>12. The role of team members is provided.</b>				
	A*	AC	NA	
<b>OVERALL RECOMMENDATION</b>				

\*A = Acceptable  
 AC = Accepted conditionally, see Comments  
 NA = Not acceptable  
 N/A = Not applicable

<b>GENERAL COMMENTS:</b>
Scientific approval <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Conditional  Comments:  Request for modifications:  Approval date: _____  _____ Signature of the person responsible for the scientific evaluation

Appendix IX  
Request for Continous Research Progress Evaluation

**REQUEST FOR CONTINUOUS RESEARCH PROGRESS EVALUATION  
FOR RESEARCH PROJECTS**

**SECTION 1 – GENERAL INFORMATION**

**1.1 Date of submission:**

**1.2 REB reference number:**

**1.3 Short title (if applicable):**

**1.4 Complete title of the research project:**

**1.5 Name(s) and contact information of the Principal Investigator(s):**

- 1.
- 2.
- 3.

**1.6 Name(s) of the Co-Investigators:**

- 1.
- 2.
- 3.

**1.7 Is this research project performed as part of an academic degree?**

Yes       No

If yes:

Name of the student:

Department and faculty:

Supervisor(s):

## SECTION 2 – INFORMATION PERTAINING TO THE RESEARCH PROJECT

### 2.1 Indicate the current status of the research project:

- Ongoing/Recruitment not started
- Ongoing/Actively recruiting
- Ongoing/Recruitment finished
- Project currently interrupted

### 2.2 Date of initial REB approval?

### 2.3 Estimated date of completion of the research project?

### 2.4 Have you already submitted a request for an Annual Research Progress Evaluation?

- Yes       No

If yes, please specify the date of your last evaluation:

### 2.5 Give a brief description of the research project in layman's terms, with no cross-references to the research proposal.

### 2.6 Give a brief description of the current status of the research project (active recruitment, data analysis, etc.).

### 2.7 Please provide the following information concerning the research subjects:

Proposed number of subjects to be recruited:

Number of subjects having been recruited up until now:

## SECTION 3 – PROGRESS OVER THE PAST YEAR

### 3.1 Have there been any modifications:

- To the research proposal?

- Yes       No

- Last approved version:

- Date of REB approval:

- To the consent forms?

Yes             No

- Last approved version :

- Date of REB approval :

- To other documents (questionnaires, publicity flyers, etc.)?

Yes             No             N/A

- Last approved version:

- Date of REB approval:

### **3.2 Was the research project temporarily interrupted?**

Yes             No

If yes, was the REB informed?

Yes             No

Please provide a justification for the interruption:

### **3.3 Have the results obtained from the research project been published or presented?**

Yes             No             N/A

If yes, please provide details:

### **3.4 Have any Co-Investigator(s) joined or withdrawn from the research team?**

Yes             No

If yes, please provide their name(s):

Joined             Withdrawn

Joined             Withdrawn

Joined             Withdrawn

**SECTION 4 – INFORMATION FOR THE RESEARCH CENTRE**

**4.1 Have you encountered any problems with the recruitment process in general?**

Yes       No

If yes, please describe:

**4.2 Have you encountered any logistical problems with the departments or sectors (e.g. phlebotomy or information technology services)?**

Yes       No

If yes, please describe:

**4.3 Have you encountered any problems or events that have hindered the execution of the research project in a given facility (e.g. equipment problems, lack of materials, etc.)?**

Yes       No

If yes, please describe:

**4.4 Is the initially proposed budget for the research project still valid? Is the research project still financially viable?**

Yes       No

If no, please describe:

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (printed)

In case of absence, please append an acknowledgement of receipt from the Principal Investigator

**Form completed by      on**

**For the Ethics Office use only**

**Approval:**

Full REB

Delegated Evaluation

\_\_\_\_\_  
Ethics Office Manager

Annexe X  
Request for Amendment

**REQUEST FOR AMENDMENT  
OF A RESEARCH PROJECT**

**SECTION 1 – GENERAL INFORMATION**

**1.1 Date of submission:**

**1.2 REB reference number:**

**1.3 Short title (if applicable):**

**1.4 Complete title of the research project:**

**1.5 Name(s) and contact information of the Principal Investigator(s):**

- 1.
- 2.
- 3.

**1.6 Name(s) of the Co-Investigator(s):**

- 1.
- 2.
- 3.

**1.7 Nature of the request for amendment:**

## SECTION 2 – INFORMATION PERTAINING TO THE RESEARCH PROJECT

### 2.1 Indicate the current status of the research project:

- Ongoing/Recruitment not started
- Ongoing/Actively recruiting
- Ongoing/Recruitment finished
- Project currently interrupted

### 2.2 Indicate the nature of the request for amendment (check all the elements that apply):

- | <u>Nature of the request for amendment</u>  | <u>Date and version</u> |
|---|-------------------------|
| <input type="checkbox"/> Modifications to the research proposal   |                         |
| <input type="checkbox"/> Modifications to the consent forms   |                         |
| <input type="checkbox"/> Addition of a new consent form   |                         |
| <input type="checkbox"/> Modifications to materials used for the recruitment of research subjects (e.g. publicity)                    |                         |
| <input type="checkbox"/> Addition of materials used for the recruitment of research subjects (e.g. publicity)                         |                         |
| <input type="checkbox"/> Modifications to questionnaires or other research documents (including documents given to research subjects) |                         |
| <input type="checkbox"/> Addition of questionnaires or other research documents (including documents given to research subjects)      |                         |
| <input type="checkbox"/> Modifications to the research team   |                         |
| <input type="checkbox"/> Modifications to the research project budget   |                         |
| <input type="checkbox"/> General administrative modifications (e.g. phone number, grammatical errors etc.)                            |                         |
| <input type="checkbox"/> Other modifications<br>Specify:  |                         |

**Please append the modified documents and identify modifications made.**

**2.3 Provide a brief justification as to why the modifications were made (nature and consequences).**

**2.4 Do these modifications need to be approved by Health Canada (e.g. no objection letter from Health Canada)?**

Yes       No       N/A

If yes, please append the no objection letter from Health Canada.

**2.5 Do the new modifications require renewed consent from the already enrolled research subjects?**

Yes       No       N/A (recruitment finished)

If yes, how will you go about renewing the consent (contact with subjects)?

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (printed)

In case of absence, please append an acknowledgement of receipt from the Principal Investigator

**Form completed by                      on**

For the Ethics Office use only	
<b>Approval:</b>	
<input type="checkbox"/> Full REB	<input type="checkbox"/> Delegated Evaluation
_____ Ethics Office Manager	

Appendix XI  
End of Research Project Notice

**END OF RESEARCH PROJECT NOTICE**

**SECTION 1 – GENERAL INFORMATION**

**1.1 Date of submission:**

**1.2 REB reference number:**

**1.3 Short title (if applicable):**

**1.4 Complete title of the research project:**

**1.5 Name(s) and contact information of the principal investigator(s):**

- 1.
- 2.
- 3.

**1.6 Name(s) of the Co-Investigator(s)**

- 1.
- 2.
- 3.

## SECTION 2 – INFORMATION PERTAINING TO THE RESEARCH PROJECT

### 2.1 Has the research project taken place?

Yes       No

If no, please explain:

### 2.2 Did the research project end earlier than what was proposed?

Yes       No (Go to question 2.3)

If yes:

- a) End date of research project:
- b) Why has the research project ended earlier than what was proposed?
- c) Please describe how the research subjects were informed of the premature ending of the research project.
- d) Have the research subjects been informed of potential risks associated with the premature ending of the research project?  
 Yes       No
- e) Will research subjects receive the necessary clinical follow-ups to assure their safety and well-being?  
 Yes       No

### 2.3 End of the project

- a) End date of the project:
- b) Number of research subjects to be recruited?
- c) Number of research subjects actually recruited?
- d) If the numbers in b) and c) are significantly different, please explain.
- e) Number of research subjects who have withdrawn from the research project?

**By signing this form, I agree to retain all data and documents pertaining to the  
aforementioned research project for a period of 5 years (starting at the end date of the  
research project).**

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (printed)

In case of absence, please append an acknowledgement of receipt from the Principal  
Investigator

**Form completed by** \_\_\_\_\_ **on** \_\_\_\_\_

**For the Ethics Office use only**

**Approval:**

Full REB

Delegated Evaluation

\_\_\_\_\_  
Ethics Office Manager