Application for Approval of a Research Study

* Before proceeding, read the “Guidelines and Procedures for Research/Evaluation Studies Involving TVCC Clients and Families” including the “Role of the TVCC Research Contact,” and “Guidelines for Initial Contact with TVCC Clients and Families For Participation in Research Studies” available at [TVCCGuidelinesProcedures.pdf](%5C%5C%5C%5CServer-1%5C%5Cdata%5C%5CDOCS%5C%5CResearch%5C%5CRAC%5C%5CGuidelines%5C%5CTVCCGuidelinesProceduresApril2015.docx)
* Contact TVCC’s Director of Quality Management before completing this application.
* Ensure that your professional/technical terminology is explained and understandable to those without knowledge of your area of expertise. Explanations of terminology will greatly assist the review of your proposal.
* The Committee will review and comment on the relevance and scientific merit of your proposal.
* This application form was created with MS Word. You may type text directly or copy and paste from another document.
* Send 10 copies of this form (each with attachments and CVs) to TVCC’s Research Program at the above address. Do not try to send the application by fax or by email.
* If a grant proposal has been prepared for another institution, please include 1 copy of that complete proposal along with the TVCC application.

Use staples or clips to secure your application, TVCC is a latex-free Centre.

Please Note: Incomplete submissions will not be reviewed

# Program Title:

Enter

# Principal Investigator (PI): Enter

 Title/Position: Enter

 Affiliation: Enter

 Mailing Address:

 Street: Enter

 Room #: Enter

 City: Enter Province: Enter Postal Code: Enter

 Telephone: Enter

 Email: Enter

 Administrative Contact: Enter

 Administrative Contact Telephone: Enter

 Administrative Contact Email: Enter

# Signature of PI:

 Date: Enter

# RAC Submission Date:

Enter

# Names and Affiliations of All Other Investigators

 Attach Abbreviated curriculum vitae for all investigators (not to exceed 3 pages for each CV).

 Contents required for curriculum vitae are listed below.

| Name | Title/Position | Affiliation | CV Attached |
| --- | --- | --- | --- |
| Enter | Enter | Enter |[ ]
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Important: use the following format for Curriculum Vitae Attachments

Please provide only the information requested below for each study investigator.

Do not exceed three pages per CV.

Name:

Position Title:

Education:

Positions and Employment:

Selected Peer-review Publications (from last five years or ten most relevant):

Research Support (Grants Received from last five years):

# Student Project

 Is this a student project? Yes [ ]  No [ ]

 If yes, provide Supervisor’s Name: Enter

 Supervisor’s title: Enter

 I have reviewed and approved the materials in this application.

 Supervisor’s signature:

 [ ]  Yes, attached is a copy of Supervisor’s abbreviated curriculum vitae (not to exceed 3 pages).

 See above list of CV requirements.

# Ethics Approval

 Has the project received ethics approval from a university institution?

 [ ]  Yes

 From which university? Enter

 Dates of approval from: Enter to: Enter

 A copy of the ethics approval letter is attached Yes [ ]  No [ ]

 [ ]  Submitted, not yet approved

 To which university? Enter

 Date submitted: Enter

 [ ]  To be submitted

 To which university? Enter

 Planned submission date: Enter

Remember a copy of the ethics approval letter must be received by the Research Program before proceeding to approach potential participants.

# Funding

 Has the project received grant funding?

 [ ]  Yes

 From which agency/institution? Enter

 Amount of award: Enter

 Duration of award (dates): Enter

 [ ]  No

# Abstract

 General abstract of the project (100 words maximum) stated in easy-to-read language.

 This abstract will be used in TVCC publications.

 Enter

# Aim/Hypothesis

 General aim of study of hypothesis to be tested.

 Enter

# Procedures Not Part of Ordinary Services

 List all procedures to be done for the purpose of this study that are not part of the ordinary services provided to participants.

 Enter

# Summary of Proposed Research

 Please insert the following (do not exceed 10 pages in total for this section, excluding references)

## Background/literature review and justification

 Briefly summarize knowledge base and past research, which has led to this study.

 *(1 page maximum, adhere to page limitations)*

 Enter

## Research objectives

 Provide a clear statement of the purpose and objectives of the project (i.e. Why are you doing the study?) *(1 page maximum, adhere to page limitations)*

 Enter

## Participants

 *(1 page maximum, adhere to page limitations)*

1. State number of participants from TVCC:

 Clients: Enter Families/Caregivers: Enter Therapists/Service Providers: Enter

 Others, please explain: enter number and explain

1. If appropriate (e.g., multi-centre study), please provide a breakdown of the number of participants from TVCC and other sources.

 Enter

1. Describe the participants to be included in the study (e.g., age, gender, diagnosis) and any inclusion and exclusion criteria.

Enter

## TVCC Staff Assistance in Data Collection

If TVCC staff members will be assisting in the collection of data for the study, will be trained regarding study procedures, and will be receiving reimbursement for their involvement, please give details.

 Enter

## Methodology

* Describe the study design and what procedures will be carried out at each stage of the research.
* Describe the method of recruiting participants, who will be contacting them, and where the research will be conducted.
* Specifically indicate why a particular design was selected.
* Address the strengths and weaknesses of the selected design.

*(3 page maximum - adhere to page limitations)*

Enter

## Measures

* Describe and provide psychometric information and justification for all study measures.
* Attach copies of each of the measures.
* State who will be administering/completing the measures.

*(2 page maximum - adhere to page limitations)*

 Enter

## Analysis

Describe in detail how the data will be analysed to fulfil each objective.

(1 page maximum - adhere to page limitations)

 Enter

## Sample Size and Power Calculation/Reference

1. *page maximum - adhere to page limitations)*

 Provide a sample size calculation or power calculation.

 Enter

 If a table in a published source was used instead of a calculation, provide description and the reference(s).

 Enter

 If a software package was used, provide a description of the package used and/or the URL for internet-based packages.

 Enter

 If a calculation was not performed, justify why it is not required or possible, and give a rationale for the proposed number of subjects.

 Enter

## Reference List

 Please restrict the list to 10 of the most relevant references.

 Enter

## Letter(s) of Explanation

 Please attach all Letters of Explanation.

## Participant Consent Form(s)

 Please attach all Participant Consent Forms.

# Risks and Discomfort Involved

1. Discuss the risks/discomforts of the proposed research, specifying the particular risks/discomforts associated with each procedure, test, etc.

 Enter

1. Will management or treatment be prolonged or delayed?

 Enter

1. Are any standard therapies or diagnostic procedures to be withheld for the purpose of the study? If yes, please specify the risks and benefits to the participants.

 Enter

# Time to Complete Project

 Total length of time for the project, years and/or months: Enter

 Start date: Enter Completion date: Enter

 Projected length of time for each different phase of the project (data collection, analyses, etc.):

Enter

# Confidentiality

* Describe the procedures adopted for preserving the confidentiality of participants.
* Explain how written records, videotapes, recordings and questionnaires will be kept, and disposed of, after the study is completed.

Enter

# Communication of Findings to TVCC Staff and Clients/Participants

 Describe your plans for providing TVCC staff and/or participants with feedback about the findings of the research project.

Enter

# Describe Other Plans for Presenting and Publishing the Study Results

Enter

# Briefly Discuss the Relevance of the Research to the Centre

Enter

Checklist for Application for Approval

of a Research Study

# To be included with your application

Have you done the following before submitting the application?

I have done the following:

 [ ]  Submitted this project to a university ethics review committee.

 [ ]  Contacted and discussed my project and its relevance to TVCC with the Director of Quality Management, who also provided me with the name of the appropriate Clinical Program Director to contact to arrange support for my project.

 Date of Contact: Enter

 Comment: Enter

 [ ]  Contacted and discussed my project with the appropriate Centre Clinical Program Director and made arrangements for the Director to complete the “Summary of Staff and Program Management Support” section (#20) of my application form to give to the Research Officer. If TVCC staff will be paid to assist with the study, an agreement regarding that funding must be arranged with the Program Director should the study be approved by the Research Advisory Committee.

 Name of Program Director: Enter

 Program: Enter

 Date of Contact: Enter

 Arranged for Program Director to complete application page Comment: Enter

 [ ]  Contacted and discussed with the Centre Clinical Program Director the TVCC staff member who will be my Research Contact.

 Name of Research Contact: Enter

 Comment: Enter

I have attached to each of the applications the following:

 [ ]  Curriculum vitae of **all** investigators (not to exceed three pages each)

 [ ]  Copy of my Ethics Approval Letter

 [ ]  I will send a copy of the Ethics Approval Letter as soon as I receive it.

 [ ]  Copies of the measures to be used in the study

I have submitted to the Research Officer:

 [ ]  **10** copies (with **all** attachments) of the completed TVCC Application Form on or before the submission date.

 [ ]  **1** copy of my previously completed proposal (if a grant proposal has already been prepared for another institution)

Do not include this page with your application

# This page is included in the application to let the applicant know the types of information requested from the RAC Chair and the Program Director.

## Section to be completed by TVCC Research Advisory Committee Chair

*The RAC Chair will fill out this section after the application has been received by the Research Program. The Research Program will add this page to all of the application copies.*

**FULL TITLE OF PROJECT**

# Potential Burden to Clients and Families Of TVCC (Given Other Ongoing Research)

 RAC Chair Signature:

 Date:

# Investigators are to arrange before the submission date for the Program Director to fill out this section.

*The Research Program will add this page to all of the application copies.*

# Section to be completed by TVCC Clinical Program Director

# Summary Of Staff And Program Management Support

**FULL TITLE OF PROJECT**

1. Please indicate the pros and cons of your Program’s (or the Centre’s) involvement with this project. Briefly discuss the impact that this project may have on clinical practice.
2. Are you in agreement with the plans outlined for how the study findings will be shared with TVCC staff and/or participants?
3. If the investigator(s) is (are) not Centre staff, please indicate the name of designated Research Contact person at the Centre for this project:

TVCC Research Contact: Program:

1. Will TVCC staff be paid to assist with the study? Yes [ ]  No [ ]

 If yes, an agreement regarding that funding must be arranged between the Program Director and the Principal Investigator should the study be approved by the Research Advisory Committee.

 Signature Clinical Program Director:

 Date:

 Clinical Program: