

# Guidelines and Procedures for Research / Evaluation Studies Involving TVCC Clients and Families

All research studies wishing to involve Thames Valley Children's Centre (TVCC) clients and their families must first submit an application for review and receive approval from TVCC's Research Advisory Committee. The Committee's high standards ensure that the Centre's clients and families are involved in quality research.

There are procedures that need to be followed to protect all involved (study participants, investigators, and TVCC). Guidelines also exist to ensure client confidentiality in research studies and to ensure that, when seeking their participation in a research study, TVCC staff members **make the initial contact with parents and clients**.

## Research Advisory Committee Approval

TVCC's Research Advisory Committee (RAC) reviews **all research study applications** and discusses them according to the criteria outlined below. Applications are reviewed by the RAC approximately **every two to three months**.

The Committee reviews each application and uses the following criteria to determine project approval:

- Scientific merit
- Relevance of the research to the Research Program's two key theme areas:
  - i. Evaluation of therapies and aspects of service delivery, or
  - ii. Psychosocial aspects of disabilities and interventions
- Ethics clearance from a university committee
- Absence of an appreciable burden to clients/participants given other ongoing projects at the Centre (determined by the RAC Chair, who makes a recommendation to the RAC about the study's burden, given ongoing projects and the populations they are involving)
- Agreement / approval of the Program Director, cooperation of Centre staff, and an assigned Research Contact Person to determine appropriate clients/families and to make the initial contact.

## RAC Members

Members of the Research Advisory Committee include:

- A TVCC Researcher (Chair)
- TVCC's Medical Director
- A Medical Staff Consultant
- Faculty members from The University of Western Ontario
- Members of rehabilitation disciplines

The Chair of the Committee meetings does not take part in the decision-making.

## University Ethics Approval

The RAC will review applications that have not yet received ethics clearance, but will make their **approval conditional upon** the project receiving ethics approval, and the Research Program **receiving a copy** of the signed approval letter, before the study may begin.

## Approval Process

The RAC will meet to review and discuss each application. They will make decisions about approval and provide feedback (and may require additional information or changes). The Committee **may recommend that** an application be:

1. **Approved**
2. **Approved Conditionally** (that minor revisions are made and/or additional information provided)
3. **Revised and Resubmitted** (a request to address major concerns)
4. **Not Approved**

Applicants will receive either **an email or phone call of the results** of the RAC's review on the day of the review meeting, and a **formal letter** outlining the Committee's feedback by mail within 2 weeks.

## Expectations / Conditions of Approved Projects

Please note that conditions of approval are that, within six months of the completion of the study, the investigator will:

1. Complete a TVCC Project Status Report outlining the findings and clinical impact.
2. Disseminate their results to participants.
3. Provide the Research Program with any other publications or presentations information.
4. Present the study findings to TVCC staff.

## University Student Applications

University students seeking to do research/evaluation studies at TVCC **must be supervised** on these projects by a University faculty member (or co-supervised by a faculty member and a TVCC staff member). To ensure that their advisor is aware of and approves the details of the research study, students need to include the name, title, and **signature of their thesis advisor** on the Application Form.

## Changes to the Study

Be aware that the RAC approves applications as written and if there are any major changes to the study (i.e., participant characteristics, etc.) the **Committee will need to** receive a copy of any ethics amendments that are approved by the original university ethics review board.

## PROCEDURES

### Role of the Research Program

The RAC Chair provides administrative information and, on request, provides content feedback to investigators prior to the final submission of an application. The **applications are screened for completeness** before arrangements are made for them to be reviewed by the RAC. **Incomplete submissions will not be reviewed.**

Note: No research can be conducted with TVCC clients and their families without the approval of the Research Advisory Committee.

## Pre-Application

1. **Contact TVCC's Director of Quality Management** (Karen Lowry) to discuss your proposed research. The Director of Quality Management will decide if your research is relevant to TVCC and if so, will match you with the TVCC program that includes clients who meet your inclusion criteria, and will give you the name of the appropriate TVCC Clinical Program Director to contact.
2. **Contact the Clinical Program Director** to discuss the general feasibility of your project within TVCC; the most appropriate clients, families, and / or staff members to be involved in your study. (The Clinical Program Director and program staff members need to support the project, and agree to assist.)
3. **Arrange with the Clinical Program Director** to complete the page in your application that provides information of the staff and program management support, the pros and cons of the Program's involvement with this project, the impact this project may have on clinical practice, and the name of the Research Contact. 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.
4. **Know the name of your Research Contact:** The TVCC Clinical Program Director will determine which staff member will be the Research Contact for your project. (All external researchers must have a TVCC staff member as the Research Contact.) This person will determine the most appropriate participants given your inclusion/exclusion criteria, and make the initial contact with potential participants.

## Application

1. Download TVCC's **Guidelines and Procedures and the Application for Approval of a Research Study** from the [TVCC Website \(www.tvcc.on.ca\)](http://www.tvcc.on.ca).
2. Carefully review the Guidelines, complete the Application, and submit 10 copies to the Research Program on or before the submission date.

Note: **Explanation of terminology will greatly assist the RAC in reviewing your proposal.** Since each member of the RAC has expertise in a different discipline, it is suggested that all **professional terminology and processes be explained** in your proposal for the benefit of those members who are unfamiliar with your area of expertise.

3. After the proposal has been submitted, the RAC Chair will complete the application page that states the potential burden to TVCC clients, their families, and TVCC staff (given other ongoing research). This page will be included in all copies of the application.

## Post-Application

The RAC will meet to review and discuss each application, and make decisions about approval and will provide feedback about their decision. The Committee may recommend that an application be 1) Approved, 2) Approved Conditionally (that minor revisions are made and / or additional information provided), 3) Revised and Resubmitted (addressing major concerns), or 4) Not Approved. Applicants will receive either **an email or phone call of the results** of the RAC's review on the day of the review meeting and a **formal letter** that includes the Committee's decision and feedback by mail within 2 weeks.

If **approved**, get in touch with your Research Contact to discuss procedures and begin participant selection and contact.

## Research Advisory Committee Review Submissions Dates for Approval

Submit **10 copies** of the completed “**Application for Approval of a Research Study**” to TVCC’s Research Program on or before the submission date. If a grant proposal has been prepared for another institution, include 1 copy of the complete proposal along with the completed applications.

The Research Program will arrange for review of the application by TVCC’s Research Advisory Committee (RAC). The RAC Chair will notify applicants of the committee’s decision shortly after the meeting. Applicants will receive a formal letter that includes the Committee’s decision and feedback by mail within 2 weeks.

The Research Advisory Committee meets approximately every two to three months. The submission and meeting dates are listed below.

### Application for Approval of a Research Project Submission Dates and RAC Meeting Dates 2020

#### Application Submission Dates

Monday, January 6, 2020

Monday, March 16, 2020

Monday, May 11, 2020

Monday, September 14, 2020

Monday, November 9, 2020

#### RAC Meeting Dates

Monday, February 3, 2020

Monday, April 20, 2020

Monday, June 15, 2020

Monday, October 19, 2020

Monday, December 7, 2020

Application for Approval of Research Study

Accepted **ONLY** on the above submission dates

## Guidelines Re: Role of the TVCC Research Contact

### Purpose of Guidelines:

To outline the role of the TVCC Research Contact for studies initiated by researchers external to the Centre. The Research Contact is responsible for facilitating the research process, coordinating participant recruitment (including making initial contact with Centre clients and families), and informing the RAC Chair of the research progress.

### Responsibilities:

1. The initial contact with TVCC clients and families about participation in a research project must be from a TVCC staff member via letter, face-to-face contact, or by phone. **Names of clients and families must not be released** to those outside of the Centre without prior consent of the individuals themselves.
2. Part of the role of the Research Contact Person is to **facilitate the research process** between external investigators and clients / families at TVCC. This person is preferably a therapist who knows the clients and families, or works in the area of the research being conducted. TVCC's Director of Quality Management will refer external investigators to Clinical Directors of TVCC programs in order to determine whether there is a staff person who is interested in being a Research Contact. It is the **outside investigator's responsibility to ensure that the study has a designated Research Contact at TVCC.**
3. The Research Contact **must agree to be involved** in the study and have the approval of their Clinical Program Director.
4. The specific activities required of the TVCC Research Contact are to:
  - i. **Coordinate**, with TVCC's Centre Information Services, the identification of participants who meet the study's inclusion / exclusion criteria, and oversee participant selection
  - ii. **Establish first contact** (via a letter, face-to-face, or telephone) with TVCC clients, families, or staff members regarding their participation in research studies. Please see Guideline Re: Initial Contact with Clients and Families When Soliciting Participation in Research Studies. The investigator is responsible for supplying the TVCC Research Contact with example of a cover letter to be signed by the Research Contact, information packages, envelopes, stamps, scripts for face-to-face or telephone contact, etc.

## Guidelines for Initial Contact with TVCC Clients and Families

### Purpose of Guidelines:

To ensure that when soliciting the participation of subjects for both internal and external project, initial contact is made by a TVCC Research Contact. This ensures that families do not receive unexpected letters or phone calls from people outside the Centre who have confidential information about families. External projects will be assigned a TVCC staff member as a Research Contact.

### Procedures:

The initial contact with TVCC clients and families about participation in a research project must come from a TVCC staff member via letter, face-to-face contact, or by phone. **Names of clients and families must not be released** to those outside of the Centre without prior consent of the individuals themselves. **Once they consent** to being approached, the investigator may then proceed to explain the research to the participant and seek written consent.

#### 1. Written Contact

The TVCC staff member/Research Contact provides clients and/or families with a **cover letter** (described below) on TVCC letterhead and signed by the Research Contact, a **package of information** (prepared by the investigators) which will include an easy-to-read letter of information about the study (described below), a **consent form** (including appropriate space for their address for future contact should they agree to participate), a copy of TVCC's ***Would You Like the Opportunity to Participate in Research Projects?***, a copy of TVCC's ***Participating in Research*** brochure, and an **addressed and stamped return envelope**.

The **cover letter** should include the following:

- an easy-to-read explanation of the study,
- a statement that the study has received the approval of TVCC's Research Advisory Committee,
- a statement that subjects are under no obligation to participate and that should they choose not to participate, their care at TVCC will not be affected,
- a statement regarding confidentiality, and
- the name of person to contact should they have any questions.

Investigators are encouraged to refer to The University of Western Ontario's **Information and Consent Documentation** from the Research Ethics Board for Review of Health Sciences Involving Human Subjects at [Research Ethics - - Western University](#)

#### 2. Face-to-Face Contact

A TVCC staff member / Research Contact provides those clients and/or families who meet the inclusion criteria with a cover letter, a package of information about the study (see above), the consent form provided by the study investigator, and in some cases, a stamped return envelope. The TVCC staff member/Research Contact collects completed consent forms from the clients and families, and returns the forms to the investigator. Alternatively, the clients/families may take the package and return the forms at a later date by mail to the investigator.

#### 3. Telephone Contact

The investigator provides the TVCC staff member / Research Contact with a script of what the staff member is to say about the project. The TVCC staff member / Research Contact introduces the study to the potential participants, determines interest, and if the family is interested, says the investigators will send them the information package and forms.