

**Title: Research Proposal Submission – Research Ethics Committee**

<b>Manual: Management</b>	<b>Section: General</b>
<b>Document Number:</b>	<b>Issuing Authority: Board of Directors</b>
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**PURPOSE:**

The process for submitting research proposals at the BCHS.

**POLICY STATEMENT:**

The Brant Community Healthcare System will support participation in healthcare research, which is designed to improve patient care and/or the efficiency and effectiveness of health care delivery.

The **Research Ethics Committee**, through the **BCHS Ethics Committee** and the **Medical Advisory Committee** will review each research proposal submission to determine the degree to which the activities to be conducted meet ethical, professional and scientific standards.

Research proposals submitted to the committee may be one of five types:

- 1) Clinical Trial without approval by an Accredited Ethics Research Board
- 2) Clinical Trial with prior approval by an Accredited Ethics Research Board
- 3) Chart Audit/Study Review
- 4) Clinical Trial Renewal
- 5) Clinical Trial Amendment

All research proposals, submissions involving Human Subjects must:

- Be approved by the Chief of the Medical Staff Department to which the physician is assigned or the Vice President, Medical Affairs.
- Be approved by the Senior Leadership Team, Medical Advisory Committee, BCHS Ethics Committee and Board of Directors prior to initiation.
- Comply with the criteria indicated in the Policy/Procedure of the Brant Community Healthcare System Research Ethics Committee.
- The Principal Investigator is responsible for ensuring any and all outside researchers comply with hospital standards regarding confidentiality, access to Health Records and identification.
- All consent forms will be printed on Brant Community Healthcare System letterhead.
- Have a workload and financial impact analysis if staff and other departments are involved including financial compensation disclosure.

**PROCEDURE:**

- 1) The Principal Investigator:
  - Will be a member of the Medical Staff or Hospital staff. Investigators not on staff must appoint a member of the Brant Community Healthcare System staff as the Principal Investigator.
  - Obtain a calendar of committee meeting dates.

**DISCLAIMER:** This is a CONTROLLED document. The most current version is in electronic format on the BCHS intranet site. Any documents appearing in paper form are NOT controlled.

- Complete the Application for Research Ethics Committee Review form with the applicable fee (if required).
  - Submit the Application for Review of a Research Proposal and other documents to the Co-Chair of the Brant Community Healthcare System Research Ethics Committee.
  - Following approval, the Principal Investigator will inform all departments impacted by the study.
- 2) The Research Ethics Committee:
- Will evaluate the proposal using the guidelines as outlined above.
  - Will approve the research proposal or return it to the Principal Investigator with an explanation or recommendations.
  - Will recommend to the BCHS Ethics Committee / Board of Directors for approval.
- 3) The Chairperson:

If the research proposal is approved, the Chair will send the original copy of the letter of approval to the Principal Investigator and a copy to the Chief of the Department or Departmental Head.

### **FEES**

Applications for projects which are sponsored by external agencies (e.g. pharmaceutical companies or other commercial bodies) require a submission fee of \$1,500, payable to the BCHS Research Ethics Committee on submission. Further fees of \$100 - \$200 will be charged for amendments and/or renewals of such studies.

A submission application fee will not be charged for applications by individual researchers, students, non-profit organizations and internal staff members for non sponsored projects. The BCHS Research Ethics Committee, at its discretion, reserves the right to waive fees.

### **RELATED PRACTICES AND / OR LEGISLATIONS:**

None.

### **REFERENCES:**

None.