APPLICATION
FOR RESEARCH ETHICS COMMITTEE
REVIEW OF RESEARCH PROJECT
(NOT approved by any other Ethics Board)

A. GENERAL INFORMATION

PRINCIPAL INVESTIGATOR(S)

_____	_____
Name	Signature
_____	_____
Dept. /Div.	Position
_____	_____
Email Address	Telephone No. (Include area code and ext.)

BCHS SITE INVESTIGATOR

_____	_____
Name	Signature
_____	_____
Dept. /Div.	Position
_____	_____
Email Address	Telephone No. (Include area code and ext.)

STUDY CO-ORDINATOR

_____	_____
Name	Signature
_____	_____
Dept. /Div.	Position
_____	_____
Email Address	Telephone No. (Include area code and ext.)

B. DETAILS OF PROJECT

1. Project Title _____

2. Proposed Number of Research Subjects _____

3. Expected Start Date of Study: _____

4. Expected Completion Date of Study: _____

5. Is this project funded? ☐ Yes ☐ No

6. Sponsor _____

NOTE: 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, **upon submission of this application**. Further fees of $100 - $200 may be charged for amendments and renewals to such studies.

7. Duration of Funding: from (D/M/Y) ____/____/____ to ____/____/____

8. Funding Details:

9. Conflict of Interest Declaration – Do you have any conflicts of interest (actual, apparent, perceived or Potential) relating to this project?* ☐ Yes ☐ No

   Description of conflict of interest _____ Mandatory

   Signature _____

*Conflicts of interest include but are not limited to the following situations and also must be disclosed under institutional policy for review: if you are any of the involved research team members or your/their dependants have:

(1) Employment or consulting arrangements and/or financial interest in the sponsor of the study, or with proposed subcontractors, vendors or collaborations; or
(2) a financial interest in the subject of the study.

10. **Protocol:** A copy of the study or protocol must be attached to this application, as well as the investigator's brochure where applicable. The study protocol must include the following components:
    (a) Introduction and purpose of the research study
    (b) Objectives
    (c) Methods
    (d) Statistical analysis
    (e) Anticipated Public or Scientific Benefit
    (f) Duration of Research
    (g) Foreseeable harms and Benefits of Research (describe how harms will be addressed)

11. **Consent:** Have you obtained consent from the individuals to collect and use the identifying information on this project:

☐ NO Explain why:

☐ YES attached is a sample consent form (must have Brant Community Healthcare System corporate logo on consent).

12. **Case Report Form:** A copy of the forms that will be used to capture patient information must be attached to this application. If a Case Report Form is not available – complete Section C below.

13. Is there an independent data monitoring group involved in this study? If so, what is their name and contact information?

(a) _____
(b) _____
(c) _____

C. INFORMATION REQUEST

1. What patient information do you require?

2. What patient information source are you accessing?

☐	Health Records	Specify which
☐	Electronic Database	Specify which
☐	Outside Institution	Specify which
☐	Other	Specify which

3. Are you requesting information that identifies or potentially identifies individuals?
☐ NO
☐ YES

If yes, explain why you cannot use anonymized or aggregate information:

4. What security measures will be in place to protect the information during transmission?

D. INFORMATION TRANSMISSION Note: where a formal privacy agreement exists and a copy provided, the following sections D-H will not require completion.

1. What security measures will be in place to protect the information during transmission?

_____

2. Does your project involved linking any information from this require to other information?
   ☐ NO
   ☐ YES

   If yes, describe what information is to be linked

E. DISSEMINATION OF ANALYSIS AND/OR REPORTS:

1. How do you plan to disseminate and/or publish the results of your analyses?

2. What is the expected date of dissemination and/or publication?

F. DISCLOSURE AVOIDANCE PRACTICES

1. How will you ensure that information will be aggregated prior to disclosure, to the level required in the information sharing agreement, confidentiality agreement, privacy policy and other applicable policies and procedures?

2. Are any sensitive issues raised in this study or its publication (e.g. HIV status, mental health status, subject identifiable, other)

   ☐ NO
   ☐ YES

   If yes, please specify _____

G. SECURITY AND ACCESS

1. The information obtained from the records described above will be used for the outlines research purposes only:

☐ NO If no, a separate request must be submitted
☐ YES

2. List all of the persons who will have access to the records in an individually recognized form for the research purpose described and why they need this access: (name and role in research)

H. SECURITY MEASURES

1. Describe how you will keep information secure:

I. WORKLOAD/FINANCIAL IMPACT TO THIS FACILITY

1. Identify the services that will be impacted by this research study:
☐ Laboratory ☐ Pharmacy
☐ Health Records ☐ Other Services: please specify: _____

2. **Laboratory Tests:**
(a) Does this study involve laboratory tests? ☐ YES ☐ NO
(b) Where will they be performed and at whose expense?
(c) What is the amount of expense that this will incur on the Laboratory Department?

If the answer to 2(a) is YES, please obtain signature from the Associate Director Diagnostic Laboratory Medicine.

Signature: _____ Date: _____
Printed Name: _____

3. **Health Records:**
(a) Will you require access to patient personal health information through the Health Records Department?
☐ YES ☐ NO
(b) Will you require assistance in identifying your research population?
☐ YES ☐ NO
(c) Will you require statistics from Health Records for your project?
☐ YES ☐ NO

If the answer to 3(a, b or c) is YES, please obtain signature from the Director Information Communication & Technology, Health Information Management & Chief Privacy Officer.

Signature: _____ Date: _____
Printed Name: _____

4. **Pharmacy**
   (a) Does this study involve drugs and/or pharmacy services?
   ☐ YES ☐ NO
   (b) If yes, what expenses will this incur for the Pharmacy Department?

   If the answer to 4(a) is YES, please obtain signature of the Director Clinical Services Pharmacy, IPAC, Ambulatory Care & Oncology.

   Signature: _____ Date: _____
   Printed Name: _____

5. **Diagnostic Imaging**
   (a) Does this study involve Diagnostic Imaging Department?
   ☐ YES ☐ NO
   (c) If yes, what expenses will this incur for the DI Department?

   If the answer to 5(a) is YES, please obtain signature of the Associate Director, Diagnostic Imaging, Cardiac Diagnostics & EMG.

   Signature: _____ Date: _____
   Printed Name: _____

6. **Space:**
   Will this study impact on utilization of space within the hospital?

J. HAS THIS APPLICATION RECEIVED APPROVAL FROM OTHER HOSPITAL/INSTITUTION RESEARCH ETHICS BOARDS?

☐ YES ☐ NO

If YES, attach copy of approval and recommendations if any.

Attach:

☐ Completed Proposal
☐ Copy of Informed Consent
☐ Privacy Agreement where available
☐ Copy of Case Report Form
☐ Letter of approval if study reviewed by a Hospital, University or Institutional Ethics Review Board.