Complete the application in a font no smaller than 10 point: Handwritten submissions are not accepted

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| Please refer to the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans – TCPS2 (2010) prior to completion of this form <http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf> | | | | |
| **Is this a student project?**  Yes  No  If **YES**, please specify:  Post-doc  PhD  Masters  Undergrad  Resident/Fellow | | | | |
| **NH Project #**  **(will be assigned by REB office)** | |  | **Date:** |  |
|  |  | |  |  |

|  |  |
| --- | --- |
| **Title of Project/Study:** |  |

**Investigator Information:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **FULL NAME and DEGREE(s)** | **UNIVERSITY TITLE / POSITION** | **DEPT/CLINCAL PROGRAM** | **HOSPITAL AFFILIATION** | **STREET ADDRESS** | **PHONE NUMBER** | **EMAIL ADDRESS** |
| **Principal Investigator** |  |  |  |  |  |  |  |
| **Local Principal Investigator** |  |  |  |  |  |  |  |
| **Global Principal Investigator (if different from above)** |  |  |  |  |  |  |  |
| **Sub-Investigators** |  |  |  |  |  |  |  |
| **Research Assistants or Project Coordinators** |  |  |  |  |  |  |  |

**INSTRUCTIONS AND GUIDELINES**



**How do I know if this is quality assurance?**

|  |  |  |
| --- | --- | --- |
|  | **TRUE** | **FALSE** |
| 1. The study involves a systematic monitoring, assessment or evaluation of various aspects of an organization (e.g. a service, program, project or facility of the organization, or performance of its employees or student). This falls within the mandate of the organization through its role in employment, leadership or training. It is done to ensure that standards of quality are being met, or to correct or enhance the various aspects of the organization. The individual or team conducting the quality assurance is mandated to do so by the organization reviewed. |  |  |
| 1. The study is not an investigation to establish facts, principles or generalizable knowledge. |  |  |
| 1. No personal identifiable information is collected. |  |  |
| 1. There will be no patient intervention or contact |  |  |

If you answered true to all of these questions your application may be handled through submitting this form. Those who need only aggregate data complete questions 1 through 10. Those whose retrospective chart review includes collection of possible patient identifiers complete this form in its entirety. Those whose research does not fall within those criteria are asked to complete the’ Application for REB Review’ form. When in doubt please contact the REB office. Please note all studies are assessed upon receipt. It will be forwarded for expedited or full board review depending upon reviewer assessment.

**Application Process**

**Quality Assurance Studies**: Please submit the application for quality assurance studies to the appropriate health records department (Do not fax)

**Research Studies**: Please submit the appropriate application forms together with supporting documentation to the Research Ethics Board. Following the approval process for research studies the REB will forward the request to the health records department and notify the Local Principal Investigator of the approval in writing.

Research Ethics Board

Niagara Health

65 Third St.

Welland ON L3B 4W6

(905) 378 4647 Ext. 32202

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| **Medical Health Records NH Contact Information** | | |
| **Ms. Karen Pietrangelo**  **Douglas Memorial Site**  230 Bertie Street  Fort Erie, ON L2A 1Z2  Tel: 905.378.4647 Ext. 52464 | **Ms. Karen Pietrangelo**  **Greater Niagara General Site**  5546 Portage Road  Niagara Falls, ON L2E 6X2  Tel: 905.378.4647 Ext. 52464 | **Ms. Cindy Beldman**  **Welland Site**  65 Third Street  Welland, ON L3B 4W6  Tel: 905.378.4647 Ext. 41710 |
| **Ms. Cindy Beldman**  **Port Colborne Site**  260 Sugarloaf Street  Port Colborne, ON L3K 2N7  Tel: 905.378.4647 Ext. 41710 | **Ms. Sherry Lafratta**  **St. Catharines Site**  1200 Fourth Avenue  St. Catharines, ON L2S 0A9  Tel: 905.378.4647 Ex 40105 |  |
| **Director: Ms. Jane Doan**  1200 Fourth Avenue  St. Catharines, ON L2S 0A9  Tel: 905.378.4647 Ext. 44440 | **Privacy and Information Specialist: Ms. Mary Wall**  1200 Fourth Avenue  St. Catharines, ON L2S 0A9  Tel: 905.378.4647 Ext. 46203 | |
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| 1. This study is a: | | | | Quality assurance study | | | | | |  | | | **OR** | | | | | | | Research study | | | | | | |  | | |  | | | | |
| *(see instruction page for criteria)* | | | | | | | | | |  | | | | | | | | | |  | | | | |  | | | | | | | | | |
| 1. What is the purpose of the study, the objectives and the question(s) that the research seeks to answer? (Describe briefly please) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. List five key words that describe this project: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. Is this a funded study? | | | | | | | Yes | | | |  | | | No | | | |  | | Seeking funding | | | | | | | |  | | |  | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. If yes (or seeking) please indicate source of funding agency or partner: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. Please indicate the site(s) where the study will be conducted: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DMH |  | GNG | | |  | NOTL | |  | PCGH | | | | | |  | | SCS | | | | |  | | WHS | |  | | |  | | |  | | |
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| Other (please list): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| * 1. Will this study be reviewed by another research ethics board or institution? | | | | | | | | | | | | | | | | | | | | | | | Yes | | |  | | | No | | | |  |  |
|  | | |  |
| If yes please attach any REB or institutional approvals | | | | | | | | | | | | | | | | | | | | | | | Attached | | |  | | | To follow | | | |  |  |
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| 6) Conflict of interest: Will any investigators, members of the research team, and or their partners or immediate family members receive any personal benefit (e.g. reimbursement, intellectual property rights, rights of employment, consultancies, board membership, shares, stock options, etc.) as a result of connection to this study? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | Yes | | | | | | | | |  | | | | No | | |  | |  | | | | | | | | | | | | | |

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| * 1. If yes please explain how the will be managed to ensure that participant’s rights and welfare are not affected. (Do not include conference travel expense, possible academic promotion or other benefits which are generally considered integral to the process of conducting research) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. Individuals who will be accessing/reviewing health records.( All persons must be included) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Name Title/Degree** | | | | | | **Role on Research Team** | | | | | | | | | | | **Site/Clinical Program** | | | | | | | | | **Hospital and/ or University Affiliation** | | | | | | | | | | |
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| * 1. Additional individuals who will be given access to the data. (All persons must be included). | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Name Title/Degree** | | | | | | **Role on Research Team** | | | | | | | | | | | **Site/Clinical Program** | | | | | | | | | **Hospital and/ or University Affiliation** | | | | | | | | | | |
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| 1. Risks and Benefits: What are the anticipated public and scientific benefits of the study. (Describe briefly): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| * 1. What are the possible harms/risks to patients and how will you manage the risks to patients and how will you manage the risks? (Describe briefly): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. What patient information sources will be accessed? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | |  | | | | |  | |  | | |  |  |  |  | Specify | | | | | | | | | | | | | | |
| Health Records/ Files | | | | | | | | Yes | | | | |  | |  | | | No |  |  |  |  | | | | | | | | | | | | | | |
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| Electronic Data Base | | | | | | | | Yes | | | | |  | |  | | | No |  |  |  |
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| Outside Institution Information | | | | | | | | Yes | | | | |  | |  | | | No |  |  |  |
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| Other | | | | | | | | Yes | | | | |  | |  | | | No |  |  |  |
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| What are your search criteria? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| * 1. Will you require **only** **aggregate** data? (e.g. reports on the number of cases, length of stay etc.) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | Yes | | | | |  | |  | | | No |  |  |  | C:\Users\stamel\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.IE5\3DUMLB3R\PngMedium-red-stop-sign-4660[1].gif | | | If you require only aggregate data go to signing page. | | | | | | | | | | | |
|  | |  |
| * 1. Will you require **personal level** data? (e.g. names, admission dates, medical record numbers) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | Yes | | | | |  | |  | | | No |  |  |  |  | | |  | | | | | | | | | | | |
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| * 1. If yes will you get **patient consent** to collect personal level data? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | Yes | | | | | | | | |  | | No | | | |  |  | | | | | | | | | | | | | | | |
| **( If you answered yes this is not the correct form. Complete ‘*Application for REB review’*)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| If you do not require personal level data you may go to the signing page | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| * 1. If you answered **no** please provide justification for the waiver. ( Criteria for waiver include impracticality of obtaining consent, research cannot be conducted without the information, confidentiality is maintained and public interest in the research exceeds associated risk to privacy): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. Please indicate the direct identifiers you are collecting. If you are collecting personal information the minimal amount required to facilitate the research is the standard (e.g. initials in lieu of names, partial postal codes rather than full etc.) See CIHR best practice guidelines for protecting privacy and confidentiality at <http://www.cihr-irsc.gc.ca/e/29072.html> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Identifiers** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Full Name | | | | | | | |  | | Initials | | | | | | | | | | | | | | | | |  |  | | | | | | |
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| Gender | | | | | | | |  | | Date of Birth | | | | | | | | | | | | | | | | |  |
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| Address | | | | | | | |  | | Full Postal Code | | | | | | | | | | | | | | | | |  |
|  | | | | | | | |  | |  | | | | | | | | | | | | | | | | |  |
| Telephone | | | | | | | |  | | Health Care Provider | | | | | | | | | | | | | | | | |  |
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| Admission/Discharge Date | | | | | | | |  | | Date of Service | | | | | | | | | | | | | | | | |  |
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| Health Card Number | | | | | | | |  | | Fax Number | | | | | | | | | | | | | | | | |  |
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| SIN | | | | | | | |  | | Medical Device number | | | | | | | | | | | | | | | | |  |
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| Email | | | | | | | |  | | License | | | | | | | | | | | | | | | | |  |
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| Medical Record Number | | | | | | | |  | | VIN | | | | | | | | | | | | | | | | |  |
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| Photograph | | | | | | | |  | |  | | | | | | | | | | | | | | | | |  |
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| Other (describe): | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. Please justify the reason each item of personal identifier that you are collecting is required: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. What is the minimum number of records required to achieve your study? | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | |
| 1. What is the time period for the data collection? (Please include dates) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. Attach Data Collection Tools. (mandatory) | | | | | | | | | | | | | | | | | | | | | | | Attached | | | | | | | | | |  |  | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | |  | | |  | | |  |  |  | |
| 1. Do you plan to link the data to any other data base | | | | | | | | | | | | | | | | | | | | | | | | | | Yes | | |  | | | No |  |  | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. If yes, please specify the data base and the items to be linked: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 1. Please check the measures that are in place to ensure security of the information that you are collecting | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Restricted Access | | | | | | | |  | | File Password Protected | | | | | | | | | | | | | | | | |  |  | | | | | | |
|  | | | | | | | |  | | |  | | | | | | | | | | | | | | | |  |
| Electronic Audit Trail | | | | | | | |  | | File Encryption | | | | | | | | | | | | | | | | |  |
|  | | | | | | | |  | |  | | | | | | | | | | | | | | | | |  |
| Records in Locked File Cabinet | | | | | | | |  | | Computer Virus/ Malware Protection | | | | | | | | | | | | | | | | |  |
|  | | | | | | | |  | |  | | | | | | | | | | | | | | | | |  |
| Master Locked in PI Office | | | | | | | |  | | Confidentiality Agreements | | | | | | | | | | | | | | | | |  |
|  | | | | | | | |  | |  | | | | | | | | | | | | | | | | |  |
| Password Protected Computers | | | | | | | |  | | Computers in Locked Office | | | | | | | | | | | | | | | | |  |
|  | | | | | | | |  | |  | | | | | | | | | | | | | | | | |  |
| Backup files locked in PI office | | | | | | | |  | |  | | | | | | | | | | | | | | | | |  |
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| 1. Will data be sent outside of the institution where it was collected or will data be received from an outside institution? | | | | | | | | | | | |
|  | Yes |  | |  | | | | No |  |  | |
|  | | | | | | | | | | | |
| * 1. If yes please indicate where it will be stored, who will have access and security measures to be taken: | | | | | | | | | | | |
|  | | | | | | | | | | | |
| 1. Will this chart review be entered into an ongoing data base or used for future study? (Please note that secondary analysis requires REB approval). | | | | | | | | | | | |
|  | Yes |  | |  | | | | No |  |  | |
|  |  |  | |  | | | |  |  |  | |
| * 1. If yes please indicate how it will be stored and what the proposed uses may be: | | | | | | | | | | | |
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| 1. How long will the data be stored? | | |  | | | | | | | | |
| 1. How will the data be destroyed? (e.g. the data that could link to the identity of the patient): | | | | | | | | | | | |
|  | | | | | | | | | | | |
| **\*\*NOTE: NIAGARA HEALTH IS NOT RESPONSIBLE FOR THE STORAGE OF RESEARCH PROJECT INFORMATION/RECORDS. STORAGE, AND ALL ASSOCIATED COSTS ARE THE RESPONSIBILITY OF THE PRINICPAL INVESTIGATOR\*\*** | | | | | | | | | | | |
|  | | | | | | | | | | | |
| **Name of Principal Investigator (please print or type):** | | | | | | | | | | | |
| **Signature of Principal Investigator:** | | | | | | | | | | | |
| **Date (mm/dd/yyyy**): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | |
|  | | | | | | | | | | | |
| **Office Use Only** | | | | | | | | | | | |
|  | | | | | | Date/Signature | | | | | |
| **Quality Assurance Study** | | | | | |  | | | | | |
| Forward to health records) | | | | |  |  |  | | | |  |
|  | | | | |  |  | | | | | |
| Health Records Approval | | | | |  |  | | | | | |
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| **Research Study** | | | | |  |  | | | | | |
|  | | | | |  |  | | | | | |
| Requires further REB review | | | | |  |  | | | | | |
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| Approved by REB forward to health records | | | | |  |  |  | | | |  |
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| Approved by Health Records | | | | |  |  | | | | | |
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