# 



**TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB) / HEALTH RECORDS**

**APPLICATION FOR RETROSPECTIVE REVIEW OF**

**PERSONAL HEALTH INFORMATION (**Medical Charts/Health Records)

###### INSTRUCTIONS & GUIDELINES

*When to use this form?*

*Retrospective review pertains to records that exist at this time. Please use this form ONLY if you plan to conduct research that involves a retrospective review of medical records and if you will NOT collect ongoing or other any other information FROM OR ABOUT the patient. This form is meant to capture the necessary elements of the research plan for this project. If you are proposing to contact patients for consent or for any other purpose, please use the standard “Application Form” instead.*

*Is this Quality Assurance or Research?*

*Research involves a systematic investigation to establish facts, principles or generalizable knowledge. Research requiring ethics review according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Article 1.1) includes all research involving living human subjects, as well as research involving human remains, cadavers, tissues, biological fluids, embryos or fetuses.*

*Quality assurance studies are considered to be internal studies related directly to assessing the performance of the institution or its employees or students within the mandate of the institution. Whenever there is any doubt as to whether a particular study is research or not, the opinion of the Tri-Hospital Research Ethics Board (THREB) should be sought.*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | |  | | *When do I use*  *this form?* | |  | |  | |  | | | |
|  | |  | |  | |  | |
|  | |  | *▼* | |  |  | |  | *▼* | |  |  | | | |
|  | | *IF RESEARCH, does it involve contacting patients?* | | | |  | | *IF QUALITY ASSURANCE…* | | | |  | | | |
|  | | *▼* | | *▼* | |  | |  | | | |  | | | |
|  |  | *YES* |  | | *NO* |  |  |  | | | |  | |  | |
| *▼* | |  | | | | *▼* | |  | | | |  | *▼* | |  |
| *If YES…complete “Application for REB Review” form* | |  | | | | *If NO...complete “Application for Retrospective Review”* | |  | | | | *…contact Health Information or Health Records directly* | | | |
|  | |  | | | |  | |  | | | |  | | | |

|  |  |
| --- | --- |
| *Is this Quality Assurance?* | *True / False?* |
| * *The study involves the systematic monitoring, assessment or evaluation of the various aspects of an organization (e.g., a service, program, project or facility of the organization, or performance of its employees or students within the mandate of the organization or according to the terms of employment or training) to ensure that standards of quality are being met, or to correct or enhance the various aspects of the organization and does not seek to establish generalizable knowledge.* | *False* |

*If you answered True to the above statement, there is no need to submit an application to THREB. Contact Health Records or Health Information directly (see below for contact information) and use their application form. If, however, your retrospective review of records is research, this application form will serve also for Health Information or Health Records. When in doubt contact the THREB Office.*

*Do I need to get patient consent?*

*Federal and provincial privacy regulations require that all individuals provide informed consent and authorization for the use of their personal health information [For Ontario: Personal Health Information Protection Act (PHIPA - Nov. 1, 2004)]. The provisions of the regulations cannot be waived unless the following criteria are met: (a) the research purposes cannot be achieved without the information; (b) it is impracticable to obtain consent; (c) the information is used in a manner that will ensure its confidentiality; and (d) the public interest in conducting the research exceeds the public interest in protecting the privacy of the individuals. A Research Ethics Board is allowed to waive the requirement for subject consent and authorization if these criteria are met. The THREB will review this application and determine whether consent is required. However, it is the responsibility of the applicant to provide the justification for waiver of consent.*

*Personal Identifiers*

**Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives.**

The use of personal health information for research is regulated in Ontario by the Personal Health Information Protection Act (PHIPA):

<http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm>.

The act defines personal health information and for research on personal health information it requires review by a research ethics board and provides some criteria on which the REB should base its decisions.

For further information, consult the “Guidelines for Protecting Privacy and Confidentiality in the Design, Conduct and Evaluation of Health Research: Best Practices” from the Canadian Institutes of Health Research: <http://www.cihr-irsc.gc.ca/e/22085.html>

***Approval Process***

1. For applications involving **Grand River Hospital**, Administrative Approval of this research must be obtained prior to submission to THREB for ethics review. For information on administrative requirements, contact: Kelly McDonnell, GRH Research Ctte Member, 519-749-4300 ext. 5159 [kelly.mcdonnell@grhosp.on.ca](mailto:kelly.mcdonnell@grhosp.on.ca)

2. For applications involving Cambridge **Memorial Hospital and St. Mary's General Hospital**, applications are submitted directly to THREB. Following review and approval by THREB, the application form will be sent to the appropriate Health Information Manager(s) for further review and final approval.

3. For all three hospitals, once approval by administration (GRH) or the Health Information Manager(s) (CMH, SMGH) is received by THREB, along with THREB approval, the final notice of approval will be sent to the investigator.

**Mail completed research applications (Original + 5 copies) to:**

Laurie Dietrich (Schulze), Administrative Coordinator

Tri-Hospital Research Ethics Board

Kaufman Building, Rm K503

Grand River Hospital

835 King Street West

Kitchener, ON N2G 1G3

Phone #1-519-749-4300, extension 5367

FAX #1-519-749-4274

Email: [laurie.dietrich@grhosp.on.ca](mailto:laurie.dietrich@grhosp.on.ca)

**Contacts for Health Information/Health Records:**

|  |  |  |
| --- | --- | --- |
| Cambridge Memorial Hospital:  Danielle Myers, Manager of Health Records and Chief Privacy Officer  519-621-2333 ext. 2507  <DMyers@cmh.org> | Grand River Hospital:  Betty Devenny, Interim Health Information Protection Coordinator  519.749.4300 ext.6973  [betty.devenny@grhosp.on.ca](betty.devenny@grhosp.on.ca%20) | St. Mary’s General Hospital:  Dan Chavez  Operational Lead & Release of Information Officer  519-749-6436  [dchavez@smgh.ca](mailto:dchavez@smgh.ca) |





**TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)**

**APPLICATION FOR RETROSPECTIVE REVIEW OF PERSONAL HEALTH INFORMATION**

**(MEDICAL CHARTS/HEALTH RECORDS)**

**Project #** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(assigned by THREB)

1. **a) Title of Study**:

Retrospective Chart Review of Patients Treated for Esophageal Cancer: Evaluating the Clinical Uptake and Effectiveness of Trimodality Therapy.

**b) List up to 5 keywords that describe this project:**

* Cancer
* Esophagus
* Chemotherapy
* Radiotherapy
* Surgery

**2. Is this a student project?** [ X ] Yes [ ] No

1. **Name(s) & Degree(s) Title(s) or Clinical Hospital**

**of Investigator(s) Position(s) Program Affiliation Phone # FAX# Email**

**(a) Locally Responsible Investigator:** (Only one person can be designated as the Locally Responsible Investigator. The Locally Responsible Investigator must be employed at or have an appointment at the hospital to which the application is being submitted for review)

|  |  |
| --- | --- |
| **LOCAL RESPONSIBLE INVESTIGATOR** |  |
| NAME: GRH DOCTOR, MD | TEL: |
| HOSPITAL: Grand River Hospital | FAX: |
| UNIVERSITY AFFILIATION & DEPT: | EMAIL:dr@grhosp.on.ca |
|  |  |
| **PRINCIPAL INVESTIGATOR if different from above** |  |
| NAME: | TEL: |
| INSTITUTION: | FAX: |
| UNIVERSITY AFFILIATION & DEPT: | EMAIL: |
|  |  |
| **CO-INVESTIGATOR(S)** |  |
| NAME: WRC STUDENT, BHSc & MD Candidate | TEL: |
| INSTITUTION: McMaster University, Waterloo Regional Campus | FAX: |
| UNIVERSITY AFFILIATION & DEPT: McMaster University, Waterloo Regional Campus | EMAIL: STUDENT@medportal.ca |
|  |  |
| **STUDY COORDINATOR** |  |
| NAME: None |  |
|  | EMAIL: |
|  |  |
| **APPROVAL LETTER TO BE SENT TO THE FOLLOWING PERSON AND ADDRESS**:  XXXXXXXX  Grand River Regional Cancer Centre/GRH 835 King St. W. PO Box 9056  Kitchener, ON – Canada  N2G 1G3  Phone 519-749-4370 ext. XXXXX  Fax XXXXXX  XXX@grhosp.on.ca | |

**(b) Funding Source** (Name of research sponsor/funding agency/industry partner – state full name):

None.

**(c) Indicate location(s) where the study will be conducted:**

[ X ] Cambridge Memorial Hospital

[ X ] Grand River Hospital

[ X ] Grand River Regional Cancer Centre

[ X ] St. Mary’s General Hospital

[ X ] Community – specify: Dr Sharkey’s , Dr Kilmurry’s Office

[ ] Other – specify:

**(d) Will this study be reviewed by another Research Ethics Board or Institution?** [ ] YES [ X ] NO

If YES, please attach any other REB or institutional approvals. [ ] Attached [ ] To follow

**(e) Conflict of Interest:** Will any investigators, members of the study team, or their partners or immediate family members:

1. Function as an advisor, employee, officer, director or consultant for the sponsor? [ ] YES [X ] NO
2. Have direct or indirect financial interest in the drug, device or technology employed

(including patents or stocks) in this study? [ ] YES [X ] NO

1. Receive an honorarium or other benefits from the sponsor (apart from fees for service)?[ ] YES [X ] NO
2. If the answer is YES to any of the above, please describe and explain how that conflict of interest

is being managed to ensure that participant rights and welfare are not affected. [ ] Attached

1. ***Individual(s) who will be reviewing/abstracting medical records/charts:***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Name and Degree(s)*** | ***Staff Affiliation? (Specify CMH,GRH, SMGH or None*** | ***Profession*** | ***Precise Role on Project*** |  |
| ***GRH DOCTOR, MD*** | ***GRH*** | ***Radiation Oncologist*** | ***Supervision of student research*** | ***Leave this*** |
| ***WRC STUDENT, BHSc*** |  | ***Medical Student*** | ***Chart review, analysis, presentation of results*** | ***column blank*** |

1. ***Additional individuals on the research team who will be given access to the collected data:***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Name and Degree(s)*** | ***Staff Affiliation? (Specify CMH,GRH, SMGH or None)*** | ***Profession*** | ***Precise Role on Project*** |  |
|  | **No Staff Affliation.**  **Faculty, McMaster University, Waterloo Regional Campus** | **Research Lead, WRC;**  **Ass. Prof., Dept. of Medicine** | ***Supervision of statistical analysis. Will have no role in data collection or any personally identifying information.*** | ***Leave this*** |
|  |  |  |  | ***column blank*** |
|  |  |  |  |  |
|  |  |  |  |  |

1. ***What is the purpose of the study, the research objectives and the research question(s)? (Describe briefly)***

The purpose of the study is to determine the outcome of patients treated for non-metastatic esophageal cancer (eg. radiation, chemotherapy, surgery).

***Research Questions:***

Provincial guidelines recommend trimodality therapy using radiation and chemotherapy in addition to surgery. We will evaluate the use of trimodality therapy in patients with non-metastatic esophageal cancer at the Grand River Regional Cancer Centre, by:

* 1. Evaluating the adoption of trimodality therapy at our centre over time,
  2. Compare the outcomes of patients treated with trimodality therapy compared to the alternative options of surgery, or radiotherapy (with or without chemotherapy), and
  3. Exploring the association between PET-scans and the course of treatment in these patients.

1. ***Risks and Benefits of the Proposed Study.***
2. ***What are the anticipated public and scientific benefits of the study? (Describe briefly)***

The results of the study may validate the trimodality approach for esophageal cancer at our centre. It may also support the use of PET scan prior to treatment.

1. ***What are the possible harms/risks to patients if personal health information was inappropriately released and how will you manage the risks? (Describe briefly)***

Patient confidentially will be maintained throughout the retrospective chart data collection and analyses.

The electronic medical record will be reviewed in a secure location at the Grand River Regional Cancer Center, and the information saved to a secure password protected database. This information is available only to Dr. GRH DOCTOR (circle of care) and WRC STUDENT (medical student).

In preparation for this project, the student candidate (WRC STUDENT) has completed the McMaster tutorial for research conducting retrospective chart reviews. This tutorial educates researchers on patient confidentiality and privacy, as well as ethical consideration when accessing patient records.

Follow-up information from the surgical offices of Dr.P Sharkey and Dr. M Killmurry, will be collected at their offices according to a unique study number without personal identifiers. This non-identifiable information will be stored on a password protected USB drive and immediately transferred back to the Cancer Centre secure database location.

Once the data collection is completed, all personal identifiers (name, DOB, and MRN) will be removed for transfer to McMaster University School of Medicine (Waterloo Campus) for the purpose of statistical analysis. Only the unique study patient number and “Age at diagnosis” will be retained for this analysis. The non-identifying data will be stored and analyzed on a password protected office computer under the care of Dr. Andrew Costa.

At no time will personally identifying data leave the Grand River Regional Cancer Center. Non-identifiable data will be transported securely using password protections, and stored on a secure, password protected computer. If non-identifiable data were released in any way there would be no treat posed to patients given that: 1) no personally identifying information would be released, and 2) only project research would understand the coded data.

1. ***What patient information source are you accessing?***

**[ x ] Health Records/Clinic/Office Files? (Specify which)** Physician Portal (GRH), Meditech (CMH,SMH)

**[ x ] Electronic Database (Specify which)** Aria (GRRCC)

**[ x ] Outside Institution (Specify which)** Dr. P Sharkey, Dr. M. Kilmurry office charts

**[ ] Other (Specify which)**

**9*. What type of data do you need?***

**[ ] Aggregate**(i.e. you do not need to view individual medical charts/health records, e.g. you want to determine how many post-op wound infections occurred in patients with hip replacement surgery?)

**or [ X ] Person level data**(i.e. you need to view individual medical charts/health records)***?***

**10. *If you require only aggregate data (i.e. no access to individual health records), indicate your search criteria (e.g. diagnosis, procedure, time period, other)***

**11. *If you require person level data, are you planning to obtain consent from each patient for access to and use of their personal health information?***

**[ ] YES –** If YES, this is the incorrect form – refer to the Instructions on “When to use this form”.

**[ X ] NO –** If NO, provide justification for a waiver of consent (see Instructions under “Do I need to get patient consent?”)

Itemized justification:

(a) The research purposes cannot be achieved without the information; as we need to identify patients across hospitals by name and DOB,

(b) It is impracticable to obtain consent; a significant proportion the patients have died, or are no longer followed at the Cancer Centre,

(c) Data collection comes from the minimal secondary use of existing records,

(c) The information is used in a manner that will ensure its confidentiality,

(d) All data not housed at the Cancer Centre will have no subject identifiers, and the identity of any subject cannot be known from the data,

(e) The public interest in conducting the research exceeds the negligible privacy threat posed by the patients. The research involves very little or no risk on the part of the patients, cannot affect her/his rights or welfare.

This request complies with the requirements for waiver of consent according to the Tri-Council Policy Statement on the Ethical Conduct of Research Involving Humans and the Health Canada Good Clinical Practice: Consolidated Guideline.

***COMPLETE FOR AGGREGATE DATA ONLY:***

***There is no further information required at this time if you require only aggregate data. Please 1) sign here to verify that you will not be abstracting personally identifiable information from patient charts, 2) sign the Confidentiality agreement at the end of the Application and submit the Application to the THREB. Otherwise continue completing the Application.***

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Locally Responsible Investigator Date***

**12. *If you require person level data, are you collecting any of the following personal identifiers?*** (Please check all applicable):

|  |  |  |  |
| --- | --- | --- | --- |
| ***DIRECT IDENTIFIERS*** |  | ***INDIRECT IDENTIFIERS*** |  |
| ***Full Name (Recommend initials)*** | ***X*** | ***Initials*** |  |
| ***Address*** |  | ***Full Date of Birth (day/month/year)*** | ***X*** |
| ***Telephone Number*** |  | ***Age at time of data collection or year of birth*** |  |
| ***OHIP #*** |  | ***Full Postal Code (recommend first 3 digits only)*** |  |
| ***Social Insurance Number*** |  | ***Healthcare Provider (recommend type of provider, eg. Family Physician, VON)*** |  |
| ***Email address*** |  | ***Discharge Date*** |  |
| ***Medical Record Number*** | ***X*** | ***Other date (e.g. date of service)*** |  |
| ***Full Face Photograph*** |  | ***Fax Number*** |  |
|  |  | ***Medical Device Identifier*** |  |
|  |  | ***Certificate/License number*** |  |
|  |  | ***Vehicle Identification1*** |  |

1 Vehicle identification numbers (VIN) and serial numbers including license plates.

Investigators should plan to collect personal data at the lowest level of identifiability necessary to achieve the study objectives. Even a dataset without direct identifiers may present a risk of indirectly identifying data subjects if the dataset contains sufficient information about the individuals concerned. For advice, consult the CIHR Best Practice Guidelines for Protecting Privacy and Confidentiality: <http://www.cihr-irsc.gc.ca/e/pdf_22427.htm>

***If you are collecting any of the above personal identifiers, justify why each item is required:***

Patients may have chemotherapy and radiation therapy at Grand River Regional Cancer Centre (GRH), Surgery at St Mary’s Hospital and follow up at Cambridge Memorial Hospital, or a surgical office. Name and Date of Birth will be needed to cross reference charts. Once the data collection is completed, the personal identifiers of name and MRN will be removed to protect the privacy of the patient. Only the unique study patient number and DOB will be retained for analysis. Aggregate data only will be presented. At no time will personal identifiers leave the Cancer Centre.

**13. *How will relevant patient records be identified?***

Patients will be identified by a search of the Cancer Center’s Database for “Esophageal Cancer” patients treated with “radiotherapy”.

**14. *PRIVACY TUTORIAL: Have all those who have access to personal health information completed the Grand River Privacy Tutorial? [ ] YES [ ] NO***

***or***

***Have those accessing personal health information completed an equivalent type of privacy tutorial? (e.g.*** [***http://ethics.mcmaster.ca/chart/***](http://ethics.mcmaster.ca/chart/) ***) [ X] YES [ ] NO***

***If yes, which one?*** http://ethics.mcmaster.ca/chart

***NOTE: As of January 1, 2008 those requiring access to personal health information must successfully complete a privacy tutorial. Those requiring access to personal health information at Grand River Hospital must successfully complete that tutorial.***

1. ***How many patient records will be reviewed?*** 120 (estimated)
2. Data to be abstracted for the time period of (from when to when?):

Start date: Jan 2006 End date: Dec 2012 (inclusive)

1. ***Attach data collection form or list of fields to be abstracted.*** (**NOTE: This is mandatory**: Application will be returned if this information has not been included.) Attached.
2. **How will study subjects be identified on data collection forms *(e.g. study number, initials...)*** *?* Unique study number, Name, DOB and MRN
3. Are any sensitive issues raised in this study which may require subject consent? (e.g. HIV status, mental health problem or diagnosis, subjects identifiable, e.g. pedigrees, other)

[ ] YES If yes, justify not getting patient consent and specify additional safeguards for confidentiality:

[ X ] NO

1. Do you plan to link the locally collected data with any other data set(s): NO  *(e.g. OHIP data, census tract data)*? If so:
   1. identify the data set(s),
   2. explain how the linkage will occur,
   3. justify why the linkage is necessary, and
   4. provide a list of data items used.
2. **Will a portable device (e.g. laptop computer, USB key) be used to collect or transfer data? [ X ] Yes [ ] No**

**If yes, justify:**

Follow-up information from the surgical offices of Dr. P Sharkey and Dr. M Killmurry, will be collected at their offices according to a unique study number without personal identifiers. This information will be stored on a password protected USB drive and immediately transferred back to the Cancer Centre secure database location.

1. Indicate the steps to be taken to ensure security of data with personal identifiers. Please check all that apply.

|  |  |
| --- | --- |
| ***PROCEDURAL MEASURES*** |  |
| * Data access to the segregated/identified data will be limited to a “need to know” basis 2 | X |
| * There will be an audit trail of access to electronic records | X |
| ***PHYSICAL*** |  |
| * Completed data abstraction forms will be stored in locked filing cabinets in secure location – Specify: |  |
| * Computers will be housed in a locked secure location – Specify: | X |
| * Data file backup will be stored in a separate, locked secure location – Specify: GRH DOCTORS office Grand River regional Cancer Centre | X |
| * Other – Specify: |  |
| ***TECHNICAL*** |  |
| * Data will be stored on a computer which is password protected | X |
| * Data will be stored in a computer file which is password protected | X |
| * Data will be encrypted (at least 128 bit encryption protocol) | X |
| * Frequent backups of data will occur |  |
| * Data will be stored on computer systems with virus protection | X |
| * Data will be stored on computer systems with uninterrupted power source | X |

2 Reminder: All amendments to previously approved research plans require THREB approval, including any subsequent amendment in who is given access to the data.

1. (a) Will data be sent outside of the institution where it was collected?

[ X ] YES

[ ] NO -- go to Question 23.

(b) Why is it necessary to send data outside of the institution where it was collected?

Once the data collection is completed, the personal identifiers of name, MRN will be removed for transfer to McMaster University School of Medicine (Waterloo Campus) for the purpose of statistical analysis. Only the unique study patient number and “Age at diagnosis” will be retained for this analysis.

(c) How will the data be sent? [ ] Fax (Describe security at the receptor site)

[ ] Private Courier (must be able to trace delivery)

[ ] Canada Post – Xpresspost or Priority Courier (Regular mail may not be used.)

[X ] Other (Please specify): Password protected USB with personal identifiers removed as above, transported in person (WRC STUDENT)

(d) Where will data be sent? Specify the names and affiliations of persons outside of your research team

(e.g. technical service providers, other researchers) who will have access to the data:

Andrew Costa, PhD, Research Education Coordinator, McMaster DeGroote School of Medicine, Waterloo Regional Campus.

Dr. Costa will provide the means for the student to analyze the data as well as support the analyses.

(e) A Data Transfer Agreement or Research Data Agreement must be completed before any transfer of information is made. Has the Data Transfer Agreement or Research Data agreement been approved by the hospital privacy office?

**[ ] YES**

**[ ]**  **NO *If NO, explain.***

1. Will this chart review be entered into an ongoing electronic database for future use in another research study?

(Please note: Any secondary analysis must be approved by the THREB prior to implementation.)

[ X ] YES If yes, specify where it will be stored, who will be the custodian (i.e. the person responsible for data storage

and integrity), who will have access to it, and security measures:

Data will be kept for the possibility of update with longer follow up. All electronic data will be kept on GRH DOCTORS secure password protected institutional database/ computer at Grand River Hospital. Non-identifiable data at McMaster University will be destroyed after the completing of the student project.

[ ] NO

1. (a) How long do you plan to keep the data? – Specify:

(Please note: You are required to destroy identifiers [or links] at the earliest possible time.)

Personal identifiers will be removed as soon as the follow up data collection is completed. The de-identified data will be kept indefinitely. Non-identifiable data at McMaster University will be destroyed after the completing of the student project.

(b) Will data be [ ] destroyed or [ X ] irreversibly anonymized (i.e. the key identifying the link between data

and the individual’s identity is deleted)? When? At the end of follow up data collection. (Sept 2013 projected)

Confidentiality Agreement

THE FOLLOWING REPRESENTS THE TERMS AND CONDITIONS UNDER WHICH THE HANDLING OF CONFIDENTIAL INFORMATION FOR THE PROJECT SHALL PROCEED. THESE TERMS AND CONDITIONS HAVE BEEN DRAFTED IN COMPLIANCE WITH THE *PERSONAL HEALTH INFORMATION PROTECTION ACT* AND OTHER PRIVACY LEGISLATION.

1. All information received or exchanged will be held in strict confidence.
2. Information will not be used for any purpose other than for the project for which it was provided. The information will be shared only with those individuals listed on this form, who are working directly on the project, except for authorized oversight of the study.
3. No attempt will be made to contact any individual to whom the information relates, directly or indirectly.
4. Information will be stored in a location that is physically and/or technically secure and to which access is given only to the individual(s) listed on this form.
5. All direct identifiers will be segregated/stripped from clinical data; a unique study identifier (i.e. a randomly generated or unique identifying number) will be assigned to each patient record; the Master list linking the ID with identifiable material will be stored in a separate computer file and/or physical location; the Master list will be locked, and password protected and encrypted if information is to be put on any portable device.
6. Data sent outside of the institution will require that the parties enter into an information transfer agreement before the data transfer takes place.
7. Policies and procedures on the retention and destruction of information must be in place by the party undertaking the project.
8. It is strongly recommended that members of the research team and any individual(s) listed below read the *Personal Health Information Protection Act*.
9. Publication of confidential information regarding the institution requires adherence to the following principles:
10. The institution agrees to allow the publication of the information as it pertains to the project providing that the institution or its practices are not the main focus of the publication.
11. In cases where the publication focuses on the institution, the institution reserves the right to review and approve the use of this information prior to publication.
12. The institution will be acknowledged within any publication as providing the source information.
13. A copy of the publication will be given to the institution.
14. Information that is lost or stolen must be reported to the Chief Privacy Officer of the appropriate institution at the first reasonable opportunity.
15. A breach of institutional policy regarding access to information and protection of privacy may have serious consequences or be just cause for termination of my employment and/or affiliation with the institution.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the Locally Responsible Investigator Date

Signatures of Research Team members:

|  |  |  |
| --- | --- | --- |
| Print Name | Signature | Date Signed |
| WRC STUDENT | ::Desktop:DSC_0096.JPG | Feb 20, 2013 |
| Andrew Costa | ::Desktop:Screen Shot 2013-02-22 at 11.07.32 AM.png | Feb 11, 2013 |
|  |  |  |
|  |  |  |
|  |  |  |

**For research at Cambridge Memorial Hospital and St. Mary's General Hospital**

***For REB/Health Information/Health Records Use only (when patient record source is Health Records or Health Information Dept)***

**THREB Project #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Title of Study:**

Retrospective Chart Review of patients treated for Esophageal Cancer.

**Locally Responsible Investigator:**

GRH DOCTOR MD

Radiation Oncologist

[ ] Requires further review by Research Ethics Board: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

THREB Chair Date

[ ] Approved by REB – forward to Manager,

Health Records/Health Information \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

THREB Chair Date

Michael D. Coughlin, Ph.D.

[ ] Approved by Health Records/Information \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Manager, Health Records/Information Date

Print Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Comments:**

**FINAL APPROVAL:** Following approval by THREB the application form with the signature of the Chair will be sent to the appropriate Manager for further review and final approval. Once approval is given by the Manager, a copy of the application form signed by both THREB and Health Records/Information will be returned to THREB to complete their records and THREB will send out a final letter of approval.

**For research at Grand River Hospital**

# **ADMINISTRATIVE/INSTITUTIONAL APPROVAL OF RESEARCH PROJECT**

(Projects must receive separate approval from each institution involved.)

**Project #** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(will be assigned by THREB)

**1. Local Responsible Investigator** (max 100 characters)**:**

|  |
| --- |
| Dr. GRH DOCTOR |

**2. Project title** (max 400 characters)**:**

|  |
| --- |
| Retrospective Chart Review of patients treated for Esophageal Cancer. |

**3. Executive Summary**

a. Research Question (max 350 characters):

|  |
| --- |
| Provincial guidelines recommend trimodality therapy using radiation and chemotherapy in addition to surgery. We will determine how patients with esophageal cancer are treated at GRRCC. We will look at the adoption and effectiveness of trimodality therapy. We will investigate the utility of staging PET-scans. |

b. Identify any staff involvement (max 250 characters):

|  |
| --- |
| Dr. GRH DOCTOR and WRC STUDENT (McMaster Waterloo Regional Campus medical student) |

c. Expected number of patient records to be accessed: 120

4. **Research Data Agreement**

Has a Research Data Agreement been completed? Yes No

**5. Contract**

Is there a contract involved? Yes No

If “yes,” has the contract been submitted to the institution?  Yes  No

**NOTE**: If there is a contract, authorization to begin a study will require a completed contract approved by the institution.)

**5. ADMINISTRATIVE APPROVAL**

I have reviewed the attached protocol and confirm that resource and contract issues at this institution have been or are being satisfactorily addressed and I give administrative approval for the THREB review of this project.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Signature)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(Print name)

**For GRH**: Tina Mah 519-749-4300 x2876

**FINAL APPROVAL:** Once administrative approval has been forwarded to THREB, the application will be reviewed by THREB, normally by delegated review. Once approved by THREB, THREB will send out a final letter of approval.