UNIVERSITY OF MANITOBA

Bannatyne Campus Research Ethics Boards
P126-770 Bannatyne Avenue
Winnipeg, Mb R3E 0W3
Phone: (204) 789-3255

| For Administrative use only | | |
|---|---|---|
| REB File Number: | Date Received: | Initials: |

# BANNATYNE CAMPUS RESEARCH ETHICS BOARD SUBMISSION FORM for RETROSPECTIVE CHART OR RECORDS REVIEW

**(Including Application Instructions and Application Review and Notification)**

**This form must only be used to submit a request for ethical approval to conduct a retrospective chart/record(s) or retrospective database review where there is no intent of contacting individuals.** Please complete the full Bannatyne Campus Research Ethics Board Submission Form for all other studies

***An Example Submission Prepared at MCHP Focusing on Fields Relevant for Projects Using the Population Health Research Data Repository***

Annotations and Examples Highlighted in Yellow **Recommended Responses in Blue**
**Recommended Responses Specific to Deliverables in Green**

## Application Instructions:

- Members of the Colleges of Medicine, Dentistry, Pharmacy, Rehabilitation Sciences and the affiliated teaching hospitals, their associated research foundations, and Winniepg Regional Health Authority Researchers (WRHA) may submit their protocols to the applicable Bannatyne Campus Research Ethics Board (REB).
  - To qualify as a WRHA Researcher you must be a researcher who is (i) employed by the WRHA or have a written contract for services with the WRHA; or (ii) have privileges under the WRHA's Medical Staff By–Law. If you are requesting review as a WRHA Researcher, your study must be carried out at facilities owned by or operated by the WRHA or under the direction of the WRHA.
- Submit **one copy:**
  - of this submission form.
  - a data capture sheet. *<not required; see Q. 20 on data fields.>*
  - Master List <not required (for human samples)>
  - supporting documentation (e.g. a protocol if applicable). **NOTE:** A protocol is not required if this submission form is completed in full.
  - CV template required with first ethics submission by the Principal Investigator for the calendar year
- Submit **one electronic copy** of each document listed above on a CD or Flash drive
- COMPLETE ALL SECTIONS OF THE FORM AS REQUIRED. **DO NOT REFERENCE PAGES in ATTACHED DOCUMENTS (e.g. do not indicate - See protocol).** INCOMPLETE SUBMISSIONS WILL BE RETURNED to the applicant for completion.
- Use no smaller than 10 point font; handwritten submissions are not acceptable.
- Deliver completed submission to the *Health Research Ethics Board* by the monthly full board **submission deadline date for new studies** (DO NOT FAX or EMAIL). The submission deadline for all new studies, including those that qualify for expedited/delegated review, and those that require full Board review is the same date. (Please see web site for specific deadline dates.)
- The form is locked which will allow you to tab to each question. To conduct a spell check you must first unprotect the document. Go to **"*Tools*"** on the Tool Bar and in the drop down menu select "***Unprotect Document",*** no password is required. If working with Word 2007, go to "***Review***" tab, then click the "**Protect Document**" pane, click on ***"Restrict Formatting and Editing"*** and then click on "**Stop Protection**". No password is required.
- DO NOT DELETE QUESTIONS OR THE SUBMISSION WILL BE RETURNED to the applicant.

## Application Review and Notification:

- Forms are date stamped upon receipt in the Research Ethics Board Office (REB).
- Forms submitted after the submission deadline date for the full Board meeting may be deferred to the next month.
- Applications requesting and qualifying for delegated/expedited review typically reviewed by the Health Research Ethics Board (HREB) Chair.

- The HREB Chair may refer the application to the full Board or to another University of Manitoba Research Ethics Board (REB) member or REB. In this case you will be contacted to provide additional or revised copies of the application.
- Certificates of approval or letters of conditional approval will be sent to the local Principal Investigator (or designate) within approximately 5-7 business days following the full Board meeting date (provided the submission deadline is met**). If you have not received a response within the period stated above please contact our office at 789-3255.**

# BANNATYNE CAMPUS RESEARCH ETHICS BOARD SUBMISSION FORM for RETROSPECTIVE CHART OR RECORDS REVIEW

| **Date:** | |
|---|---|

## LIST DOCUMENTS INCLUDED WITH SUBMISSION:

| **Document Name** | **Version Date** | **# of paper copies** |
|---|---|---|
| Submission Form for Retrospective Chart or Records Review –**Required** (Please see website to download form.) | | 1 Copy |
| Data Capture Sheet -**Required** | | 1 Copy |
| Master List <not needed for deliverables> | | 1 Copy |
| Bannatyne Campus CV Template -1 copy **Required** - if first time submitting in the present calendar year (Please see website to download form.) | | 1 Copy |
| ***Certificate of CORE on line tutorial completion*** - **Required** As of September 1, 2011, researchers applying to a University of Manitoba Research Ethics Board for research involving humans must include a certificate of completion from the Interagency Advisory Panel on Research Ethics (PRE) online tutorial, TCPS 2: Course on Research Ethics (CORE). Evidence of this completion will be required prior to release of the final ethics certificate of approval**. If you have previously submitted this documentation please indicate that this has been done.** | | 1 Copy |
| | | 1 Copy |
| | | 1 Copy |
| Please include an electronic copy (on CD or flash drive) of each document included in your submission. Ensure to label and date each document. | | |

## PART A:

## TYPE OF STUDY:

**1.0 Indicate which of the following best describes the type of investigation proposed:**

☐ **Retrospective Chart Review** ☐ **Retrospective Database Review**

**This form must only be used to submit a request for ethical approval to conduct a retrospective chart/record(s) or retrospective database review where there is no intent of contacting individuals.** Please complete the full Bannatyne Campus Research Ethics Board Submission Form for all other studies or your submission will not be processed and will be returned to the submitter.

## PART B:

## PROJECT REGISTRATION:

**2.0 Title of Research Study:**

*<The title should be the same as the title for the HIPC submission.>*

**3.0 Is this proposal closely linked to any other proposal previously/simultaneously submitted to either the Biomedical Research Ethics Board (BREB) or Health Research Ethics Board (HREB)?**

☐ **Yes** ☐ **No**

**If yes**, describe the relationship of this proposal to the primary study and provide the REB file **#:**

**4.0 Principal Investigator:**

The Principal Investigator must be:

- an employee or student of the University of Manitoba; or
- have an academic appointment or affiliation with the University of Manitoba; or
- a researcher affiliated with the WRHA (see definition below).

University of Manitoba Employee or student ID number:

Name and Title(s):
Department/Program:
☐ College of Medicine ☐ College of Dentistry ☐ College of Pharmacy
*Depends on the PI's affiliation but for MHCP it is College of medicine*
☐ College of Rehabilitation Sciences
OR,
☐ WRHA Researcher *(To qualify as a WRHA Researcher you must be a researcher who is (i) employed by the WRHA or have a written contract for services with the WRHA; or (ii) have privileges under the WRHA's Medical Staff By–Law. If you are requesting review as a WRHA Researcher, your study must be carried out at facilities owned by or operated by the WRHA or under the direction of the WRHA.)*

Institution:
Mailing Address:
Phone: Fax: E-Mail Address:

**5.0 Is this the Principal Investigator's first time submitting to the Research Ethics Board during the present calendar year?** ☐ **Yes** ☐ **No**

***If yes, please summarize your credentials/experience relevant to this project in the University of Manitoba Bannatyne Campus CV template (maximum two page document) provided on the website and include one copy with this submission. Do not submit your full CV unless requested by the Board.***

**6.0 Is the Principal Investigator a student?** ☐ **Yes** ☐ **No**

**If yes**, name of supervisor:
Department/Program:
☐ College of Medicine ☐ College of Dentistry ☐ College of Pharmacy
☐ College of Rehabilitation Sciences OR, ☐ WRHA Researcher (defined in question # 8.0)
Institution:
Mailing address (if different from the Principal Investigator):

Phone: Fax: E-Mail Address:
Purpose of Study: ☐ Course Work ☐ Thesis ☐ Dissertation

**7.0 Co-Investigators**

Name: Institution:
Name: Institution:
Name: Institution:
Name: Institution:

**8.0. Name of Study Coordinator (if applicable):**

**Name:** **Institution:**
**Mailing Address:**

**Phone:** **Fax:** **E-Mail Address:**

**9.0 REB correspondence to be directed to (*Note: correspondence will be forwarded to one contact only*):**

☐ **Principal Investigator or** ☐ **Study Coordinator**

## INSTITUTIONAL APPROVAL:

***Prior to commencing any research related activity, approval of the custodian of records and/or institutional approval are required. It is the Principal Investigator's responsibility to contact the site to inquire as to the procedures required to obtain approval at the institutional level. Please provide evidence of this approval for our file. This approval can be submitted following final Research Ethics Board approval.***

**10.0 Indicate locations(s) where the study will be conducted and the custodian(s) of any records accessed:**

☐ University of Manitoba
☐ Winnipeg Regional Health Authority — Specify: _____
☐ HSC ☐ SBGH ☐ Concordia ☐ Victoria
☐ SOGH ☐ Miscercordia ☐ GGH
☐ Deer Lodge Centre
Other –specify: _____
☐ Cancer Care Manitoba (CCMB)
☐ Community — Specify: _____
☐ Manitoba Health
☐ Manitoba Centre for Health Policy
☐ School Division/School — Specify: _____
☐ Diagnostic Services Manitoba
☐ Other Specify: _____

**11.0 Has your research proposal/protocol been submitted for approval to the custodian of records and/or the Research Department of the institution where you intend to conduct the research?**

☐ **Yes** **Date submitted or anticipated date:** ***An MCHP project feasibility form must be completed***

☐ **No**

**If no,** indicate the rationale for not requesting institutional approval**.**

## FUNDING SOURCE/SPONSOR AND BUDGET:

**12.1** **Funding Source(Name of sponsor/funding agency/industry partner – state full name and address**):

**Manitoba Health, Seniors and Active Living (MHSAL)**
**300 Carlton St. Winnipeg, Manitoba R3B 2K6**

**12.2** **Classify the type of funding:**

☐ **For-profit sponsor** ☐ **Grant** ☐ **U of M Internal Funds** ☐ **No Funding** ☐ **Other**

**If other please specify:** _____ **DELIVERABLES: University contract with MHSAL**

**12.3** **For studies that receive funding from a "for profit sponsor", please provide either a University of Manitoba Account # or the billing contact and address of the sponsor:**

***The office of the Dean of Medicine will assess a fee of $2500.00 for protocols that are funded by the private sector.*** *Protocols that are not funded by a private sector organization and protocols with small external grants will not be billed.* ***The $2500.00 fee is NOT dependent upon approval and is applied whether the study is submitted to the full Board or expedited review.*** *The review fee will also apply if the submission is withdrawn after it has been reviewed.*

**DELIVERABLES: Studies done for MHSAL as deliverables are funded as part of the baseline funding from MHSAL to MCHP. As such, a specific budget is not developed for each deliverable.**

**12.4** **Is a budget attached or outlined below?** ☐ **Yes** ☐ **No**

**If no,** please explain why: (*A budget of predicted expenditures must be submitted for all studies regardless of whether they are funded or not, prior to the REB granting final approval for the study.*)

**12.5** **If the study is funded, where and by whom will the budget be administered?**

☐ No funding
☐ University of Manitoba (Please provide Project # if applicable: _____)
☐ Winnipeg Regional Health Authority
  ☐ HSC ☐ SBGH ☐ Concordia ☐ Victoria
  ☐ SOGH ☐ Miscercordia ☐GGH
  ☐ Deer Lodge Centre
  Other –specify: _____
☐ Cancer Care Manitoba (CCMB)
☐ Community — Specify: _____
☐ Manitoba Health
☐ Manitoba Centre for Health Policy
☐ School Division/School — Specify: _____
☐ Diagnostic Services Manitoba
☐ Other - Specify: _____

## PART C:

## PROJECT DESCRIPTION:

**13.0** **Provide a clear statement of the purpose, objectives and the question(s) to be examined in the review.**

**14.0 Outline the anticipated public and scientific benefits expected from the research.**

**15.0 Provide background information and/or literature supporting the potential benefits to follow from the proposed review.**

## PARTICIPANT POPULATION:

**16.0 Specify the population being studied, including the ages and conditions of the subjects, etc.**

Manitoba Population

**16.1 Will the research hypothesis be concerned with whether or not a participant is Aboriginal (Inuit, Métis and members of First Nations)?** ☐ **Yes** ☐ **No**

**16.2 Will the analysis of the research results use Aboriginal community membership as a variable?** ☐ **Yes** ☐ **No**

**16.3 Will the interpretation of the research results refer to Aboriginal people, language, history or culture?** ☐ **Yes** ☐ **No**

**If yes to any of the above (16.1-16.3), please outline any process to be followed respecting the consultation with the appropriate community in the design and conduct of the study.**

## SAMPLE SIZE:

**17.0 Provide an approximation of the number of charts/records that you expect to review: _____** e.g., We will look at all available health, social assistance, and education records for the Manitoba population of approximately 1.4 million people from 2001 to the current year.

## RECRUITMENT:

**18.0 Indicate how the charts/records to be reviewed are to be obtained?**

e.g., This study involves an analysis of already collected administrative data from the Manitoba Population Research Data Repository held by MCHP; therefore, no recruitment or direct contact with individuals is necessary.

e.g., Administrative data to be used are part of the Data Repository as per the data sharing agreements negotiated between the University of Manitoba, Manitoba Health, Seniors and Active Living (MHSAL), the Manitoba Department of Family Services and Consumer Affairs, the Winnipeg Regional Health Authority, and the Department of Manitoba Education.

e.g., *If new database*: <*New database*> will be transferred to the Data Repository at MCHP, as per approval from <*name of data provider*> and the data sharing agreement with MHSAL.

## INFORMED CONSENT PROCESS AND DOCUMENTATION:

**19.0 Will consent be obtained from potential participants prior to reviewing the chart(s)/record(s) or database(s)?** ☐ Yes ☒ No

**19.1** **If no**, please explain why participant approval to review their charts/records is impractical, impossible, and /or would adversely affect the research and proceed to question 20.0?

Consent will not be obtained from study subjects, as permitted under section 24(3)c of the Personal Health Information Act.

**19.2** **If yes**, describe the procedures/processes used to obtain informed consent including where, by whom and under what circumstances.

## DATA TO BE COLLECTED:

**20.0 Identifiability of data to be reviewed in the study:**

☐ De-identified or anonymized data (e.g. larger datasets that have scrambled PHINs or other anonymized identifiers)

☐ Identifiable data (e.g., chart records with names included)

**21.0 Provide a copy of the data capture sheet or list the fields that details precisely what specific information/variables will be extracted and collected and from the specific source (s):**

☐ Data capture sheet (attached) is mandatory for chart review studies (The submission will be returned to PI and not reviewed if this is not included**)**

☐ List of data fields (attached) for large database studies is acceptable
***NOTE – see Question IV(a) in the HIPC submission. It is recommended to use general categories or descriptive requirements. If specific fields are listed, the wording may be prefaced with "for example", "including", "such as", or similar phrasing. Otherwise, you may only use the fields you specify, and an HREB Amendment form will need to be submitted for approval; this also applies to descriptions contained in the study protocol and in the HIPC submission>***

**22.0 If person/identifiable level data is to be used, are you collecting any of the following personal identifiers?** Investigators should plan to collect personal data at the lowest level of identifiably necessary to achieve the study objectives. Even a dataset without direct identifiers may present a risk of indirectly identifying data subjects if the database contains extensive information about the individuals concerned. For guidance, consult the "***CIHR Best Practice Guidelines for Protecting Privacy and Confidentiality***":

| DIRECT IDENTIFIERS | YES | NO | INDIRECT IDENTIFIERS | YES | NO |
|---|---|---|---|---|---|
| **Full Name (recommend only initials)** | ☐ | ☒ | **Initials** | ☐ | ☒ |
| **Address** | ☐ | ☒ | **Date of Birth (day/month/year)** | ☒ | ☐ |
| **Telephone number** | ☐ | ☒ | **Age at time of data collection or year of birth** | ☒ | ☐ |
| **PHIN#** | ☐ | ☒ | **Full postal code (recommend using first 3 digits only)** | ☒ | ☐ |
| **e-mail address** | ☐ | ☒ | **First 3 digits of Postal Code** | ☐ | ☒ |
| **Medical Records Number** | ☐ | ☒ | **Health Care Provider (recommend** | ☒ | ☐ |

| | | | | | |
|---|---|---|---|---|---|
| | | | **type of provider, {e.g. family physician, VON} only)** | | |
| **Full Face Photograph** | ☐ | ☐ | **Fax number** | ☐ | ☐ |
| **OTHER *(Specify below:)** | ☐ | ☐ | **Scrambled PHINs or other anonymized identifier (Specify:** | ☐ | ☐ |
| | ☐ | ☐ | **OTHER (Specify below:)** | ☐ | ☐ |
| | ☐ | ☐ | | ☐ | ☐ |
| | ☐ | ☐ | | ☐ | ☐ |
| | ☐ | ☐ | | ☐ | ☐ |
| | ☐ | ☐ | | ☐ | ☐ |

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

e.g., Date of birth and scrambled PHIN will be used to link databases within the Data Repository at MCHP <*also mention here if linking to new data*>. Date of birth will also be used for calculating age at time of e.g., date of service. Full postal code is required to allow assignment of individuals to their areas of residence in Manitoba. Descriptive analyses will report some information by type of health care provider, such as family physicians and specialist physicians.

**23.0 Describe in general terms how the information to be collected relates to the study's purpose, hypotheses, and study questions. If the information does not relate directly to these, provide explanation why the information is being collected.**

**24.0 Describe the methodology and data analysis to be used in the chart/record review process.**

**25.0 Specify the approximate time period during which information from the charts/records will be extracted (e.g. April-May, 2008). From: _____ to _____**

**26.0 Specify the approximate time range over which the information in the charts/records was collected (e.g. all patients seen between 2000 - 2008).**

suggested that the end of the time range be "Latest available", e.g. all patients seen from 2000 - latest year available

## DATA PRESENTATION/PUBLICATION OF RESULTS OF REVIEW:

**27.0 Outline your intentions with respect to how the data will be used with respect to reports, presentations, and/or publication:**

- ☐ **Only aggregate data will be presented**
- ☐ **Individual de-identified/anonymized data will be presented**
- ☐ **Other – Please specify:**

## PRIVACY AND CONFIDENTIALITY:

**28.0 Specify where the charts/records are maintained and where the abstracting of the information from them will occur, paying particular attention to the privacy and security of the work environment in which the information extraction is to occur.**

All of the analyses will be conducted within the secure computer environment of the Manitoba Centre for Health Policy (MCHP) located at 408 - 727 McDermot Avenue,

Winnipeg, Manitoba R3E 3P5.

**29.0 Provide a detailed description of the methods that will be used to protect the privacy and confidentiality of individuals whose information is being reviewed.** *(**Note**: Data capture should be done only on paper or electronic forms that are coded and do not contain personal identifying information. All direct identifiers should be segregated/stripped from clinical data; a unique study identifier (i.e. a randomly generated or meaningless ID number) should be assigned to each patient/participant record; the Master list linking the ID with identifiable material should be stored in a separate compute file and /or physical location; and the Master list should be locked and password protected).*

MCHP operates according to rigorous standards regarding security, privacy, and confidentiality of data files contained in the Manitoba Population Research Data Repository. Physical measures include restricted, alarm-protected, access to the facility. Electronic measures include multiple levels of passwords, electronic firewalls, encryption of transmitted information, and other security measures.

Repository data is in the form of de-identified computer files, stored on a Secure Windows environment and data server within MCHP, at the University of Manitoba. Privacy of information is protected through a number of measures, most notably that no files at MCHP contain names or addresses, and that identifiers (e.g., Personal Health Information Number (PHIN) and Registration Number) are changed by Manitoba Health to be not recognizable.

Access to, and use of, the data are carefully controlled and monitored on an ongoing basis. All MCHP staff sign a Confidential Information Agreement and comply with terms related to the use and dissemination of information derived from the data repository. Analyses involving 5 or fewer events or persons are suppressed. Publications generated from database analyses are reviewed by Manitoba Health, Seniors and Active Living (MHSAL) prior to release and are compliant with legislative requirements.

Security measures to protect the privacy and confidentiality of individuals are described in MCHP policies and procedures documents (available upon request), and are based on the Data Sharing Agreement in place between MHSAL and other data providers and the University of Manitoba.

**30.0 Indicate the steps to be taken to ensure security of data with direct or indirect personal identifiers. Please check all that apply.**

**NOTE**: *If direct identifiers must be retained they should be isolated on a separate dedicated server/network without external access (i.e. research databases with participant information should not be housed on portable devices such as laptops or flashcards).*

| ***PROCEDURAL MEASURES*** | Yes | No |
|---|---|---|
| • Data access to the segregated /identified data will be limited to a " need to know" basis | ☒ | ☐ |
| • There will be an audit trail (i.e. who accessed the data and when) of access to electronic records (***An audit trail is required if direct identifiers are maintained in electronic form– NOTE: Word, Excel and Access programs do not have audit trail capability)*** | ☒ | ☐ |
| ***PHYSICAL*** | ☐ | ☐ |
| • Completed data abstraction forms will be stored in locked filing cabinets in secure location – Specify: | ☐ | ☐ |
| • Computer will be housed in a locked secure location – Specify: **All analyses will be conducted within MCHP on a secure Secure Windows environment and data server. Linkages of files by scrambled PHIN are conducted for the specific analyses only; no permanent datasets are retained beyond the study period, or transmitted outside MCHP offices.** | ☒ | ☐ |
| • Data file backup will be stored in a separate, locked location – Specify: **As above** | ☒ | ☐ |
| • Other – Specify: | ☐ | ☐ |

| ***TECHNICAL*** | ☐ | ☐ |
|---|---|---|
| • Data will be stored on a computer which is password protected | ☐ | ☐ |
| • Data will be stored in a computer file which is password protected | ☐ | ☐ |
| • Frequent backups of data will occur | ☐ | ☐ |
| • Data will be stored on a computer systems with virus protection | ☐ | ☐ |
| • Data will be stored on computer systems with uninterrupted power source | ☐ | ☐ |

**31.0 Will individual level data be sent outside of the institution where it was collected and/or will you be receiving individual level data from other sites (for example, in the case of a multi-site study where you are the coordinating site receiving data)?** ☐ **Yes** ☐ **No**
**(If no, go to question 32.0)**
**If yes,** explain why is it necessary to send/receive data outside of the institution where it was collected.

**31.1 How will data be transmitted?**

| **Transmission of data via:** | Sent? | Rec'd"? |
|---|---|---|
| Fax – Security of the receptor site MUST be described: | ☐ | ☐ |
| E-mail (Encryption protocol MUST be attached) | ☐ | ☐ |
| Private Courier (Must be able to trace delivery) | ☐ | ☐ |
| Canada Post Expresspost or Priority Courier (Regular mail may NOT be used) | ☐ | ☐ |
| Other – Specify: | ☐ | ☐ |

**31.2 Where will data be sent?**

**31.3 Specify the names and affiliations of persons or commercial companies outside your study team (e.g. technical service providers, other researchers) who will have access to the data. Also specify the level of identifiably or the data they will have access to (e.g. personal, identifiable, anonymized, etc.)** *Data sent or received by the institution may require that the parties enter into an information/data transfer agreement before the data transfer takes place.*

**32.0 Specify how long study data including personal data will be retained and the procedures for securing/storing records.**

All study-associated data and programming code will be archived at the time of study completion and removed from MCHP's analysis system. Study completion is identified by the principal investigator or by the submission of a final REB notification of study completion. Consistent with University of Manitoba protocols, archives will be maintained at MCHP for a period of at least seven (7) years and no more than ten (10) years after completion to allow time for questions and clarifications of publications and then all study-associated data will be destroyed. The programming code may be retained indefinitely.

**33.0 Specify whether and when the data will be destroyed or irreversibly anoymized (i.e. the key identifying the link between data and the individual identity is deleted). Describe the procedures used to destroy or anonymize study data.**

Data used at MCHP are de-identified at the source. Manitoba Health, Seniors and Active Living (MHSAL) datasets created for the purposes of this study will be deleted after completion of analysis for the report and scholarly articles. Source data are maintained in the Manitoba Population Research Data Repository.

**34.0 Identify all individuals by name, staff affiliation and their precise role in the project who will have access to the master list (with personal identifying information), data capture information and how access to this information is secured and monitored.**

**The Personal Health Information Act(PHIA)requires that all employees, students, or agents who handle or are exposed to personal health information take the University of Manitoba PHIA Orientation and sign a pledge of confidentiality that acknowledges that they are bound by written policy and procedures.**

**35.0 Has PHIA Orientation and pledge-signing been completed by all employees, students and agents who will handle or be exposed to personal health information?**

☐ **Yes** ☐ **No**

**If "No," the Principal Investigator must contact the University Access & Coordinator's Office to make arrangements for completing this requirement.** fippa@umanitoba.ca

**Where individuals have not completed PHIA Orientation and signed a pledge, and for the purpose of ensuring that they do, Principal Investigators' contact information will be provided to the University Access & Privacy Coordinator's Office.**

**36.0 Will an electronic database be created in the process of the review?** ☐ **Yes** ☐ **No**

**If yes,** indicate whether the database will be used only for the purpose of data analysis and outline any intention to maintain the data for a period of time beyond the data analysis phase of the review.

***If new data are being used:*** Although we are not creating a new database, a de-identified copy will be transferred to MCHP to become part of the Repository which is housed in a secure server at MCHP.

***If no new data are being used:*** Although we are not creating a new database, copies of de-identified data have been transferred to MCHP to become part of the Repository which is housed in a secure server at MCHP.

**36.1 If yes to question 35.0, explain how this database is complaint with the Personal Health Information Act of Manitoba (PHIA).** Information with respect to compliancy can be found on the Bannatyne Campus Research Ethics Board website - "Requirement of PHIA compliancy for Databases".

## POTENTIAL CONFLICT OF INTEREST:

**37.0 Do any of the study personnel or immediate family members have any affiliation with, or financial involvement in any organization or entity with a direct or indirect interest in the participant matter or materials of this research?** ☐ **Yes** ☐ **No**

**If yes, please describe:**

## SIGNATURES:

**Signature of Principal Investigator attesting that:**

a) all investigators/co-investigators have reviewed the research as outlined in this application and are in agreement with the application submitted;
b) all investigator/co-investigators have read the Tri-Council Policy Statement and the University of Manitoba Policy 1406 and agree to abide by the guidelines therein;
c) I and all study personnel will adhere to the **application** as approved by **a** Bannatyne Campus Research Ethics Boards (REB);
**d) I and all study personnel have signed a pledge of confidentiality with the institution(s) from which we are collecting data**
e) **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 except for authorized oversight of the study**;
f) **information will be kept in a location that is physically secure and to which access is given only to the individuals(s) listed on this form**
**g) all direct identifiers will be segregated/stripped from clinical data; a unique study identifier (i.e. a randomly generated or meaningless ID number ) will be assigned to each patient/participant record; the Master list linking the ID with identifiable material will be stored in a separate compute file and /or physical location; and the Master list will be locked and password protected:**
h) as the principal investigator I will be responsible for notifying the REB of any changes made to the application as per Bannatyne Campus REB guidelines;
i) the study will not commence until I have received the final certificate of approval from the REB;
j) the study will not commence until the appropriate institutional approval (i.e. local hospital approval or local ethics approval) has been obtained;
k) I will submit a request for annual approval to the REB prior to the expiry date indicated on the approval certificate;
l) I will submit a final study status report to the REB when all study activity is completed at the local site;
m) if I am a University researcher, I hereby consent that the REB may provide written notice of their approval of this protocol to the institution in which the research will be conducted;
n) if I am a WRHA Researcher, I hereby consent that the REB may provide written notice of their review of this protocol to the WRHA and any WRHA facility in which the study will be conducted. The written notice may include my name, whether the protocol was approved or rejected, the reasons for any rejection and any conditions placed on approval.
**o)** I understand that the **$2,500 fee assessed for REB review on applicable protocols (for profit private funder) is NOT dependent on approval and must be paid in a timely manner**. The review fee applies even if the submission is withdrawn or not approved by the Research Ethics Board. **I have made the sponsor aware of this policy.**

**Printed Name of Principal Investigator:**

**Signature of Principal Investigator:** _____ **Date:** _____

**Required Signature for Student Projects:**

**Printed Name of Supervisor:**

**Signature of Supervisor:** _____ **Date:**_____

**Required Department Head or Delegate Signature for all Projects:**

**If you are having difficulties obtaining the department head signature prior to the submission deadline, please provide explanation in a cover letter to the board indicating when these signatures will be obtained. The department head signature/delegate is required prior to releasing the certificate of final approval.**

**Signature of Department Head or Delegate attesting that:**

I have reviewed this research protocol and confirm that there is sufficient scientific merit to warrant this submission.

**Printed Name of Department Head or Delegate:**

***(The department head or delegate signature cannot be involved in the trial as the Principal, Co-Principal Investigator or study coordinator.)***

**Signature of Department Head or Delegate:** _____ **Date:**_____

**Want to conduct a spell check?**

**The form is locked which enables you to tab to each question and check box with ease. To conduct a spell check you must first unprotect the document. After you have completed answering all questions, go to "*Tools*" on the tool bar and in the drop down menu select "*Unprotect Document".* No password is required. *If working with Word 2007, go to "Review" tab, click on "Protect Document", click on "Restrict Formatting and Editing" and then click on "Stop Protection".* No password is required.**

**DO NOT DELETE QUESTIONS on this form or THE SUBMISSION WILL BE RETURNED to the applicant.**