REB FILE NUMBER:	(office use)

Toronto Academic Health Sciences Network (TAHSN)
Application to Access Retrospective Data for Research Purposes

(This Application may also be used for research involving non-identifiable human biological materials OR research involving secondary use of identifiable human biological materials where the researcher satisfies all the requirements in Article 12.3 of the TCPS.)

INSTRUCTIONS

- **All sections** of this application **MUST** be completed before it will be considered for REB review.
- A complete application must be submitted to **each site** where this research will take place.
- A separate detailed protocol must be included with each application.
- All research must be compliant with:
  - The Tri-Council Policy Statement, available at **http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf**
  - The Ontario Personal Health Information Protection Act (2004), available at **http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm**
  - Principles for Development of Policy & Guidelines on Security of Personal Health Information used for Research Purposes **http://www.research.utoronto.ca/wp-content/uploads/2009/03/TAHSN_PHI.pdf**
  - Any other relevant regulations or guidelines.
- TAHSN Research Ethics Boards may request and share information related to the review, approval and continuing ethics review of research conducted at other sites.

SECTION I: GENERAL INFORMATION

1. PRINCIPAL INVESTIGATOR (PI) NAME

If your institution requires the PI to be a staff member, the on-staff investigator accepts the role and responsibilities of PI at this institution.

Title:	Last Name:	First Name:
Credentials (MD, PhD, etc):		

2. FULL STUDY TITLE

Sponsor Protocol Number (if applicable):

2A. Is this protocol directly related to a previously approved study at this institution (e.g., extension, rollover, subsequent to a pilot study)? ☐ Yes ☐ No

If **YES**, specify:

Name of Principal Investigator:
REB file number:

3. INVESTIGATORS

3A. Principal Investigator Contact Information and Signature

PRINCIPAL INVESTIGATOR AGREEMENT – I assume full responsibility for the scientific and ethical conduct of the study as described in this application and submitted protocol and agree to conduct this study in compliance with the current edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects, Personal Health Information Protection Act and any other relevant laws, regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will

only use or disclose the information as set out in this application and submitted protocol, the conditions of the REB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information custodian who supplies the information. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project.

Dept/Div:	Program:		Institution:	
Telephone:	Pager:		Fax:	
Street Address:				Room/Suite #:
City:	Province:	Postal Code:	Email:	
Signature of Principal Investigator		Date		

3B. Co-Investigator(s) Contact Information and Signature

CO-INVESTIGATOR AGREEMENT – I agree to participate in this study as described in this application and submitted protocol and agree to conduct this study in compliance with the current edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects, Personal Health Information Protection Act and any other relevant laws, regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will only use or disclose the information as set out in the application and submitted protocol, the conditions of the REB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information custodian who supplies the information. I will notify the Principal Investigator immediately if there is any deviation from the protocol or other adverse event.

If one or more co-investigators is a student participating as part of an academic training program, 3C must be completed.

1	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
2	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
3	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
4	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	

5	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	

3C. Faculty Supervisor (for student/fellow/resident research studies) ☐ Not Applicable.
NOTE: If this research is part of an academic (University) **training program**, please provide the following information.

☐ Post-Doctoral ☐ PhD ☐Masters ☐Undergraduate ☐Resident/Clinical Fellow

Name(s) of Student(s):			
Name of Supervisor:			
Dept/Div:	Program:	Institution:	
Telephone:	Pager:	Fax:	
Street Address:			Room/Suite #:
City:	Province:	Postal Code:	Email:

4. STUDY COORDINATOR/CONTACT PERSON FOR THIS APPLICATION IF NOT THE PRINCIPAL INVESTIGATOR (e.g. study coordinator, research administrative contact, research student, institutional liaison).

☐ Not Applicable

Title:	Last Name:		First Name:
Dept/Div:	Program:		Institution:
Telephone:	Pager:		Fax:
Street Address:			Room/Suite #:
City:	Province:	Postal Code:	Email:

Indicate to whom correspondence should be sent: ☐ Principal Investigator ☐ Study Coordinator/Contact Person

5. DEPARTMENT/DIVISION/PROGRAM HEAD APPROVAL (refer to your institutional guidelines). For institutions that require the PI to be a staff member, approval must come from the Department / Division / Program Head of the same institution as the PI.

Department/Division/Program Head Approval - I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I attest that the Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study". **This section can not be signed by the Principal Investigator or a Co-Investigator.** An alternative approval signature is required.

Title:	Last Name:	First Name:
Signature of Dept/Div/Program Head	Date	

SECTION II: STUDY SUMMARY AND ETHICAL ISSUES

(The full protocol must still be attached)

6. Provide a study summary and rationale (suitable for a public access or lay audience).

(Max ¼ page)

7. What is the primary objective and hypothesis?

(Max ¼ page)

8. List the inclusion and exclusion criteria.

(Max ¼ page)

9. Briefly explain what methods will be used to analyze study data.

References to protocol for this question are acceptable. Indicate applicable page(s) of protocol.

(Max ¼ page)

10A. Which of the following will this study involve?

☐ **Retrospective data**

☐ **Human biological materials (specify):** *(Defined in TCPS as: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.)*

- ☐ **Secondary use of identifiable human biological materials** (human biological materials originally collected for a purpose other than the current research purpose)
- ☐ **Non-identifiable human biological materials**

10B. To apply for access to retrospective data or human biological materials, an alteration or permission to do research without consent must be granted by the REB. Explain how your request for an alteration of consent will comply with TCPS2 Chapter 3, TCPS2 Articles 5.5 and/or 12.3 (human biological materials) and PHIPA 44, 3c, 3d.
(http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf)
(http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm)

(Max ¼ page)

10Ci. What tools will be used to access the retrospective data or human biological materials?

☐ Health record/clinical chart (specify source(s)):
- ○ Number of charts in total (across all participating sites):
- ○ Number of charts at this site:

☐ Existing database (specify source(s)):
- ○ Does the Principal Investigator maintain the database? ☐ Yes ☐ No
- ○ If **NO**, identify the entity that maintains the database:
  - ○ Has access/use for research purposes been granted? ☐ Yes ☐ No ☐ Yes pending REB approval

NOTE The creation and maintenance of a database for research purposes is a research activity that may require a separate REB application. Consult your institutional REB.

☐ Human biological materials (specify source(s)):

☐ Other (specify source(s)):

10Cii. If multiple sources/databases will be used to access the retrospective data or human biological materials, will the data/materials be linked (i.e. to amass more data about particular individuals)?

☐ Yes ☐ No

If **YES**, explain what data/materials will be linked, how it will be linked and why the linkage is required.

(Max ¼ page)

10D. Date range of requested data or human biological materials e.g. 01/01/2000 to 31/07/2005 (in order to be considered a retrospective review, inclusive dates cannot go beyond the present).

Start Date:	End Date:

SECTION III: PRIVACY AND CONFIDENTIALITY

DEFINITIONS

(Source: Tri-Council Policy Statement, unless otherwise specified.)

Personal Health Information (PHI): In this Application, PHI has the meaning ascribed to it in the *Personal Health Information Protection Act, 2004* (PHIPA). With limited exceptions, PHI is defined as identifying information about an individual in oral or recorded form, if the information,
a) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,
b) relates to the providing of health care to the individual,
c) is a plan of service within the meaning of the *Long-Term Care Act, 1994* for the individual,
d) relates to payments or eligibility for health care in respect of the individual,
e) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,
f) is the individual's health number, or
g) identifies a provider of health care to the individual or a substitute decision-maker of the individual.

Identifiable Information: Information that may reasonably be expected to identify an individual, alone, or in combination with other available information. Also referred to as “personal information.”

Directly Identifying Information: The information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

Indirectly Identifying Information: The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).

Coded Information: Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual name so data can be re-linked if necessary).

Anonymized Information: The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

Anonymous Information: The information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Data Set: A collection of information to be used for research purposes, including human biological materials.

Key Code: A document that links the coded information with the identifying information of the individual. This must be stored separately from the data set.

COLLECTION, USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION AND DATA

11A. Identify all persons including non-institutional service providers that will have access to the personal health information now or in the future and their roles in the study (do not list the Principal Investigator and Co-Investigators already listed in the Application). Attach additional pages if required.

1	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
2	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
3	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
4	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
5	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:

11B. Has your research team completed training in privacy and confidentiality issues for this study?
☐ Yes ☐ No

If **NO**, when will training be provided?

(Max ¼ page)

11C. List the identifying information and personal health information that will be collected, used, or disclosed.
(**NOTE**: If any of the boxes below have been checked, each individual (i.e. patient) should be assigned a unique participant ID # to be included with the data set and a key code created to link the ID# with the information below.)

☐ Name	☐ Images (e.g., photographic, x-ray, MRI scans)
☐ Address/postal code	☐ Social Insurance Number
☐ Telephone/Fax Numbers	☐ Medical Record Number
☐ Email Address/IP Address/URLs	☐ Date of Birth
☐ Health Card Number	☐ Dates related to unique/rare disease/treatment
☐ Other information (specify):	

11D. List ALL data elements required for collection and/or attach a copy of the data collection form.
(**NOTE**: The data collection form or list of data elements should NOT include any of the identifying information checked off in 11C above.)

(Max ¼ page)

11E. Indicate how study participants will be identified on data collection forms.

☐ Participant Identification #
☐ Other (specify): If using other, please justify:

12A. Indicate how data will be stored.

☐ Computerized files (specify below) ☐ Server ☐Portal ☐Laptop with encrypted hard drive Server (specify): ☐ Internal ☐Contracted Service Provider: ☐Other: ☐Third Party:
☐ Hard copy

☐ Audio recordings
☐ Video recordings
☐ Encrypted USB key or similar portable storage device (must be encrypted)
☐ PDA, E-reader or similar hand-held computer
☐ Other:

12B. Indicate where the data will be stored.

☐ On-site ☐ Off-site; specify location(s) including institution name, city and country: If off-site, will a back-up copy be stored on site? ☐ Yes ☐ No If **NO** justify:

12C. Indicate which of the measures will be undertaken to protect the confidentiality and security of the data, including any physical and technical safeguards.

☐ Access to records and data limited to authorized persons
☐ Study data will be **de-identified or coded.** A master linking log with identifiers will be kept and stored separately from the data
☐ Study data will be **anonymized.** All identifiers will be removed once the data has been: ☐collected ☐verified ☐analyzed
☐ Study data will be **anonymous.** Identifiers/identifying information will not be collected
☐ Other:

12D. Indicate if any information that could potentially identify participants will be disclosed outside of the custody of the Health Information Custodian (Hospital or responsible institution) (e.g., names, initials, DOB, OHIP #)**.**
☐ Yes ☐ No

If **YES**, to whom? (**NOTE:** A contract/agreement may be required, see Funding, Conflicts and Agreements section and contact your institutional department responsible for facilitating contracts/agreements.)

(Max ¼ page)

12E. Indicate how long the personal health information will remain identifiable and explain why.

(Max ¼ page)

12F. Explain why the research cannot reasonably be accomplished without using personal health information.

(Max ¼ page)

12G. Describe any harms that could arise if personal health information was inappropriately released (e.g., embarrassment, refusal of employment or insurance coverage, stigmatization of individuals / groups, loss of reputation for the responsible organization) and how any consequences would be addressed.

(Max ¼ page)

12H. Indicate how long data will be retained after completion of the study and prior to confidentially destroying the data.

(Max ¼ page)

12I. Indicate who will have access to the data in the future.

(Max ¼ page)

12J. Will the data be reported publicly (e.g. publication)? ☐ Yes ☐ No

If **YES**, provide further details.

(Max ¼ page)

12K. Will the data be used (now or in the future) for commercial purposes? ☐ Yes ☐ No

If **YES**, provide further details.

(Max ¼ page)

SECTION IV: FUNDING, CONFLICTS AND AGREEMENTS

13. Is this a multi-centre study? ☐ Yes ☐ No

If **YES**, identify the coordinating/lead site.

(Max ¼ page)

14A. Does this study require funding?
☐ Yes ☐ No

If **NO**, explain why (and then go to question 15)

(Max ¼ page)

14B. How will this study be funded?

☐ Grant	Source:
☐ Industry (attach budget)	Source:
☐ Internal	Source:

14C. Is this study receiving U.S. federal funds?
☐ Yes ☐ No

15. MANAGING CONFLICTS OF INTEREST

Conflicts of Interest do not imply wrong-doing.

It is the responsibility of the PI to determine if **any of the conflicts** listed below apply to **any persons** involved in the research study or any member of their immediate family. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflict of interest may also arise with regard to the disclosure of personal health information.

☐ **Not applicable.** There are no Conflicts of Interest to disclose.

Describe and detail any Conflicts of Interest and how they will be managed.

(Max ¼ page)

16. CONTRACTS AND AGREEMENTS

"Institutions and REBs should require the satisfactory amendment or removal of any confidentiality clauses or publication restrictions that unduly limit either the content of the scientific information that may be disseminated or the timing of dissemination. Contract should also ensure that principal investigators have the necessary access to original trial data, and the opportunity to analyze them, to ensure that they can report trial findings fairly and accurately, particularly with respect to both efficacy and safety." (TCPS 2, 11E)

REBs also legitimately seek assurances that other contractual rights and obligations are consistent with the statements in the protocol. This is why the REB requests information regarding agreements related to transfers of personal information and biological material (for privacy issues), liability (to ensure that participant reimbursement is appropriately available) and publication. Review by the institution ensures that certain institutional policies are met.

16A. Contract/Research Agreement

Is there any party external to the institution involved with the research that will be entering into an agreement or contract with the institution? (**NOTE:** If any money, data or material (biological or otherwise) is being transferred outside of or between institutions/parties, a contract/agreement may be required. Contact the department responsible for contracts/agreements at your institution.) ☐ Yes ☐ No

If **YES**, provide names and roles of those involved (i.e. Regulatory Sponsor, contract research organization, funder, collaboration institution, vendor or researcher).

(Max ¼ page)