Fleming College

This form is for researchers who are planning to conduct research at Fleming College only.

Application to Involve Human Participants in Research

SECTION A – GENERAL INFORMATION

1. Title of the Research Project: Data Sharing in Academic Collaborations

2. Investigator Information

	Name & position	Dept./Address	Phone No.	E-Mail
Principal Investigator (PI) *:	Brian Baumal Principal	Thinklounge Research	416-945-9557	bb@thinklounge.ca
Faculty: Co-Investigator(s)	Paula Green	York/Seneca Partnership	416-736-2100 x 77666	pgreen@yorku.ca
Student: Investigator(s)				
Other: Investigator(s)				

* **The advisor must be listed as PI for any student investigators. Student investigators are faculty /staff who are completing research for educational purposes.**

3. **Proposed Date** a) of commencement:October 1, 2017 b) of completion:April, 2018

Note: **The commencement date should be the date the principal investigator (PI) expects to actually begin interacting with human participants (including recruitment). The completion date should be the date that the PI expects that interaction with human participants, including any feedback or follow-up, will be complete.**

4. **Indicate the location(s) where the research will be conducted:**

In person meetings and focus groups at York University (though participants can participate through audio/video conference and telephone calls where a participant can take the call anywhere.

5. **Other Research Ethics Board Approval**

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a) Has any other institutional Ethics Board approved this project? ☒ **Yes** ☐ No ☐ N/A

i. If **Yes**, please provide the following information:

Title of the project approved elsewhere: Same title as above
Name of the Other Institution: York University, Seneca College, Durham College, UOIT, and Trent University have all approved the study
Name of the Other Ethics Board:
Date of the Decision: Ranging between November 2017 and January 2018
A contact name and phone number for the other Board: Jennifer Sullivan (Seneca College), 416.491.5050 ext. 2402; Alison Collins Mkaris, York University (416) 736-5914)
OR
A copy of the clearance certificate/approval **AND**
final copies of all supporting documentation already approved

6. **Project Funding**

a) Is this project currently funded? ☒ **Yes** ☐ No ☐ N/A

i. If **YES,** please indicate:

Period of Funding: From September 2017 To: April 2017
Agency or Sponsor (funded or applied for)
☐ CIHR:
☐ NSERC:
☐ SSHRC:

Other: ONCAT

Note: If the funding source changes, or if a previously unfunded project receives funding, you must submit a change/amendment form to each Research Ethics Board that has approved your project.

8. **Conflict of Interest**

a) Will the researcher(s), members of the research team, and/or their partners or immediate family members:

i. Receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options etc.) as a result of or connected to this study?

☐ Yes ☒ **No** ☐ N/A

ii. If **YES**, please describe the personal benefits below. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are integral to the general conduct of research.)

If **yes**, please explain.

b) Are there any real, perceived or potential conflicts of interest of which you are aware (for example, researchers who will benefit financially from the research, research which may be in conflict with institutional roles and responsibilities, faculty members who may be responsible for awarding participant grades)? ☐ **Yes** ☒ No ☐ N/A

Brian Baumal is an independent researcher and is being remunerated for his work on this study. He will not financially benefit from the results of the research one way or another

c) Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that the sponsor or institution has placed on the investigator(s)? ☐ Yes ☒ **No** ☐ N/A

All primary research such as transcripts, recordings and notes will remain confidential. The report produced by the research will not include identifiable information. The report will be released on ONCAT's website.

d) Is there the possibility of commercialization of the research findings? ☐ Yes ☒ **No** ☐ N/A

If **yes**, please explain.

SECTION B – SUMMARY OF THE PROPOSED RESEARCH

9. **Rationale**

a) Describe the purpose and background rationale for the proposed project, as well as the hypothesis(es)/research question(s) to be examined.

ONCAT was established in 2011, to "enhance student pathways and reduce barriers for students looking to transfer among Ontario's 45 public postsecondary institutions."This study will examine how institutions transfer and share student level data with each other for research/planning purposes, and when students transfer from one institute to another. At present, there are no frameworks, or guidelines, regarding this transfer of data, and the **benefit** to you and the broader post-secondary community of your participation in this research is to create set of standards and an MOU between institutions who share data to make transfer easier and more effective for the institutions and students themselves.

10. **Methodology**

a) Describe sequentially, and in detail, all procedures in which the research participants will be involved (e.g., paper and pencil tasks, interviews, surveys, questionnaires, physical assessments, physiological tests, time requirements etc.)

Note: Attach a copy of all questionnaire(s), interview guides or other test instruments. Check with the individual REB re letterhead requirements if they are intended for public dispersal.

Secondary research – literature review of publicly available research and information on the topic.

One-on one interviews with up to 40 individuals at post secondary institutions representing a number of functions – academic, administration, registrar, privacy/legal, IT. Attached are invitations and question guides to be used.

Focus groups – two focus groups with the above segments that will provide input into draft MOU's data sharing templates and a data sharing framework. The focus group introduction and permission form has been provided, but the guide itself has yet to be developed, pending the completion of the above one-on-one interviews.

b) Does the nature of the research create vulnerability for any of the groups listed below? ☐ Yes ☒ **No** ☐ N/A

i. If **YES**, check all that apply:

☐ People with relevant health issues
☐ People in medical emergencies
☐ Aboriginal people
☐ People in long-term care
☐ People with mental-health issues
☐ Children
☐ Elderly people
☐ People in poverty
☐ People in prison
☐ People who are unable to consent

☐ Other

If **OTHER**, please specify:

i. If **YES in 10b) above**, please explain your screening process (maximum 5 lines):

Please explain your screening process:

Note: **Researchers must destroy all information collected during screening in a secure manner as soon as screening is complete.**

Please explain how you will destroy your screening data securely:

11. **Recruitment**

a) How do you plan to recruit participants (please check all that apply):

☐ Investigators will approach their own students/patients
☒ **Investigators will receive referrals from other faculty**
☐ Indirect advertising (e.g. poster, e-mail, web-based).
☐ Database of people who consented to future contact.
☐ Direct approach (e.g. random digit dialing, blogs and chat room)
☐ Educational records (e.g. academic performance information, Student Information System)
☐ Other

If **OTHER**, please specify:

b) Do you screen personal health information to identify potential participants? ☐ Yes ☒ **No** ☐ N/A

c) Does your recruitment plan require you to contact potential participants by:

a) Telephone ☐ Yes ☐ No ☐ N/A
e) Personal E-mail ☒ **Yes** ☐ No ☐ N/A
f) Anonymous Email ☐ Yes ☐ No ☐ N/A
g) Letter ☐ Yes ☐ No ☐ N/A

Note: **If you answered YES to any category above, please attach a copy of all telephone scripts and recruitment correspondence.**

12. **Informed Consent**

a) Will you be seeking *written* consent from participants? ☒ **Yes** ☐ No ☐ N/A

i. If **YES**, please attach a copy of the Information Letter and Consent form for Participants.

Note:

- **Participants should *actively* choose whether or not to participate. A lack of response (i.e. a statement such as "you will be assumed to want to participate unless you indicate otherwise to the researchers") should not be construed to imply consent.**
- **Written consent is not required in all circumstances. For example, you could require participants to click a box in an online survey or provide verbal consent.**

b) If consent will not be written, please provide details of how you will obtain consent in the box below.

Focus group consent will be written. Telephone interview consent will be verbal after participants have heard about the research from email invitations and during the introduction of the interview phone call

c) Will any participants be minors (i.e. age 0-15)? ☐ Yes ☒ **No** ☐ N/A
d) Will all participants be competent to consent? ☒ **Yes** ☐ No ☐ N/A
e) If the participants are minors, or are not competent to consent, describe the proposed alternate source of consent. Please include any permission/information letter to be provided to the person(s) providing the alternate consent.

Please explain.

f) Who will obtain consent to participate for minors or those not competent to consent?

Please explain:

g) When and where will this be done?

Please explain:

h) Do you need to request a waiver of consent? ☐ Yes ☐ No ☒ N/A

i. If **YES**, please explain:

Please explain:

i) Will any of the investigators have a position of power or authority

over the participants? ☐ Yes ☒ **No** ☐ N/A

i. If **YES**, how will you manage and minimize any undue influence?

Please explain:

j) Will continuing consent (for example, research which may continue beyond an academic year) be required during the study? ☐ Yes ☒ **No** ☐ N/A

i. If **YES**:

Please explain:

k) Will participants have the option to withdraw from this study? ☒ **Yes** ☐ No ☐ N/A

i. If **YES**, what do they have to do to withdraw?

Please explain: Participants can withdraw their consent at any time and participation in the process immediately stops.

l) Indicate what will be done with the participant's data and any consequences for the participant withdrawing from the study.

Please explain:
If a participant withdraws from the study their data is destroyed and not included and there is no consequence for not withdrawing.

m) If the participants will not have the right to withdraw from the project, please explain the rationale:

Please explain:

n) Will you be using deception in your research? ☐ Yes ☒ **No** ☐ N/A

i. If **YES**:

Please explain.

13. **Collection of Personal Information**

a) Please check all types of data which you intend to collect:

☐ **Identifying information which identifies a participant through direct identifiers (e.g. full name, medical record number)**

☐ Identifiable information which could identify a participant through a combination of indirect identifiers (e.g. DOB plus address)

☐ De-identified/coded information in which identifiers are removed and replaced with a code; the code can be used to re-identify participants

☐ Anonymized information in which all identifiers are removed and no code is kept

☐ Anonymous information in which no identifiers are collected

b) Will all data be treated as confidential? ☒ **Yes** ☐ No ☐ N/A

i. If **NO**:

Please explain.

c) Will you collect any Personal Health Information (PHI)?

☐ Yes ☒ **No** ☐ N/A

Note:

- **The collection, use and disclosure of Personal Health Information (PHI) are regulated by the Personal Health Information Protection Act (PHIPA). Researchers must comply with this legislation**
- **Collection of participant SIN (social insurance number) is prohibited, unless payments to participant exceed $500/year (required for tax purposes)**
- **PHI should be collected at the lowest level of identifiability possible (e.g. initials instead of a name, age instead of DOB)**

Please detail the specific identifiers required for this study:

Identifier (check all which apply)	Why is this necessary?
☐ **Full name**	Researchers have to know how to address participants by name
☐ Initials	
☐ Student/Employee number	
☐ Social Insurance Number	
☐ Health card number	
☐ Medical record number	
☐ Address	
☐ Full postal code	
☐ Partial postal code	
☒ **Telephone number**	This will be one of the primary contact methods for participants
☒ **Email**	This will be one of the primary contact methods for participants
☐ Physician	
☐ Date of birth	
☐ Age	
☐ Other: (Specify)	

d) How will you record study data?

☐ Case report form.
☐ Other:

Please specify:

14. **Storage and Protection of Information**

Note: PHIPA Requirements

- **Paper files with identifiable information must be kept in a locked cabinet within a locked office (but not at home)**

- **Electronic files with identifiable information may be stored on a password-protected computer on a secure network (i.e. Virus protection, file backup, firewall) or they must be encrypted.**
- **Electronic files with identifiable information may be stored on mobile devices (e.g. laptop, CD, USB, PDA), but no alternative method of storage; these files must be encrypted.**
- **Identifying and/or identifiable PHI cannot be transmitted by email unless it is encrypted**

Note: Coding

- **Identifying and/or identifiable PHI should be protected by a coding system**
- **The code (study ID and identifiable PHI) must be isolated from study data and stored in a secure manner**

a) Will you use a coding system to protect identifiable information? ☒ **Yes** ☐ No ☐ N/A

i. If **NO**:

Please explain.

b) How will you store and protect the study code (or other data with identifiers)?

Type of record	Required protection	Location (i.e. building, room)
	☐ Locked cabinet in locked institutional office	
Recordings and notes	☒ **Password protected computer on a secure network**	Home office
	☐ Encrypted (specify software used):	
	☐ Identifiers and participant data are stored separately	

c) How will you store and protect data without identifiers?

Please explain.

d) Do you plan to anonymize the study data? ☒ **Yes** ☐ No ☐ N/A

i. If **YES**, when?

No individual or source will be identified either directly or indirectly.

Note: You are required to destroy identifiers or links at the earliest possible time.

e) How long will you keep the study data?

Note: If this study requires Health Canada approval, records must be retained for 25 years. For all other studies, the REB recommends 7 years. Sponsors and institutions may set out other requirements.

f) Do you plan on physically moving the data? ☐ Yes ☒ **No** ☐ N/A

i. If **YES**, how will the data be secured while in motion?

Please explain.

g) What will you do with the study data after this period?

Note: Use of data for purposes other than those for which the data was originally collected is considered to be secondary use of data and requires participant's permission.

All data will be destroyed and only used for the purpose it was collected and is for one time use for this study only.

15. **Transmission of Data**

a) Will the research data be moved outside its original location of collection (for example, sent for transcription or uploaded to a central data repository? ☐ Yes ☒ **No** ☐ N/A

b) If **YES**, does this data to be transmitted include identifiers? ☐ Yes ☐ No ☐ N/A

i. If **YES**, please provide details on the data transfer agreement:

Please explain.

ii. If **YES**, where will the data be sent?

Please explain.

Note: Data sent to the United States, or uploaded to American servers (e.g. Survey Monkey), is open to access by American regulatory bodies. Researchers must inform study participants of this possibility.

c) Please list the names and affiliations of persons outside of your research team who will have access to the identifiable data.

Note: If you require outside sources to have access to participant data, you need to ensure that mechanisms are in place to ensure data security, confidentiality and anonymity.

Name	Institutional Affiliation
N/A	N/A

d) How will the data be transmitted?

☐ Fax

☐ Email **(Note: Encryption protocol must be attached)**

☐ Private Courier **(Note: Delivery must be traceable)**

☐ Canada Xpresspost **(Note: Regular mail may not be used)**

☐ Other:

Please explain.

16. **Secondary Use of Data**

a) Will you combine your research data with any other data sets? ☐ Yes ☒ **No** ☐ N/A

i. If **YES**, please specify:

Identify the dataset:
Explain how the linkage will occur:
Provide a list of data items contained in the dataset:

b) Will your data be entered into another database for future use? ☐ Yes ☒ **No** ☐ N/A

i. If **YES**, please specify:

Where it will be stored?
Who will be the custodian?
Who will have access to the database?
What security measures will be in place?

Note: Any secondary use of data must be approved by the REB prior to its use.

17. **Experience**

a) What is your experience with this kind of research?

I have conducted hundreds of qualitative and quantitative opinion research studies for over 25 years. I am a member of MRIA and helped establish ethical and privacy guidelines for collection of qualitative research data in Canada for the industry.

Note: It is strongly recommended that researchers complete the free online TCPS training, available at: http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

18. **Compensation**

a) Will participants receive compensation for participation?

i. Financial ☐ Yes ☒ **No** ☐ N/A

ii. Non-financial ☐ Yes ☒ **No** ☐ N/A

b) If **Yes** to **either** i) or ii) above, please provide details.

Please explain.

c) If participants choose to withdraw, how will you deal with compensation?

Please explain.

SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

19. **Possible Risks to Participants**

a) Indicate if the participants might experience any of the following risks:

	Yes	No	N/A
i) Physical risk (including any bodily contact or administration of any substance)?	☐	x	☒

ii) Psychological risks (including feeling demeaned, embarrassed worried or upset)? ☐ x ☒

iii) Social risks (including possible loss of status, privacy and/or reputation)? ☐ x ☒

iv) Economic risks (including incurring expenses, loss of incentive)? ☐ x ☒

v) Academic risks (including loss of bonus marks or course standing)? ☐ x ☒

vi) Potential access to personal data ☐ x ☒

vii) Are any possible risks to participants greater than those the participants might encounter in their everyday life? ☐ x ☒

b) If you answered **YES** to any of Points i) through vii) above, please explain the risk.

Please explain.

c) Please comment on the magnitude of harm participants are likely to encounter i.e. would you assess it as minimal, substantial, transient or longer lasting? **MINIMAL RISK**

d) Please comment on the probability that participants will encounter harm, i.e. would you assess it as low, medium or high?

Very low risk of harm. Participants are travelling to and from a focus group, so any harm incumbent in travel is possible. Otherwise participants will participate from a phone in a location of their choosing, typically an office or a cell phone.

e) Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used).

Participants have the option of participating in the focus groups by phone or skype/videoconference

20. **Possible Risks to Researchers**

No risks to researchers anticipated

21. **Possible Benefits to Participants**

a) Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific community/society that would justify involvement of participants in this study.

Participants may be exposed to data sharing strategies and techniques with which they are not aware.

SECTION D – PARTICIPANT FEEDBACK

a) Explain what feedback/ information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, or access to the results of the research). Indicate when results will be available and, if they will be made available on the internet, the URL to be used to access the results:

Note: Feedback should be provided in a way which is accessible to participants. For example, some participants may not have access to a computer so uploading results to a website may not be sufficient.

The final report of the research will be available on the ONCAT website for public viewing, about three to six months after conclusion of the focus groups.

SECTION E – MONITORING ONGOING RESEARCH

22. **Annual Review and Adverse Events**

a) Protocol review requires the completion of a "Renewal/Completed Status Report" at least annually. Indicate whether any additional monitoring or review would be appropriate for this project.

Note: It is the principal investigator's responsibility to notify the REB the project is completed, or if it is cancelled, using the appropriate form.

No

b) **Adverse events** (i.e. unanticipated negative consequences or results affecting participants) must be reported to the Research Ethics Board and the Research Ethics Coordinator as soon as possible using the form available on this website.

23. **Additional Information**

Researcher has conducted a dozen qualitative studies for pharmaceutical companies and is aware of adverse event reporting protocol.

SECTION F – SIGNATURES

Principal Investigator (PI) Assurance:

I, Brian Baumal have the ultimate responsibility for the conduct of the study described in this application including my responsibilities as an advisor to any students involved in this project. I have read and am responsible for the content of this application. The information provided is complete and accurate. I understand that, as Principal Investigator, I will be the primary link with the REB, other researchers involved with this project, and the research participants. I agree to conduct the research in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, this individual college's policies and procedures for ethical Conduct of Research, and the conditions of approval indicated by the _____Research Ethics Board.

I also understand that if I make any changes whatsoever to the sample documents provided with this application (including, but not limited to, the recruitment scripts, information and consent letters, survey questions, interview or focus group questions), I need to complete a change request form and submit this to the REB for review. I further understand that these changes, if determined to be substantive by the REB, may require a new application if they constitute new research. If any changes are made in the above arrangements or procedures, or if adverse events are observed, I will bring these to the attention of the Research Ethics Coordinator immediately. I further understand that I may not start any research without receiving a Certificate/Letter of Ethical Acceptability. I further understand that ethical approval does not constitute institutional approval of this research.

I understand that if I fail to advise the REB of any changes or adverse events, or fail to comply with research protocols outlined in this application, or make any unauthorized changes to any document submitted with this application, the Certificate of Ethical Acceptability may be rescinded by the REB.

Name of Principal Investigator: Brian Baumal

Signature of Principal Investigator:

Date:

(2018-01-30)

Signature **Date**

Please submit this application together with all relevant attachments by email to research@flemingc.on.ca and the Office of Applied Research will contact you shortly after receipt to advise as to when the REB committee will review your application and next steps.