University of Regina Research Ethics Board (REB)

Summary for External Review

Overview

The University of Regina has a single Research Ethics Board which approves all research involving human participants that falls under the auspices of the institution. Applications are received from all Faculties and Departments. The REB is managed by the Research Compliance Officer and supported by a full time administrative position. Both of these staff members belong to the Research Office and report to the Director of the Research Office. The REB is overseen by the Associate Vice-President Research. The REB receives on average 250 new applications per year and maintains approximately 500 active applications through the annual renewal process.

REB Membership

The Research Ethics Board is presently composed of 26 members which varies slightly from year to year. In practice for the last several years, the appointment of members has been delegated to the Compliance Officer. Members are selected in a variety of ways including: university wide emails, calls to specific departments, personal requests and interested individuals coming forward. An attempt is made to include members from each of the Faculties and Departments in a ratio related to the number of applications received. Maintaining community members on the committee with no affiliation has been difficult, and historically, turnover has been very high. Presently the only community members are retired faculty who served on the board previously. We recognize that this does not adequately meet the intent of the community member role. In appointing members, TCPS2 article *6.4 Basic Research Ethics Board Membership Requirements* is followed. New members are provided an information package and assigned a mentor, a senior member of the REB. The first few applications are given to the mentor/mentee pair and they are encouraged to meet and discuss the application together. There is no compensation, or incentives given to members. A coffee gift card was previously given to the mentor/mentee pair to encourage meeting, however this is now against UofR policy.

Chair

The Chair is appointed following a call to the REB. If more than one individual is interested, the Chair is determined following election by REB members. The Chair is appointed to a 2 year term and receives two course releases per year. It is estimated that the chair spends approximately 8 hours per week on REB duties. Different models for the Chair have been attempted, including a two person co-chair model which was administratively burdensome. There is interest in having a Vice-Chair position both for backup and succession planning, however the details of this have not been determined. Additionally, there is interest in having an Indigenous advisor position to lead training initiatives and the review of applications with Indigenous research and/or participants.

Reciprocity

The Research Ethics Boards in the province of Saskatchewan have a policy of full reciprocity. REB approvals by the University of Saskatchewan, University of Regina, or Saskatchewan Health Authority, will be accepted by both of those other two institutions without the need for additional REB review, provided the protocol is identical in its content and activities. The Reciprocity Agreement is currently under renewal.

Process

There are 6 different applications submitted to the REB.

- Application for Behavioural Research Ethics Review (Appendix F)
- Application for Biomedical Research Ethics Review (Appendix G)
- Course-Based Research Project Application (Appendix H)
- Application for the Use of Non-Identified Human Biological Materials (Appendix I)
- Application to Access Existing Health Data for Research (Appendix J)
- Applications with approval obtained for another University REB

All applications are received centrally to a designated email account (Research.Ethics@uregina.ca). File processing and routing is done by the Administrative Assistant.

Minimal risk behavioural and biomedical applications are sent to the Compliance Officer for initial review and comments. If deemed complete, they are then sent to two members of the REB for review. If not complete applications are returned with comments to the applicant. Reviewers are usually selected based on a queue, however, occasionally specific individuals are assigned a file based on participant groups, methodology, or discipline. Once both reviews have been received, the Chair reviews the application, the comments of the compliance officer, the two reviewer's comments and compiles the Notice of Ethical Review (NER). The administrative assistant sends the NER to the applicant. The response to the NER is reviewed by the Chair, and either further comments are sent, or approval is granted.

Applications for the Use of Non-Identified Human Biological Materials follow the same process, but these are sent to only one reviewer, specifically from the Department of Biology with expertise in molecular biology.

Course Based Applications, and those with approvals from other universities are reviewed and approved by the Research Compliance Officer. Input is requested from the Chair regarding these applications on an as-needed basis.

Above minimal risk applications are reviewed at a meeting of the full REB. Normally these would be in person, however over the past year they have been conducted via zoom. Historically there have been difficulties with quorum at meetings, which has caused some delays. The number of above minimal risk applications is low, approximately 5 per year.

All REB files from 2017 forward are electronic. The REB Chair has access to the network drive housing the applications for the required years. Reviewers are sent the files they need via email.

Appendices

Questions to guide the review panel (Appendix A)
Research Ethics Board Summary Statistics (Appendix B)
Ethics – Research with Humans – Policy (Appendix C)
Research Ethics Board Terms of Reference (Draft of Proposed) (Appendix D)
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Application for Behavioural Research Ethics Review (Appendix F)
Application for Biomedical Research Ethics Review (Appendix G)
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Questions to Guide the Review Panel

Do you see any gaps between the TCPS 2 (https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html) and the University of Regina policy? Do you have any recommendations for changes to the policy, as it is currently under review?

The University of Regina has a tri-partite governance system, with a Board of Governors, Senate, and Council. From the governance web page (https://www.uregina.ca/president/governance/)

> The Board is responsible for the general oversight of the University, including the administrative and business affairs of the institution. As such, it sets non-academic institutional policies.
>
> [Senate] has academic decision-making powers that the faculty senate or council exercises at most universities. Its primary responsibility is to consider and decide on academic matters referred to it by Council, particularly concerning: student appeals; student discipline; granting of degrees (including honorary degrees), diplomas and certificates; establishment of faculties, schools, departments, chairs and courses of instruction or major changes therein (on academic grounds); establishment of advisory councils; admission requirements; academic standards for students; and applications for affiliation and federation.
>
> The Council makes recommendations to Senate on those areas for which Senate decisions are required (see above.) Council also determines the dates for the academic year and the timetable for examinations.

Given this structure, what reporting mechanism might you suggest to fulfill Article 6.2 of the TCPS2?

> The highest body within an institution shall: establish the REB or REBs; define an appropriate reporting relationship with the REBs; and ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties. REBs are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review.

Do you have any advice with respect to the proposed Terms of Reference?

The REB membership is quite large, in order to minimize the demand on individual members yet provide 2 reviews for the Chair's consideration on every minimal risk file. However, this means it is difficult to get quorum for meetings. We also struggle with having a review done by individuals most closely related to the discipline of the application vs an uneven distribution of files, as some departments such as Psychology draw more heavily on REB resources. What recommendations would you have regarding size and composition of the REB? What are best practices around succession planning?

Currently, the Research Office transfers the value of 2 course releases to the Dean of the Chair's faculty. The Chair negotiates workload with their Dean. No one on the REB receives any compensation. What best practices are you aware of regarding compensation and incentives for REB members?

Do you have any comments on our REB application and review procedures?

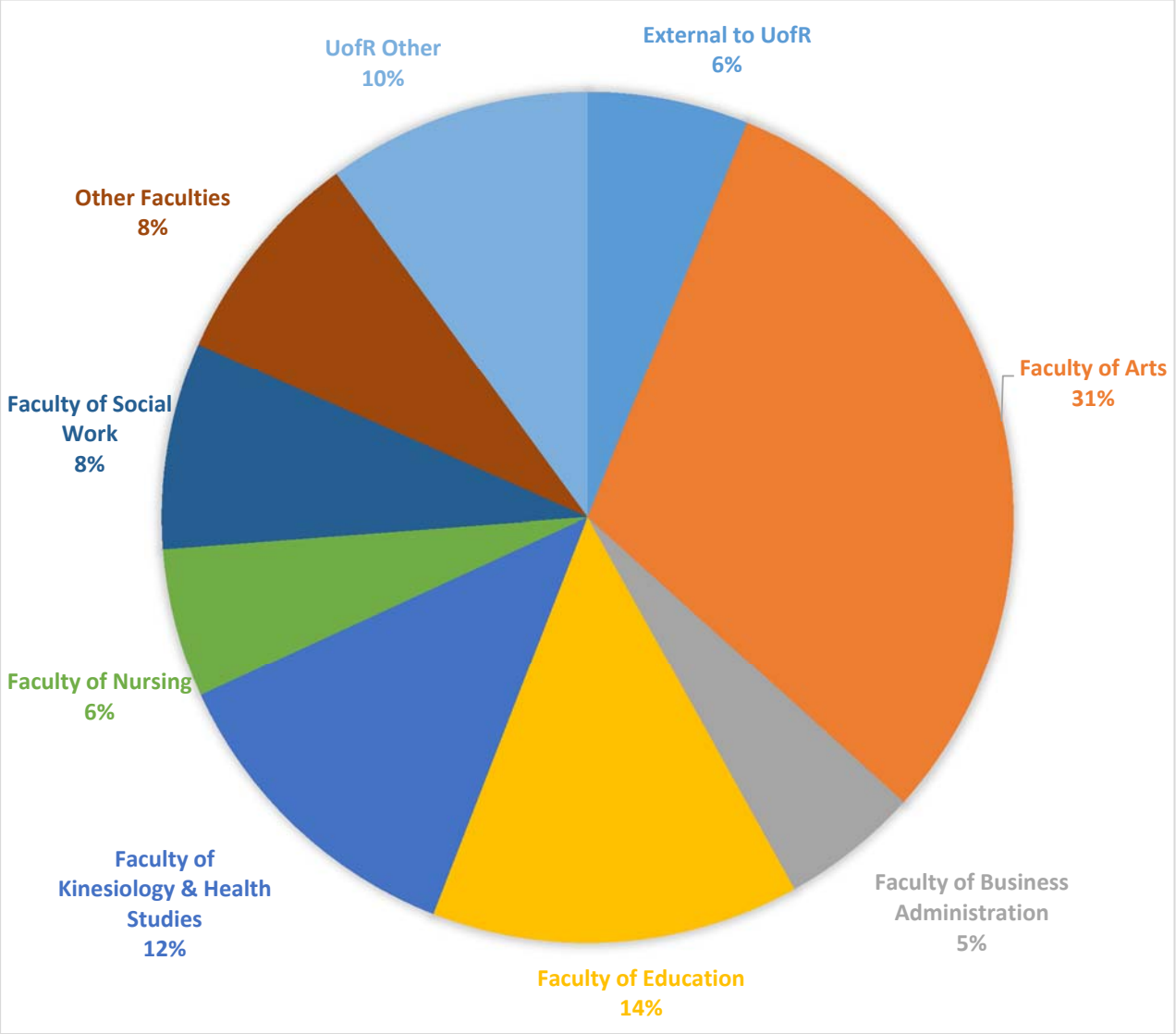
Finally, please comment on the challenges and opportunities faced by the REB as you understand them from your review and provide advice that would help us meet them.

Research Ethics Board Summary Statistics

Application Totals and Student Application Type by Year

Year	Total Applications	Above Minimum Risk	Faculty	Graduate	Undergraduate
2020	229	4	150	62	17
2019	224	3	132	80	12
2018	260	3	179	62	19
2017	229	4	162	56	11
2016	230	3	162	51	17

REB Applications by Area 2020



Reviewers
Upon recruitment, reviewers are advised they can expect 2-3 reviews per month on average.

The median number of reviews per reviewer in 2020 was **14.**
The most reviews per reviewer in 2020 was **21.**

Turnaround Times
NER – Notice of Ethical Review, the comments from the REB back to the applicant

Min Days to NER		Median Days to NER		Max Days to NER	
2019	2020	2019	2020	2019	2020
4	3	28	41	119	279

Min Days to Approval		Median Days to Approval		Max Days to Approval	
2019	2020	2019	2020	2019	2020
1	4	41	51	355	250

University of Regina

Research

Ethics – Research with Humans

Number:	RCH-020-010
Audience:	All members of the University's research community
Issued:	March 10, 2015
Last revised:	May 28, 2015
Owner:	Vice-President (Research)
Approved by:	Board of Governors
Contact:	Director, Research Office – 306-585-4775

Introduction

The University is committed to ensuring the highest standards of research ethics are understood and practiced in its community. This policy defines research ethics and research with humans and outlines the University's processes for maintaining ethics throughout research at the University of Regina.

When humans, human tissues or human data are used in the course of research or other comparable activities, it is the primary concern of the University that the rights of the participants are respected and protected and that the procedures followed comply with ethical, scientific, methodological, medical, and legal standards. The University values the academic freedom of its researchers, and the ethics review process shall not unfairly censor researchers who support unorthodox views. However, academic freedom is complemented by the requirement that the rights of human participants be respected.

The University of Regina follows the national standards articulated in the second edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. The guiding principles of this policy statement are:

- Respect for persons - This includes the recognition of the intrinsic value of human beings and respect for the autonomy of research participants. Respect for autonomy is normally reflected in the requirement to seek free and informed consent from participants both prior to and during their participation in a research project.
- Concern for welfare – This is broadly construed to mean all aspects of a person's life, including their physical and mental health, spiritual well-being, and other elements of their life circumstances. Concern for welfare includes respect for the person's privacy and confidentiality and requires that Research Ethics Boards (REB) and researchers adopt an attitude that aims to protect the welfare of research participants, minimize foreseeable risks to those participants and their communities, and inform research participants of those risks.
- Justice – This principle requires that people be treated equitably and fairly. The principle of justice takes into account the vulnerability of the person, the difference in power between participant and researcher, and seeks to equitably distribute the risks and benefits of research participation.

The University of Regina is party to the "Agreement on the Administration of Agency Grants and Awards by Research Institutions" which governs receipt of funds from Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council (NSERC), and Social Sciences and Humanities Research Council (SSHRC). Section 3.4 of this Agreement states that the University must comply with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, second edition (TCPS2),* and any amendments. In addition, research must comply with any further related agency requirements, such as CIHR's guidelines on research involving human stem cells.

Scope

This policy applies to all members of the University involved in research with human participants, human tissues or human data. Members of the University of Regina include but are not limited to, faculty, professors emeriti, sessional lecturers, staff, trainees, graduate and undergraduate students, adjunct professors, visiting professors, visiting scholars, professional affiliates, associate members, residents, and postdoctoral fellows at the University of Regina.

This policy also applies to research with human participants, tissues or data undertaken by any person or Institute/Centre associated with the University of Regina, or using any University of Regina resources inclusive of persons (i.e., students, staff, faculty), or if funds for such purposes be accepted or accounts established.

In particular,

a) All research that involves living human subjects requires review and approval by an REB in accordance with this Policy Statement, before the research is started except as stipulated below.
b) Research involving human remains, cadavers, tissues, cells, proteins, biological fluids, embryos or fetuses shall also be reviewed by the REB.
c) Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethical review. Such research only requires ethical review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols and to Article 2.3 of this Policy. (Article 2.3: REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking visibility).
d) Quality assurance studies, performance reviews or testing within normal educational requirements should not be subjects to REB review.

Definitions

- **Human Data** - information about an individual collected through or used in the research project such that the individual would be defined as a human participant.

- **Human participants or participants** - those individuals whose data, or responses to interventions, stimuli or questions by the researcher, are relevant to answering the research question.
- **REB** – Research Ethics Board
- **Research** - an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation (TCPS, Art 2.1).

Policy

Research Ethics

Consistent with the Tri-Council Policy Statement, the University of Regina has mandated the REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of the institution, using the considerations set forth in the Tri-Council Policy as the minimum standard. Such decisions will be based on ethical considerations.

The REB shall be constituted according to the current TCPS. In making its decisions, the REB will follow the specific guidelines laid out in Articles 2 through 13. Where issues raised in individual REB applications are not addressed specifically in the guidelines, the REB shall use the three core principles (Respect for Persons, Concern for Welfare and Justice) of the TCPS2 to assess the ethical considerations of the proposal.

The University of Regina has one REB. In the case of research undertaken by undergraduate students within a course, the REB has delegated this review to approved departmental or faculty level ethics review committees. Copies of all approved protocols must be forwarded to the REB. It is the responsibility of departments to ensure that the highest ethical standards are met. The REB shall maintain the right of monitoring such research. Undergraduate research that involves more than minimum risk to participants cannot be delegated for departmental review and requires REB approval.

The REB will take a proportionate approach to the review of proposals as outlined in Article 2.9. Research that is above minimal risk will be reviewed by the full REB. Research that is minimal risk will receive a delegated review as outlined in the REB terms of reference.

Research that poses minimal risk shall not normally require peer review for scholarly merit. For research that is above minimal risk, additional review shall not be required where there is an existing peer-review assessment (e.g., if the research was funded through a peer-review process). In cases where peer review is required, the Office for Research, Innovation and Partnership will co-ordinate a scholarly review of the research on behalf of the Research Ethics Board.

Initial approval is granted for one year, and can be renewed annually for a total of five years. In addition, the REB must review all substantive changes from approved research that affect participants at any stage of the process including, but not limited to, changes to the consent form, changes to the tasks or interventions involved in the research, or changes to measures to protect privacy and confidentiality. Any substantive change to the research

should not be implemented without documented approval by the REB, except when necessary to eliminate an immediate risk to the participants.

No research funds related to an REB proposal will be released until REB approval is obtained. If a project finishes or expires, funding will be frozen until the researcher either submits another proposal, reopens an existing project, or provides the Office of Research, Innovation and Partnerships with documentation certifying that all research with humans pertaining to the grant in question has been completed.

Review of Research in Other Jurisdictions

The REB at the University of Regina has the responsibility to ensure that all research conducted under its auspices, irrespective of the location where it takes place, follows the guidelines established by the current TCPS. Therefore, research approved elsewhere, through another REB or equivalent body, must also be reviewed by the REB at the University of Regina. The University has entered into a collaboration agreement with the University of Saskatchewan and the Regina Qu'Appelle Health Region that allows for a common application form and consent template.

Approval of a project by the REB is not a sufficient condition for a project to proceed. It is incumbent upon the researcher to determine whether there is a requirement for ethical approval by another body (e.g., a hospital REB). Researchers engaging in multi-center research are encouraged to review Chapter 8 of the Tri-council Policy document for a brief discussion of issues that may arise from the possibility that local REB's may reach different conclusions about aspects of the same project.

Non-Compliance

Failure to apply for and receive REB approval before conducting research with humans is one element of research misconduct. Breaches of the research ethics policy will be handled through provisions in the Research Integrity policy.

Allegations of Research Ethics Misconduct

An allegation of research ethics misconduct must be presented to the department head or dean of the person being accused of misconduct, a designate, or the Vice-President (Research). It must be in writing and signed.

The University will deal promptly (according to the Allegations and Processes sections of the Research Integrity policy) with all allegations of research misconduct.

Roles and Responsibilities

University

The University is responsible for providing the support and education required for all members of the University's research community to develop and maintain the highest standards of ethics, integrity, accountability, and responsibility.

University community

Members of the University community are responsible for reporting all instances of research ethics misconduct and for cooperating fully in an inquiry or investigation into an allegation of research ethics misconduct.

People in Supervisory Positions

People in supervisory positions at the University (including principle investigators) are responsible for ensuring everyone who works under their supervision, directly or indirectly, understands and complies with this policy. They are also responsible for ensuring their group's work is valid.

Researchers

Researchers are responsible for understanding and complying with this policy and taking responsibility for their research. Researchers who will be conducting research with human participants are advised to complete the Panel on Research Ethics tutorial, Course on Research Ethics (CORE).

Consequences for Noncompliance

The University conducts an inquiry and, if necessary, an investigation of every allegation of research ethics misconduct. Where research ethics misconduct is judged to have occurred, the University will apply remedies consistent with the seriousness of the misconduct, up to and including termination of the member's position with the University and referral to a law enforcement agency.

The Vice-President (Research) will notify the appropriate funding agencies and professional associations as required.

Related Information

- The University of Regina 2015-2020 Strategic Plan
- Agreement on the Administration of Agency Grants and Awards by Research Institutions
- GOV-070-025 – Surveys
- GOV-022-005 - Code of Conduct
- GOV-022-010 - Conflict of Interest and Conflict of Commitment
- GOV-022-020 - Safe Disclosure
- GOV-022-025 – Research Scholarly Misconduct
- RCH-020-005 – Care and Use of Animals
- Canadian Council on Animal Care
- Tri-Agency Framework: Responsible Conduct of Research

- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
- Tri-Council Polity Statement Tutorial: Course on Research Ethics (CORE)
- Harmonized process
- Forms, instructions and samples
- REB TOR/Procedures

University of Regina Research Ethics Board
Terms of Reference

A. Statement of Institutional Authority for Research Ethics Boards

The University of Regina has one Research Ethics Board (REB), established and empowered under the authority of the University of Regina Board of Governors and reports to Council through an annual report to the Council Committee on Research.

Commented [AS1]: Is this adequate to address: Art 6.2 "REBs are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review."?

B. Mandate and Accountability of the Research Ethics Board

The REB's mandate, on behalf of the University, is to protect the rights and welfare of human participants who take part in research conducted under the auspices of the University. The University of Regina's REB reviews such research to ensure that it meets ethical principles and that it complies with all applicable regulations, guidelines and standards pertaining to human participant protection. These include, but are not limited to, the University of Regina's Policy on Ethics - Research with Humans (RCH 020-010) and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd edition (TCPS 2). As per these policies, the University of Regina requires that all research involving human subjects or human biological materials conducted in its jurisdiction or under its auspices undergo review and approval by the REB prior to initiation of any research-related activities, including recruitment and screening activities, regardless of where the research is conducted.

Commented [AS2]: Do we want to add The Health Information Protection Act (HIPA)? What about OCAP?? This may be good to include.

While it is not a formal part of its responsibilities, the REB may raise concerns about the safety of researchers as part of its review. Based on the level of risk, the REB may consider referring these concerns for review by an appropriate body within the institution. REB approval would not be withheld based on these concerns alone.

Commented [AS3]: New - This is taken from the TCPS2

The University of Regina's REB also operates under applicable laws and regulations of the Province of Saskatchewan and of Canada.
The REB reviews and recommends changes as needed to the University of Regina's Policy on Ethics - Research with Humans (RCH 020-010). Changes will be recommended to the Vice-President (Research) and follow relevant policy approval guidelines.

C. Membership of the REB

Membership shall be consistent with the requirements for REB composition specified in Article 6 of the TCPS 2.

The REB shall consist of at least five members, including both men and women, of whom at least:

a two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
b one member is knowledgeable in ethics;
c one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager); and
d one community member who has no affiliation with the institution.

The Research Compliance Officer, Research Office is an ex-officio, non-voting member.

Additional members beyond those mandated above will be added to ensure breadth of research experience for review of proposals and to maintain a manageable number of proposals per reviewer.

The REB is committed to Equity Diversity and Inclusion and strives for representation from the five federally designated groups.

Commented [AS4]: New, languge from Pauline

D. Terms of Office of the REB

Members of the REB shall be appointed by the Vice-President (Research). Members of the REB shall be recommended by the Director, Research Office, following consultation with the respective Faculty Deans, Department Heads, and Directors. Members of the REB will serve a three year, renewable term. Terms will be overlapping to preserve experience and continuity of function.

Commented [AS5]: there is no consultation with Deans, Dept Heads, etc. Do faculty have to ask permission to sit on the committee they chose?
We identify members through calls, people who come forward, requests to departments, does we need to state this?

The Chair will serve a two year, renewable term. The Vice-Chair will normally be appointed to the Chair position. Where the Vice-Chair cannot assume the position of Chair, members of the REB will be advised of the opportunity to be considered for the position.

Commented [AS6]: Can the REB members elect a Chair and Vice chair?
Or is the elected member go to the VPR for approval?
How does the vice chair to Chair move fit within this? Do we give the vice-chair first right of refusal? What if the current chair wants to stay on?

The Research Office will provide the Chair's Dean with funds equivalent to two course releases per year to support the Chair. Details regarding how this support will be provided to the Chair should be discussed with the Dean prior to appointment.

Commented [AS7]: Should we add that approval from the dean is required prior to be appointed as chair?

E. Meetings of the REB

1. The REB will meet face to face regularly. In the absence of any business, meetings may be cancelled by the Compliance Officer in consultation with the Chair.

Commented [AS8]: Add "normally" to allow for zoom?

2. Additional meetings of the REB, or of a sub-committee of its members, may be called by the Compliance Officer and/or Chair, as necessary.

3. Each meeting will require the involvement of quorum, which is defined as half the total voting membership plus one. Quorum must also meet membership criteria specified by relevant research ethics guidelines and regulations (Article 6.4 TCPS2).

Commented [AS9]: This has not always been easy to obtain.

4. Members shall attend REB meetings regularly. When circumstances arise that prevent a member from attending an REB meeting in person, arrangements will be made, where feasible, with the member to participate through use of technology (e.g., telephone or video link). Where a member is frequently absent, the REB should have some mechanism for reviewing whether that member should continue to serve on the REB.

5. Members shall notify the Research Office of an anticipated absence at least one day prior to a meeting. Members who cannot attend a meeting are expected to provide written comments to the Research Office for agenda items under review at the respective meeting. This information is provided to other members of the REB and becomes part of the discussion and meeting minutes.

6. Any real, perceived or potential conflict(s) of interest related to the applications under review shall be declared by the member(s) upon receiving the application or at the outset of the meeting. Examples of conflicts of interest include but are not limited to applications on which they are listed as principal investigator or co-investigator; current or past research collaborations with investigators listed on the application; applications on which students they supervise are listed. Other members of the REB will decide whether the member with the conflict of interest should recuse him/herself from related discussions.

7. The REB as a whole will review all above minimal risk applications. The REB will reach its decisions concerning the ethical acceptability of research that is undergoing ethics review through a process of open discussion and consensus. Where consensus cannot be reached, a vote of the quorum present may be taken and recorded.

8. The REB's deliberations and decisions will be documented in comprehensive, confidential minutes that are securely maintained in the Research Office.

9. Detailed written feedback from the REB including its decision on the ethical acceptability of the research shall be communicated to the researcher(s), by the Research Office. Feedback is based on the minutes of the discussion of the research project.

10. The REB may, where appropriate, request that the Principal Investigator (PI) or his/her designate attend a meeting to provide further information about and/or to discuss his/her research. The REB will also accommodate reasonable requests from a PI to attend a meeting to participate in discussions about his/her research.

11. The REB may seek the confidential opinion or advice of ad hoc advisors/reviewers from among UofR faculty or from external consultant on a particular application to ensure it has the necessary background information and knowledge to review the ethical acceptability of the application.

AD Hoc Meetings
The Compliance Officer will normally attend all REB related meetings including those between applicants and the Chair.

Commented [AS10]: New – to ensure conversations are recorded to the file and consistent with practice and policy.

F. Responsibilities of the REB
1. To ensure that all research under REB jurisdiction involving human participants and conducted by students, staff and faculty affiliated with the University of Regina, and all research conducted under the auspices of the University of Regina or with unaffiliated students, staff and faculty researchers, undergo ethics review and approval prior to being conducted. These activities may be conducted on- or off-campus and may be funded or unfunded.

Commented [AS11]: Can we take this out? If students, staff or researchers are not affiliated with the UofR, this alone would not require us to give REB approval.

2. To review the ethical acceptability of all research projects, under REB jurisdiction, involving human participants on behalf of the institution including, but not limited to, those that

- may pose greater than minimal risk to participants (i.e., physiological, psychological, social, legal, or other);

- involve recruitment of persons who may be vulnerable as research participants in the context of a specific study, and/or cannot legally give free and informed consent
- include ethically sensitive issues, topics and/or procedures; and
- represent applications to certain granting agencies that stipulate full REB review.

In so doing, the REB may: grant ethics approval to; propose modifications to; disapprove; or terminate proposed or ongoing research conducted within the jurisdiction of the University or under its auspices to ensure that a proportionate review of risks and benefits has occurred in accordance with the ethical framework proposed under the TCPS 2 (Chapter 1).

Responsibilities of the REB Chair

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of the Tri-Council Polciy Statement.

Delegation of REB Authority Related to Ethics Review and Approval

The REB has delegated review of research undertaken by undergraduate students within a course to approved departmental or faculty level ethics review committees. Undergraduate research that involves more than minimum risk to participants cannot be delegated for departmental review and requires REB approval. Copies of all approved protocols must be forwarded to the REB. It is the responsibility of departments to ensure that the highest ethical standards are met and that the ethics policy is followed. The REB shall maintain the right of monitoring such research.

The REB delegates to two REB members as reviewers and the REB Chair, authority to:

- Review the ethical acceptability of research projects under REB jurisdiction that may pose no greater than minimal risk to participants (i.e., physiological, psychological, social, legal, or other) on behalf of the institution.

The REB delegates to the REB Chair, by virtue of their membership on the REB, authority to conduct:

1. Ethics review and approval of all revised materials and related documents associated with the ethics review feedback process involving minimal and greater than minimal risk research.

2. Ethics approval of applications where no ethical concerns are raised by reviewers.

The REB delegates to the Compliance Officer, Research Office, by virtue of their membership on the REB, authority to conduct:

1. Ethics review and approval of modifications to ongoing research under its jurisdiction, where those modifications do not increase the risk factor of the research to beyond minimal risk.

Commented [AS12]: I don't understand the purpose of this section.
Is the purpose her to layout what would go to the FULL REB for review? If so this is unclear.

However there is no mention of the definition of min risk (research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.), research attributable risk or the balance and distribution of risks and benefits.

Commented [AS13]: New – Article 6.8

Commented [AS14]: This doesn't happen, I review them.

2. Annual ethics review and approval of research under its jurisdiction that continues beyond one year where there are no proposed changes that increase the risk of the research to beyond minimal risk.

3. Annual renewals of above minimal risk research in which there has been no significant changes to the research and no increase in risk to (or other ethical implications for) the participants since the most recent review by the full REB.

4. Ethics review and approval of minimal risk, undergraduate, course based projects.

5. Ethics review and approval of projects with REB approval from other academic insitutions.

Responsibility for Record Keeping and Research Ethics Education
The Research Office ensures that:

1. REB members are provided with opportunities for research ethics education during their tenure on the REB beginning with a new member orientation session.

2. Comprehensive, accurate records (all documents and associated correspondence) of the initial and continuing (i.e., modifications, annual) ethics review and approval processes are securely maintained in the Research Office for all research under its jurisdiction.

3. REB meeting dates and submission deadlines are easily accessible by researchers through information posted on the Research Office website.

Commented [AS15]: This is administratively burdensome, we do not currently do this.

4. Timely information and regular reports are received on any unanticipated issues (events) that have occurred in association with research under its jurisdiction.

5. UofR guidelines, procedures and sample materials related to the conduct of research with humans are reviewed and updated on a regular basis (e.g., annually) to ensure that they remain current in an evolving research ethics environment.

6. Educational activities (e.g., in-class presentations, seminars and workshops) are provided to UofR students, faculty and staff involved in research with human participants.

7. Legal or other advice is sought by the Compliance Officer, as required, on matters related to the protection of human participants in research.

8. Where appropriate, the Compliance Officer will coordinate with other departments on campus responsible for health and safety to ensure recommendations by the REB are consistent with what is required by those offices.

9. Timely information on guidelines, procedures, and other matters related to the conduct of research with human participants is provided to the REB as well as student, staff and faculty researchers who conduct research with humans.

G. Reconsideration and Appeal of REB Decisions

1. Reconsideration Process

A Principal Investigator may make a written request for reconsideration of an REB decision when ethics approval is not granted, or when ethics approval is conditional on revisions that the Principal Investigator (PI) believes may jeopardize the feasibility or integrity of the research. The Compliance Officer, Research Office, will refer such a request, including documentation and supporting materials received for reconsideration from the PI, to other members of the REB for discussion at its next meeting. The REB will review the written documents, and where appropriate, will request an informal meeting with the PI (or his/her designate). Following consideration of all additional information (verbal and written), the REB will reach a final decision with respect to its position on the original decision. Every attempt will be made by the Research Compliance Officer and REB, in consultation with the PI, to reach a resolution by this informal route.

2. Appeal Process

In the event the matter cannot be resolved through a reconsideration or informal process, the institution shall provide the PI with prompt access to an established appeal process through which the PI may appeal the REB's decision. An appeal can be requested for procedural or substantive reasons. An appeal committee shall be appointed through the same authority that established the REB, ensuring that members of the appeal committee will have expertise and knowledge to be able to competently judge the ethical acceptability of the research ethics application under review. Members of the REB whose decision is under appeal shall not serve on the appeal committee. The appeal committee will act impartially in its review of documentation provided by the REB and the PI (or designate), and will consult with others as required, including but not limited to, members of the REB and the PI (or designate). The appeal committee will issue a written report with its decision on the matter with copies to the PI and REB. It may approve, reject or request modifications to the research proposal. The appeal committee's decision will be final.

H. Multijurisdictional Research

1. Research Ethics Boards of Saskatchewan - Reciprocity Agreement

The Research Ethics Boards in the province of Saskatchewan have moved to a policy of full reciprocity. Applications approved by the REB of the University of Saskatchewan, University of Regina, or Saskatchewan Health Authority, will be accepted by both of the other two institutions without the need for additional REB review, provided the protocol is identical in its content and activities.

Research Ethics Board Membership

Ebin Arries	Ebin.Arries@uregina.ca	Faculty of Nursing
Dongyan Blachford	dongyan.blachford@uregina.ca	Department of International Languages
Abu Bockarie	Abu.Bockarie@uregina.ca	Faculty of Education
Fadila Boutouchent	fadila.boutouchent@uregina.ca	Faculty of Education (French)
Cara Bradley	Cara.Bradley@uregina.ca	Library
Paul Bruno	paul.bruno@uregina.ca	Faculty of Kinesiology and Health Studies
Shelagh Campbell	Shelagh.Campbell@uregina.ca	Faculty of Business Administration
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Edward Doolittle	edoolittle@firstnationsuniversity.ca	First Nations University of Canada
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Christian Riegel	Christian.Riegel@uregina.ca	Campion College (English)
Katherine Robinson	katherine.robinson@uregina.ca	Campion College Psychology
David Senkow	David.Senkow@uregina.ca	Community Representative
Michele Sorensen	Michele.Sorensen@uregina.ca	Faculty of Social Work
Valerie Triggs	valerie.triggs@uregina.ca	Faculty of Education
Warren Wessel	warren.wessel@uregina.ca	Community Representative
Lei Zhang	Lei.Zhang@uregina.ca	Faculty of Engineering

**Chair

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Application for Behavioural Research Ethics Review

Evaluating Applications

The matters of greatest concern to the Behavioural Research Ethics Board (Beh-REB) are the issues of informed consent of participants, voluntary participation, protection of individual privacy (confidentiality and anonymity), and safeguarding participants from any harmful results due to participation or non-participation in the proposed investigation or research project. Our evaluation of an application is based on the degree to which each of these concerns are satisfied; when filling out the application, researchers are urged to consider these points, and to explain to the Beh-REB the steps they will take to address the concerns. Researchers are also urged to consult the Tri-Council Policy Statement 2 for more information and guidance.

The Beh-REB acknowledges the variety of paradigms and methodologies currently available to researchers, and that each of these paradigms entails its own particular ethical issues. Thus, there may be more than one way to address an ethical issue. Researchers should feel free to suggest alternative approaches or to explain why a particular requirement is not appropriate in the context of a given project.

All text boxes will expand once <Enter> is selected or the cursor moves to the next section.

PART 1: IDENTIFICATION	
1.1	**Project Title** GN 1.1
1.2	**Principal Investigator** GN 1.2 Full Name: Mailing Address: Email: Phone: NSID number (U of S faculty only):
1.3	**University/Institutional Affiliation of Principal Investigator** GN 1.3 Position: Department: Division:
1.4	If this is a student/graduate/resident project, please provide the following information: GN 1.4 a) Student Name(s) and Student ID or NSID (s): b) Supervisor Name:
1.5	**Project Personnel (include graduates/post graduates/residents):** GN 1.5 Add Personnel Remove Last Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:
1.6	**Primary Contact Person for Correspondence (if different than Section 1.2)** GN 1.6 Full Name: Mailing Address: Email: Phone:

1.7	Research Site(s) where project will be carried out:
1.8	1.8.1 Proposed Project Period: GN 1.8 From (MM/DD/YY) To (MM/DD/YY)
1.9	**1.9.1 Has this project applied for and/or received ethical approval from any other Research Ethics Board? Will you be seeking REB approval through the Sask. ethics harmonization process?** GN 1.9 ☒ Yes ☐ No If yes, specify where and submit a copy of the certificate of approval: **1.9.2 Please be advised that approvals may need to be sought if you are collecting data from schools, within health regions and may be required from other organizations, agencies, or community groups. Will you be contacting potential participants or collecting data from any such organizations?** GN 1.9.2 ☒ Yes ☐ No If yes selected then open: Specify where, provide details and submit a copy of the certificate or letter of approval (when obtained). Please provide justification if you do not plan to seek approval.
1.10	1.10.1 Status of Funds: GN 1.10 ☒ Awarded ☐ Pending ☐ **Unfunded** 1.10.2 Provide name of funding source: 1.10.3 Source of Funds: ☐ **Industry** ☐ National Institute of Health (NIH) ☐ **Tri-Council Grant** ☐ Cooperative Group (NCIC, COG, RTOG) ☐ Not-for-Profit Foundation ☐ Internally funded
11.1	Name of Sponsor if different from above funding source:

PART 2: CONFLICT OF INTEREST

2.1	**2.1.1 Is there any real, potential or perceived conflict of interest (any personal or financial interest in the conduct or outcome of this project)?** GN 2.1 **2.1.2 Will any of the researcher(s), members of the research team and/or their immediate family members:** · Receive personal benefits in connection with this project over and above the direct costs of conducting the project, such as remuneration or employment? · Receive significant payments of other sorts from the sponsor such as grants, compensation in the form of equipment or supplies or retainers for ongoing consultation and honoraria? · Have a non-financial relationship with a sponsor (such as unpaid consultant, board membership, advisor or other non-financial interest? · Have any direct involvement with the sponsor such as stock ownership, stock options or board membership. · Hold patents, trademarks, copyrights, licensing agreements or intellectual property rights linked in any way to this project or the sponsor? · Have any other relationship, financial or non-financial, that if not disclosed, could be construed as a conflict of interest? ☒ Yes ☐ No **Please describe the personal benefits or relationship.**
2.2	Have any restrictions regarding access to or disclosure of information (during or at the end of the project) been placed on the investigators? This includes controls placed by the sponsor, funding body or advisory committee. ☒ Yes ☐ No

2.3	Please describe the arrangement and discuss the implications of any potential conflict of interest. Please describe how the conflict will be reduced, managed or eliminated as well as what additional protections have been put in place to protect project participants. The conflict of interest and how that conflict is being managed should be disclosed in the letter of information/ consent to participants.

PART 3: BRIEF OVERVIEW OF RESEARCH PROJECT

3.1 **Briefly describe the project, its objectives and potential significance (250-500 words):** GN 3.1

3.2 **Provide a description of research design and methods to be used:** GN 3.2

3.3 Provide details regarding the duration and location of data collection event(s): GN 3.3

- ☐ Questionnaire
- ☐ Individual Interviews
- ☐ Group Interview
- ☐ Video/audio recording
- ☐ Home Visits
- ☐ Other:
- ☐ Participant Observation
- ☐ Focus Groups
- ☐ Non-invasive physical measurements
- ☐ Secondary use of data or analysis of existing data
- ☐ Ethnography

PART 4: PROJECT DETAILS

4.1

4.1.1 Will you have any internet-based interaction with participants? GN 4.1

☒ Yes ☐ No

4.1.2 If you are using a third party research tool, website survey software, transaction log tools, screen capturing software, or masked survey sites, how will you ensure the security of data gathered at that site?

4.1.3 Describe how permission to use any third party owned site(s) will be obtained, if applicable:

4.1.4 How will you protect the privacy and confidentiality of participants who may be identified by email addresses, IP addresses, and other identifying information that may be captured by the system during your interactions with these participants?

4.1.5 If you do not plan to identify yourself and your position as a researcher to the participants, from the onset of the research study, explain why you are not doing so, at what point you will disclose that you are a researcher, provide details of debriefing procedures, if any, and if participants will be given a way to opt out, if applicable:

4.2	**4.2.1 Will your research involve Aboriginal Peoples including First Nations, Inuit and Métis peoples?** GN 4.2 ☒ Yes ☐ No **4.2.2 Please outline the plans to obtain community engagement for this project. Describe the nature, and extent of the community engagement as determined jointly by the researcher and relevant community. If no community consent is being sought, please justify.** **4.2.3 Describe any relevant customs and codes of research practice that apply to the particular community or communities affected by the research:** **4.2.4 Will a research agreement between the researcher and community be prepared?** **4.2.5 How will your research plan consider mutual benefit to the participating community, support capacity building through enhancement of the skills of community personnel, and the recognition of the role of elders and other knowledge holders?** **4.2.6 Will community representatives have the opportunity to participate in the interpretation of the data and the review of research finding before the completion of any reports or publications? How will final results of the project be shared with the participating community?**
4.3	**4.3.1 Will the project involve community-based participatory research?** GN 4.3 ☒ Yes ☐ No **4.3.2 Please outline the plans to obtain community engagement for this project. Describe the nature, and extent of the community engagement as determined jointly by the researcher and relevant community. If no community consent is being sought, please justify.** **4.3.3 Describe the organizational structure and community processes required to obtain approval within the specific community or communities.** **4.3.4 Will a research agreement between the researcher and community be prepared? This should outline the goals of the project, principles of partnership, decision-making processes, roles and responsibilities of partners and guidelines for how the partnership will handle and disseminate data.** **4.3.5 Will community representatives have the opportunity to participate in the interpretation of the data and the review of research finding before the completion of any reports or publications? How will final results of the project be shared with the participating community?**
4.4	**Will deception of any kind be necessary in this project?** GN 4.4 ☒ Yes ☐ No **Please explain and describe the protocol for debriefing and re-consenting of participants upon completion.**
4.5	**Indicate how the participants will be debriefed following their participation (if applicable), and describe how the information on the results of the research will be made available to participants once the study has ended. Debriefing is particularly important if deception has been used.** GN 4.5
4.6	**Will participants be compensated?** GN 4.6 ☒ Yes ☐ No Please include details:

4.7

4.7.1 Will participants be anonymous in the data gathering phase of the study? (Anonymous means that no link can be established between the participant and the research - no one including the researcher knows who has participated in the research):

☐ Yes ☒ No

4.7.2 Will the confidentiality of participants and their data be protected? (Confidentiality means that no link can be established between the collected information and the participant's identity)

☐ Yes ☐ No

4.7.3 If yes, are there any limits to confidentiality:

☐ **Limits due to the nature of group activities (e.g. focus groups): the researcher cannot guarantee confidentiality**

☐ **Limits due to context: individual participants could be identified because of the nature or size of the sample or because of their relationship with the researcher.**

☐ **Limits due to selection: procedures for recruiting or selecting participants may compromise the confidentiality of participants (e.g. participants are referred to the study by a person outside the research team)**

☐ Other:

PART 5: ESTIMATION OF RISKS AND BENEFITS

5.1

5.1.1 Do you consider this project to be: GN 5.1

☐ Minimal Risk ☐ Above Minimal Risk

5.1.2 Indicate if the participants might experience any of the following:

Risk of psychological or emotional harm or discomfort (e.g. trauma, anxiety, stress)

Legal repercussions for participating in the study(e.g. possibility of being sued, charged with criminal activity, disclosure of past or future criminal activities, etc.)

Social repercussions (e.g. ostracized, being negatively judged by peers or employer, fired from your job)

Risk of physical harm or discomfort (e.g. falling, muscle pain, tiredness, weakness, nausea)

5.1.3 Describe how the risk will be managed (including an explanation as to why an alternative approached could not be used). If appropriate, identify any resources, e.g. physician or counselor, to which participants can be referred. GN 5.1.3

5.1.4 If above minimal risk, what are the likely benefits of the research to the researcher, participant, the research community and society that would justify asking participants to participate? GN 5.1.4

PART 6: PARTICIPANT RECRUITMENT

6.1

Describe the participants and the criteria for their inclusion or exclusion. Indicate the number of participants and a brief rationale for the intended number of participants: GN 6.1

6.2

6.2.1 Provide a detailed description of the method of recruitment. GN 6.2

6.2.2 How will prospective participants be identified?

6.2.3 Who will contact prospective participants? Describe the source of the contact information, how they will be contacted and as applicable, who originally collected the contact information. Ensure any letters of initial contact or other recruitment materials are attached, e.g. advertisements. flyers, telephone script, etc.

6.3	**In cases where the research involves special or vulnerable populations, distinct cultural groups, or in cases where the research is above minimal risk, the researcher should describe their experience or training in working with the population. If none of these criteria apply, this section may be omitted. GN 6.3**
6.4	**Where relevant, please explain any relationship (pre-existing, current or expected to have) between the researcher(s) and the researched (e.g. instructor-student, manager-employee, co-workers, family members/intimate relationships, etc). Please pay special attention to relationships in which there may be a power differential. Describe any safeguards and procedures to prevent possible undue influence, coercion or inducement. GN 6.4**

PART 7: CONSENT PROCESS

7.1	**Describe the process that will be used to obtain informed consent. Please note that it is the content of the consent, not the format that is important. If the research involves collection of personally identifiable information from a research participant or extraction of personally identifiable information from an existing database, please describe how consent from the individuals or authorization from the data custodian will be obtained. If there will be no written consent, please provide a rationale for oral or implied consent (e.g., cultural appropriateness, online questionnaire, etc.) and explain how consent will be recorded.** **7.1.1 Describe the consent process. GN 7.1** **7.1.2 Who will ask for consent?** **7.1.3 Where, and under what circumstances will consent be obtained?** **7.1.4 Describe any situation in which the renewal of consent for this research might be appropriate and how this would take place (e.g. longitudinal studies, multiple data collection events, etc.).**
7.2	**If any or all of the participants are children and/or are not competent to consent, describe the process by which capacity/competency will be assessed, the proposed alternate source of consent - including any permission/ information letter to be provided to the person(s) providing the alternate consent - as well as the assent process for participants. GN 7.2**
7.3	**Describe your plans for providing project results to the participant? GN 7.3**
7.4	**How and when are participants informed of the right to withdraw? What procedures will be followed for participants who wish to withdraw at any point during the study? GN 7.4**

PART 8: DATA SECURITY AND STORAGE

Indicate the procedures you plan to implement to safeguard and store the data. Identify the person who will be assuming responsibility for data storage (University policy requires the researcher or the supervisor, in the case of student research, to securely store the data at the University for a minimum of five years upon the completion of the study. For more information see U of S Responsible Conduct of Research Policy or U of R Records and Information Management Policy.

8.1	**Who will conduct the data collection? GN 8.1**
8.2	**Who will have access to the original data of the study? GN 8.2**
8.3	**How will confidentiality of original data be maintained as well as preserving or destroying data after the research is completed. For all data (e.g. paper records, audio or visual recordings, electronic recordings), indicate the: GN 8.3** **8.3.1 Person responsible for data storage:** **8.3.2 Data security during transportation from collection site:** **8.3.3 Means and location of storage (e.g. a locked filing cabinet, password protected computer files, encryption):**

	8.3.4 Time duration of storage (Must be > 5 Years):
	8.3.5 Final disposition (archive, shredding, electronic file deletion):
8.4	**Indicate how the data collected is intended to be used (thesis, journal articles, conference presentation, media, etc).** GN 8.4

PART 9: Declaration by Principal Investigator *(or Supervisor for student projects)*

Project Title

- I confirm that the information provided in this application is complete and correct.
- I accept responsibility for the ethical conduct of this project and for the protection of the rights and welfare of the human participants who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of the University and Health Region/affiliated institutions where this project will be conducted, as well as with all applicable federal and provincial laws regarding the protection of human participants in research.
- I will ensure that project personnel are qualified, appropriately trained and will adhere to the provisions of the REB-approved application.
- I certify that any significant changes to the project, including the proposed method, consent process or recruitment procedures, will be reported to the Research Ethics Board for consideration in advance of its implementation.
- I certify that a status report will be submitted to the Research Ethics Board for consideration within one month of the current expiry date each year the project remains open, and upon project completion.
- If personal health information is requested, I assure that it is the minimum necessary to meet the research objective and will not be reused or disclosed to any parties other than those described in the REB-approved application, except as required by law.
- I confirm that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place.
- I understand that if the contract or grant related to this research project is being reviewed by the University or Health Region, a copy of the ethics application inclusive of the consent document(s), may be forwarded to the person responsible for the review of the contract or grant.
- I understand that if the project involves Health Region resources or facilities, a copy of the ethics application may be forwarded to the Health Region research coordinator to facilitate operational approval.

Signature of Principal Investigator and/or Supervisor	Printed Name of Principal Investigator and/or Supervisor	Date (MM/DD/YY)
Signature of Student Investigator	Printed Name of Student Investigator	Date (MM/DD/YY)

Department Head (UofS and RQHR only) : The signature/approval of the Department/Administrative Unit acknowledges that he/she is aware of and supports the research activity described in the proposal.

Signature of Department Head	Printed Name of Department Head	Date (MM/DD/YY)

SECTION 10: APPENDICES GN 10

Document	Included?	Description
Recruit Material(s)	☐ Yes ☐ N/A	
Letter (s) of Initial Contact	☐ Yes ☐ N/A	
Consent Form(s)	☐ Yes ☐ N/A	
Assent Form(s)	☐ Yes ☐ N/A	
Research Tool(s) (e.g. Questionnaires, focus group guides, interview scripts, etc.)	☐ Yes ☐ N/A	
Transcript Release Form(s)	☐ Yes ☐ N/A	
RQHR Operational/Departmental Approval Form	☐ Yes ☐ N/A	
Other (please specify):	☐ Yes ☐ N/A	

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Application for Biomedical Research Ethics Review

PART 1: IDENTIFICATION		
1.1	**Project Title** Protocol Number (if applicable):	
1.2	**Principal Investigator** Full Name: Mailing Address: Email: Phone: NSID number (U of S faculty only):	
1.3	**University/Institutional Affiliation of Principal Investigator** Position: Department: Division:	
1.4	**Project Personnel (including graduates/post graduates/residents)**	
	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:
	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:
	If this is a student/graduate/resident project, please provide the following information:	
	a) Student Name:	b) Supervisor Name:
1.5	**Primary Contact Person for Correspondence (if different than Section 1.2)** Full Name: Mailing Address: Email: Phone:	

1.6	**Research Site(s) where project will be carried out:**
1.7	**Proposed Project Period:** From (MM/DD/YY) To (MM/DD/YY) **Specify any time considerations the REB should be aware of (e.g. short enrolment period):**
1.8	**Has this project applied for/received ethical approval from any other Saskatchewan REB?** ☐ Yes ☐ No If yes, specify where: **Has this project applied for/received ethical approval from another Research Ethics Board outside of Saskatchewan?** ☐ Yes ☐ No If yes, specify where (if known):
1.9	**Do you consider this project to involve:** ☐ Minimal Risk ☐ More than Minimal Risk
1.10	**Provide name of funding source:** **Source of Funds:** ☐ Industry ☐ National Institute of Health (NIH) ☐ Not-for-Profit Foundation ☐ Cooperative Group (NCIC, COG, RTOG) ☐ Tri-Council Grant ☐ Internally funded ☐ Grant-in-aid **Status of Funds:** ☐ Awarded ☐ Pending
1.11	**Name of Sponsor if different from above funding source:**

PART 2: REGULATORY REQUIREMENTS

2.1 **If the project involves an investigational drug, natural product, medical device or marketed drug/device being used outside of the approved indication, check whether or not the No Objection Letter (NOL) or the Investigational Testing Authorization (for devices) has been obtained from the appropriate Health Canada regulatory agency.** GN 2.1

☐ N/A – Proceed to Question 2.2

	Yes	Pending	N/A
Therapeutic Products Directorate (TPD)	☐	☐	☐
Natural Health Products Directorate (NHPD)	☐	☐	☐
Biologics and Genetics Therapies Directorate (BGTD)	☐	☐	☐
Investigational Testing Authorization (ITA)	☐	☐	☐

Date of approval (MM/DD/YY):

Please forward the NOL and/or ITA to the Research Ethics Office when available.

2.2 **Is there a requirement for this research to comply with United States (OHRP/FDA) regulations for research ethics?**

☐ Yes ☐ No

2.3	**Clinical trials are required to be registered with clinicaltrials.gov.** Please submit confirmation of registration when available.
2.4	**Peer Review** For research with *more than minimal risk*, the REB must be satisfied about both the value and the scientific validity of the project. Under some circumstances and depending on the level of risk, the REB may request that a peer review be conducted as a condition of approval. Research that poses minimal risk will not usually require peer review. Has this research proposal received any independent scientific review? ☐ Yes (please attach) ☐ No ☐ Not applicable
2.5	According to Good Clinical Practices Section 3.1.2, the Principal Investigator should submit a current curriculum vitae (CV) providing evidence of qualifications to conduct the project. If a CV has not been submitted within last 5 years, please attach. Is the PI's CV attached? ☐ Yes ☐ Not applicable

PART 3: BRIEF OVERVIEW OF RESEARCH PROJECT (two page maximum)

3.1	**Research Question/Hypothesis** Specify the research question(s) being evaluated in the project.
3.2	**Academic Validity** Provide evidence (scientific literature, pilot projects, etc.) that the scientific reasoning and design of the project are sufficiently sound to meet the objectives of this project.
3.3	**Research Design/Methods** Provide a description of research design (e.g. parallel group or cross-over design) and methods to be used. Include a justification for the use of a placebo, if applicable. Please note that if the analysis or the interpretation of the research results refers to Aboriginal people, language, culture or history as a primary focus of the project, consultation with the appropriate community is required. Please outline the process to be followed.
3.4	**Statistical Analysis** Include a summary of the primary and secondary end-points/outcomes, the planned sample size (with justification) and planned statistical and interim analyses.
3.5	**Potential Significance/Justification** Explain the significance of the project in order to support the ethical tenet that the proposed research has value (i.e., what are the anticipated public and scientific benefits of the project?).

PART 4: PARTICIPANT RECRUITMENT

4.1	**How many participants will be enrolled in the project:** Globally? Locally?
4.2	**Describe who will be selected (target population) and the criteria for their inclusion.**

4.3	**Describe who will be excluded from participation.**
4.4	**Provide a detailed description of the method of recruitment.** a) How will prospective participants be identified? b) Who will contact prospective participants? c) How will this be done? (Ensure that any letters of initial contact or other recruitment materials are attached to this submission (e.g. advertisements, flyers, verbal or telephone script, etc.).

PART 5: CONSENT PROCESS

5.1	**Describe the consent process.** a) Who will ask for consent? b) Where, and under what circumstances? c) Describe any situation in which the renewal of consent for this research might be appropriate and how this would take place (e.g. Participant turns 18 or emergency situation).
5.2	**How long will the participant have to decide whether or not to participate?** If less than twenty-four hours, provide an explanation.
5.3	**Will all participants be able to consent on their own behalf?** ☐ Yes ☐ No If No, explain why: a) If a participant is unable to consent, who will consent on his/her behalf? b) Will the participant be able to assent to participate? ☐ Yes ☐ No If yes, explain how assent will be sought:
5.4	**If monetary compensation or reimbursements for expenses will be offered to the participants please provide the details.**
5.5	**Describe your plans for providing project results to the participant?**

PART 6: PROCEDURES AND RISKS

6.1	**Identify those procedures that are different from the current standard of care (i.e. unique to the research project).**
6.2	**What are the known risks associated with the procedures outlined in Section 6.1? Also include any risks associated with the placebo or wash out periods, if applicable.**
6.3	**What strategies will be put in place to minimize and/or manage the potential risk(s) to participants and other affected individuals?**
6.4	**For double blind projects, describe the provisions made to break the code in an emergency situation [24 hour availability], and indicate who has the code.** If it is clearly articulated in the clinical protocol, it is acceptable to append the information or provide the protocol page reference. ☐ N/A, not a double blind project

PART 7: DATA SECURITY AND STORAGE

The *Saskatchewan Health Information Protection Act (HIPA)* requires an assessment of the risks to privacy and how the risks will be minimized. Accessing existing patient information, such as Health Records, requires consent of the individual which must be addressed in the consent form.

7.1	**Indicate from which sources personal and health information data will be collected:** ☐ Participant data collected prospectively for the purpose of this project (e.g. case report form) ☐ Family physician record ☐ Heath Region – please specify Region, Site & Dept. if applicable: ☐ SK Ministry of Health ☐ SK Cancer Agency ☐ Other – please specify: ☐ Not applicable (No personal or health information to be collected). Proceed to Section 8.
7.2	**How will the confidentiality of participants and their health information be protected?**
7.3	**Describe the storage arrangements and final disposition of the project data collected.**
7.4	**List the project personnel who have access to any identifiable personal health information and who will have access to any list that links participant names to their project ID number, consent form, enrolment log, etc.**
7.5	**Check all applicable boxes below to provide an assessment of the potential privacy risks and the safeguards/solutions that you will put in place to mitigate the risks**.

Potential Privacy Risks	**Possible Safeguards/Solutions** (check all that you will use)
☐ Unauthorized external or internal access to identifying information through active use or transmission	☐ Project personnel screening/agreements ☐ Access authorization procedures ☐ Designated systems administrator ☐ Passwords/screen timeouts ☐ System access audits/disclosure logs ☐ Secure mail/transport ☐ Firewall/virus protect ☐ Encrypted transmission
☐ Identification through publication or release	☐ Aggregation levels ☐ Alternate identifiers
☐ Identification through data-matching	☐ Use of non-linkable elements or identifiers
☐ Loss of data control outside jurisdiction	☐ Confidentiality and security agreements for out-of-province recipients or storage providers

PART 8: CONFLICT OF INTEREST

8.0	**Is there any real or perceived conflict of interest (any personal or financial interest in the conduct or outcome of this project)? Will any of the researcher(s), members of the research team and/or their immediate family members:** • Receive personal benefits in connection with this project over and above the direct costs of conducting the project,

	such as remuneration or employment? ☐ Yes ☐ No • Receive significant payments of other sorts from the sponsor such as grants, compensation in the form of equipment or supplies or retainers for ongoing consultation and honoraria? ☐ Yes ☐ No • Have a non-financial relationship with a sponsor (such as unpaid consultant, board membership, advisor or other non-financial interest? ☐ Yes ☐ No • Have any direct involvement with the sponsor such as stock ownership, stock options or board membership? ☐ Yes ☐ No • Hold patents, trademarks, copyrights, licensing agreements or intellectual property rights linked in any way to this project or the sponsor? ☐ Yes ☐ No • Have any other relationship, financial or non-financial, that if not disclosed, could be construed as a conflict of interest? ☐ Yes ☐ No If yes, please describe the personal benefits or relationship.

PART 9: DECLARATION BY PRINCIPAL INVESTIGATOR

(OR SUPERVISOR FOR STUDENT PROJECTS)

Project Title:

- I confirm that the information provided in this application is complete and correct.
- I accept responsibility for the ethical conduct of this project and for the protection of the rights and welfare of the human participants who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of the University and Health Region/affiliated institutions where this project will be conducted, as well as with all applicable federal and provincial laws regarding the protection of human participants in research.
- I will ensure that project personnel are qualified, appropriately trained and will adhere to the provisions of the REB-approved application.
- I will ensure that any significant changes to the project, including the proposed method, consent process or recruitment procedures, will be reported to the Research Ethics Board for consideration in advance of its implementation.
- I will ensure that a status report will be submitted to the Research Ethics Board for consideration within one month of the current expiry date each year the project remains open, and upon project completion.
- If personal health information is requested, I assure that it is the minimum necessary to meet the research objective and will not be reused or disclosed to any parties other than those described in the REB-approved application, except as required by law.
- I confirm that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place *before* implementing the research project, and that the research will *stop* if adequate resources become unavailable.
- I understand that if the contract or grant related to this research project is being reviewed by the University or Health Region, a copy of the ethics application inclusive of the consent document(s), may be forwarded to the person responsible for the review of the contract or grant.
- I understand that if the project involves Health Region resources or facilities, a copy of the ethics application may be forwarded to the Health Region research coordinator to facilitate operational approval.

_____	_____	_____
Signature of Principal Investigator	Printed Name of Principal Investigator	Date (MM/DD/YY)
_____	_____	_____
Signature of Student Investigator	Printed Name of Student Investigator	Date (MM/DD/YY)

Department Head (U of S and RQHR only) The signature/approval of the Department/Administrative Unit acknowledges that he/she is aware of and supports the research activity described in the proposal.

_____	_____	_____
Signature of Department Head	Printed Name of Department Head	Date (MM/DD/YY)

University of Regina

Research Ethics Board
Course-Based Research Project Application

Oct 2011

Many undergraduate and graduate courses include class projects and activities designed to develop research skills. These projects may be carried out by individual students, small groups or as a single class projects. The Instructor for the course takes the role of principal investigator and submits an application for Course-Based Research Projects. This application applies to projects that will be conducted within a course. Undergraduate Honors projects and Master's thesis' projects will normally be required to complete the full application form.

This application form can be submitted to the Faculty/Department REB in Anthropology, Economics, Education, Kinesiology & Health Studies, Human Justice, Psychology, and Fine Arts. The REB may require further information prior to approving the project.

Course-based research activities will vary in scope; informational gathering activities classified as research may include:

- Students conducting interviews or distribute questionnaires to develop interview or questionnaire design skills;
- Students administer standard tests;
- Conduct research projects where students pose research questions, gather data from human participants and analyze the results for presentation or a paper;
- Other activities that would be considered research within the discipline area in which the course is being taught.

Some information gathering activities are not considered "research" as defined by the TCPS and outside of the scope of REB review. Information gathering activities are classified as professional education or development and not research when:

- The intent to use the information is to provide advice, diagnosis, or general advice for a client;
- The objective is to develop skills which are considered standard practice within a discipline (e.g. observation, assessment, intervention, evaluation, auditing);
- The information collection processes are a part of the normal relationship between the student and participants (classroom teacher and students or nurse and patient);
- The data collected or conclusions drawn are to be disseminated in a private forum such as with the client.

The requests for course-based research projects should follow the following criteria:

- Student projects should be no more than minimal risk. The TCPS2 defines minimal risk as the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research;
- Projects must not involve any personal, sensitive or incriminating topics or questions which could place participants at risk;
- Projects do not involve deception.

Section I: Identification and Purposes

1. Date:

   Professor:

   Department:

   Telephone #: E-mail:

   Course number & title:

   Number of Students in Course:

2. Briefly describe the pedagogical goal of the assignment (please attach the course/project outline to be given to students:

3. Minimal risk and delegated review: Risk to participants should be proportionate to both student experience and pedagogical goals, with appropriate levels of responsibility and supervision by the instructor. Typically, undergraduate course research should involve minimal risk, which means that the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research. Briefly explain the research risk level.

4. Please describe what research methods will be used and the range of topics. Will all students be given similar research topics and methods or choice of 2-3 research methods? If there will be student choice, please describe the common features that will be shared by all of them.

5. Please list the potential type of participants to be recruited (e.g. fellow students, members of the public, etc) and describe the range of methods by which they will be recruited.

6. Describe the consent process the instructor and/or students will use to obtain informed consent. Please note, it is the quality of the consent not the format that is important: if there will be no written consent form, please explain (e.g. culturally inappropriate). A consent and assent process may be required for any participants that do not have the competency to consent (e.g. children).

7. Explain briefly how you will prepare your students to comply with Tri-Council Policy (TCPS) guidelines and University policies in completing the course assignment(s). In particular, explain how students will be prepared to attend to the following:
   - Involvement of vulnerable populations of participants;
   - Obtain free and informed consent and understanding circumstances in which voluntary consent may potentially be compromised;
   - Exercise the right to withdraw from participation or withdraw their data from the study;
   - Management of data: safe and secure storage while under student control, submitted to instructor with student final report and secure storage in locked cabinet by instructor and appropriate disposal procedures.
   - Address anonymity and confidentiality:

   Anonymity: No link can be established between a participant and the research (i.e. no one knows who has participated in the study).
   Confidentiality: No link can be established between the collected information and a participant's identity (i.e. no one can identify who contributed a given piece of information)

8. How will the research material be used? (e.g. term paper, in class presentation)

My signature(s) below acknowledges that I:

- Certify that the information provided in this application is complete and correct.
- Am aware of my responsibility to supervise students conducting project involving human participants as a requirement to their participation in this course.
- Will comply with all policies and guidelines of the University and affiliated institutions where this study will be conducted, as well as with all applicable federal, provincial and local laws regarding the protection of human participants in research.
- Will ensure any significant changes to the proposed methods, or consent and recruitment procedures will be reported to the REB for consideration in advance of its implementation.

Signature of Instructor(s)

_____

Research Ethics Board
Application for the Use of Non-Identified Human Biological Materials

This application is intended for the use of non-identified human biological materials (B and C below). For the use of identified or coded human biological materials, where the researcher will have access to the code, please submit the Biomedical Ethics Review Form or Secondary Use of Data Form.

The following categories, provide guidance for assessing the extent to which human biological materials could be used to identify an individual:

A. Identified human biological materials – the materials are labelled with a direct identifier (e.g., name, personal health number). Materials and any associated information are directly traceable back to a specific individual.

B. Coded human biological materials – direct identifiers are removed from the materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g., a principal investigator retains a key that links the coded material with a specific individual if re-linkage is necessary).

C. Anonymized human biological materials – the materials are 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.

D. Anonymous human biological materials – the materials never had identifiers attached to them, and risk of identification of individuals is low or very low. *Category D is exempt for REB review.

*Rapid technological advances facilitate identification of information and make it harder to achieve anonymity. These activities may heighten risks of identification and possible stigmatization where a data set contains information about or human biological materials from a population in a small geographical area, or information about individuals with unique characteristics (e.g., uncommon field of occupational specialization, diagnosis with a very rare disease). Where the researcher seeks data linkage of two or more anonymous sets of information or human biological materials and there is a reasonable prospect that this could generate identifiable information, then REB review is required.

Project Title:

PI:	
Personnel:	
Proposed Project Period:	
Status of Funds:	
Source of Funds:	
Fund Reference/Grant #:	

Is there any real, potential or perceived conflict of interest (any personal or financial interest in the conduct or outcome of this project)?

Is there a Material Transfer Agreement to obtain materials for the study?

□ Approved □ In Process □ Pending □ No

Does the research involve the use of biologically hazardous materials or organisms?

□ Yes □ No

What is the source of the human biological material? (Where are the materials coming from)

Describe the original source, and if known, the privacy policies and practices of the source of materials.

Describe the human biological materials to be used.

Please submit completed application to research.ethics@uregina.ca

Research Ethics Board
Application for the Use of Non-Identified Human Biological Materials

Will the study involve pluripotent stem cells that have been derived from an embryonic source?
□ Yes □ No
Will the study involve pluripotent stem cells that will be transferred into humans or non-humans?
□ Yes □ No
If yes, an application must be submitted to the CIHR Stem Cell Oversight Committee (SCOC)
https://cihr-irsc.gc.ca/e/15351.html

What are the consent policies and practices of the source of materials?

Briefly describe the project, its objectives and potential significance.

Provide a description of research design and methods to be used.

Indicate how the data collected is intended to be used (thesis, journal articles, conference presentation, reports to funders etc).

Could the research expect to result in re-identification?

Can the samples be traced back to an individual Indigenous donor or to an Indigenous community? If yes, describe how the researcher will seek community engagement.

Who will have access to the human biological material once received?

Who will have access to the original data for the proposed study?

Describe how will the PI ensure that human biological materials are stored safely and in accordance with applicable standards, and establish appropriate physical, administrative and technical safeguards to protect human biological materials from unauthorized handling?

Location of storage of human biological materials:

Describe the practice and timelines for disposal of research materials:

Declaration by Principal Investigator (or Supervisor for student projects)

Please submit completed application to research.ethics@uregina.ca

Research Ethics Board
Application for the Use of Non-Identified Human Biological Materials

- I confirm that the information provided in this application is complete and correct.
- I accept responsibility for the ethical conduct of this project and for the protection of the rights and welfare of the human participants who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of the University and Health Region/affiliated institutions where this project will be conducted, as well as with all applicable federal and provincial laws regarding the protection of human participants in research.
- I will ensure that project personnel are qualified, appropriately trained and will adhere to the provisions of the REB approved application.
- I certify that any significant changes to the project, including the proposed method, consent process or recruitment procedures, will be reported to the Research Ethics Board for consideration in advance of its implementation.
- I certify that a status report will be submitted to the Research Ethics Board for consideration one month prior to the current expiry date each year the project remains open, and upon project completion.
- I confirm that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place.

_____ _____

Signature of Principal Investigator Date (MM/DD/YY)

Please submit completed application to research.ethics@uregina.ca

For administrative use only	
File Number:	Date received:

Application to Access Existing Health Data for Research

PART 1: IDENTIFICATION		
1.1	**Project Title** GN 1.1 Protocol Number (if applicable):	
1.2	**Principal Investigator** GN 1.2 Full Name: Mailing Address: Email: Phone: NSID number (U of S faculty only):	
1.3	**University/Institutional Affiliation of Principal Investigator** GN 1.3 Position: Department: Division:	
1.4	**Project Personnel (including graduates/post graduates/residents)** GN 1.4	
	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:
	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:	Full Name: Project Position/Role: University/Institutional Affiliation: Email: Phone:
	If this is a student/graduate/resident project, please provide the following information:	
	a) Student Name:	b) Supervisor Name:
1.5	**Primary Contact Person for Correspondence (if different than Section 1.2)** GN 1.5 Full Name: Mailing Address: Email: Phone:	
1.6	**Research Site(s) where project will be carried out:** GN 1.6	

1.7	**Proposed Project Period:** GN 1.7 From (MM/DD/YY) To (MM/DD/YY)
1.8	**Specify any time considerations the REB should be aware of (e.g. short enrolment period):**
	Has this project applied for/received ethical approval from any other Saskatchewan REB? GN 1.8 ☐ Yes ☐ No If yes, specify where:
1.9	**Provide name of funding source:** GN 1.9
	Source of Funds: ☐ Industry ☐ National Institute of Health (NIH) ☐ Not-for-Profit Foundation ☐ Cooperative Group (NCIC, COG, RTOG) ☐ Tri-Council Grant ☐ Internally funded ☐ Grant-in-aid
	Status of Funds: GN 1.10 ☐ Awarded ☐ Pending
1.10	**Name of Sponsor if different from above funding source:** GN 1. 11

PART 2: BRIEF OVERVIEW OF RESEARCH PROJECT (one page maximum)

2.1	**Research Question/Hypothesis** GN 2.1 Specify the precise research question or questions being evaluated in the project.
2.2	**Research Design** GN 2.2 Include the planned sample size (with justification), primary and secondary end-points/outcomes and planned statistical analyses.
2.3	**Potential Significance/Justification** GN 2.3 Explain the significance of the project in order to support the ethical tenet that the proposed research has value (i.e., what are the anticipated public and scientific benefits of the project?).

PART 3: DATA ACCESS

3.1	**Indicate from which sources personal and health information data will be collected (check all that apply):** GN 4.1 ☐ Physician Office Records ☐ Heath Region – please specify Region, Site & Dept. (if applicable): ☐ SK Ministry of Health ☐ SK Cancer Agency ☐ Other (please specify):
3.2	**In what format is the data you intend to access?** ☐ Medical Charts ☐ Electronic Database ☐ Other (please specify):
3.3	**What is the total number of records/cases/charts required for your project?**

3.4	**Describe the inclusion criteria for the records being requested:** GN 3.1
3.5	Section 29 of the Saskatchewan Health Information Act (SK HIPA) *legislates* that access to existing personal health information for research purposes requires consent of the individual. **If consent is not being considered for this project, please provide a justification for waiving the requirement, otherwise, please append a consent form.** GN 3.2
3.6	**How will the confidentiality of participant data be protected?** Please note that the master list and data abstraction form (i.e. list of data fields to be collected and from what source) must be submitted for all applications. GN 3.3

PART 4: DATA SECURITY AND STORAGE

4.1	**Project personnel with access to personal health information** GN 4.1 a) List project personnel that have access to identifiable health data to be collected. b) Specify who will be responsible for abstracting the data and where the data abstraction will occur. c) Who will have access to any list that links participant names to their project ID number?
4.2	**Describe the storage arrangements and final disposition of the research data collected:** GN 4.2
4.3	**Do you plan to link the locally collected data with any other data set(s)?** GN 4.2 ☐ Yes ☐ No If yes, identify the data set:
4.4	**Will data be sent outside of the institution where it was collected?** GN 4.2 ☐ Yes – If yes, specify where it will be stored at that site, who will then be the custodian (i.e. the person responsible for the data storage and integrity), who will have access to it, and security measures: ☐ No – Proceed to Question 4.6
4.5	**If you are sending your data to a collecting/coordinating site what method will be used?** GN 4.2 ☐ Web-based data collection portal ☐ Email ☐ Private courier – must be able to trace delivery ☐ Canada Xpress Post or Priority Courier – regular mail may not be used ☐ Other (please specify):
4.6	**Check all applicable boxes below to provide an assessment of the potential privacy risks and the safeguards/solutions that you will put in place to mitigate the risks**. GN 4.3

Potential Privacy Risks	Possible Safeguards/Solutions (check all that you will use)
☐ Unauthorized external or internal access to identifying information through active use or transmission	☐ Project personnel screening/agreements ☐ Access authorization procedures ☐ Designated systems administrator ☐ Passwords/screen timeouts ☐ System access audits/disclosure logs ☐ Secure mail/transport ☐ Firewall/virus protect ☐ Encrypted transmission

	☐ Identification through publication or release	☐ Aggregation levels ☐ Alternate identifiers
	☐ Identification through data-matching	☐ Use of non-linkable elements or identifiers
	☐ Loss of data control outside jurisdiction	☐ Confidentiality and security agreements for out-of-province recipients or storage providers

PART 5: DECLARATION BY PRINCIPAL INVESTIGATOR GN 5.1

(OR SUPERVISOR FOR STUDENT PROJECTS)

Project Title

- I confirm that the information provided in this application is complete and correct.
- I accept responsibility for the ethical conduct of this project and for the protection of the rights and welfare of the human participants who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of the University and Health Region/affiliated institutions where this project will be conducted, as well as with all applicable federal and provincial laws regarding the protection of human participants in research.
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- I certify that any significant changes to the project, including the proposed method, consent process or recruitment procedures, will be reported to the Research Ethics Board for consideration in advance of its implementation.
- I certify that a status report will be submitted to the Research Ethics Board for consideration within one month of the current expiry date each year the project remains open, and upon project completion.
- If personal health information is requested, I assure that it is the minimum necessary to meet the research objective and will not be reused or disclosed to any parties other than those described in the REB-approved application, except as required by law.
- I confirm that adequate resources to protect participants (i.e., personnel, funding, time, equipment and space) are in place *before* implementing the research project, and that the research will *stop* if adequate resources become unavailable.
- I understand that if the contract or grant related to this research project is being reviewed by the University or Health Region, a copy of the ethics application inclusive of the consent document(s), may be forwarded to the person responsible for the review of the contract or grant.
- I understand that if the project involves Health Region resources or facilities, a copy of the ethics application may be forwarded to the Health Region research coordinator to facilitate operational approval.

Signature of Principal Investigator	Printed Name of Principal Investigator	Date (MM/DD/YY)

Signature of Student	Printed Name of Student	Date (MM/DD/YY)

Department Head for U of S and RQHR only: The signature/approval of the Department/Administrative Unit acknowledges that he/she is aware of and supports the research activity described in the proposal.

Signature of Department Head	Printed Name of Department Head	Date (MM/DD/YY)

PART 6: ATTACHMENTS

Provide a full and accurate listing of all documents submitted with this application. GN 6.1

Please note that all applications for projects accessing or using RQHR resources will not be accepted without a completed "Part 11: Department Approvals" attachment, available online at: http://www.rqhr-rps.ca/page/reb_forms___applications/

Document	Included?	Comments
Certificate of Approval from another REB	☐ Yes ☐ N/A	
McMaster Chart Audit Tutorial certificate for all study personnel	☐ Yes ☐ N/A	
Consent Form	☐ Yes ☐ N/A	
Questionnaires, tests, interview scripts, etc.	☐ Yes ☐ N/A	
Other- please specify:	☐ Yes ☐ N/A	
Other- please specify:	☐ Yes ☐ N/A	