GUIDANCE NOTES for the Standard Research Ethics Board Application Form (Converis)
For technical instruction on how to use Converis please refer to the Converis Ethics Manual for Researchers

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General Guidance

The following Guidance Notes are intended to ensure that applicants have the necessary information to be able to fill out the Standard Research Ethics Board Application Form correctly and to construct consent and recruitment materials that meet REB standards. These procedures comply with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018).

TCPS 2 Research Requiring Research Ethics Board Review Article 2.1
The following requires ethics review and approval by an REB **before** the research commences. Research involving:

a. living human participants;
b. human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

In accordance with TCPS 2 Article 2.1, research cannot begin until the REB issues its written approval of the research project. All investigators are responsible for understanding and adhering to the TCPS 2 and other relevant guidelines. These Guidance Notes are not intended to be a substitute for this responsibility. Refer to the original documents for complete information.

The matters of greatest concern to the 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 research project. The 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 committee the steps they will take to address the concerns. Researchers are also urged to consult the TCPS 2 for more information.

The board acknowledges the variety of paradigms and methodologies currently available to researchers, and that each of these 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 to those outlined below, or to explain why a particular requirement is not appropriate in the context of a given project.

How to Use the Guidance Notes with the Converis Application Form:
The Guidance Notes are titled to correspond to a Tab and Heading in the Application Form. It is the responsibility of the researcher(s) to ensure that the information contained in the Guidance Notes is applied in a manner appropriate to each individual study for both the Application Form and any accompanying documentation. The REB requires a complete response to each question in the Application Form and must understand how each of the relevant articles of the TCPS 2 will be met.

Simply stating, for example, that the data will be kept secure is not adequate, applicants must explain the specifics of each of the measures in place to ensure the data will be secured.

Form Part 1 Tab

Title

The title given should correspond to the title listed on any funding applications, contracts, consent form(s) and recruitment material also submitted. The title of the study should accurately reflect the nature of the study.

Principal Investigator

The principal investigator (PI) is the individual who is ultimately responsible for the actions of those acting with delegated authority. They are the person responsible for the conduct of the study at a research site or the responsible leader of the team. The REB requires that all Principal Investigators be familiar with the TCPS2 and complete the TCPS 2 Course On Research Ethics (CORE) Tutorial.

The Principal Investigator for a study must notify the REB in writing when this responsibility is going to be assumed by a different researcher. PIs must also ensure that a process is put into place to ensure the ongoing safety of research participants in the event that the PI leaves or retires from their position and the study remains ongoing.

The REB will send all correspondence to the e-mail address of the PI.

Students, post-doctoral fellows, and visiting professors may serve as the PI on the ethics application with supervisor approval. In these cases, submit the Standard by Student application form. The Converis workflow will send the application to the Supervisor for approval prior to submission.

Primary Contact Person for Correspondence

If another contact besides the PI will be handling all paperwork and correspondence related to this file, please indicate here. The primary contact can initiate the REB application, however the PI will need to complete the Declaration by Principal Investigator and submit the application. The presence of a Primary Contact does not change the responsibilities assigned to the PI.

Supervisor

Include the name of the project or research supervisor. The supervisor takes responsibility for ensuring that the PI conducts the research project ethically, in accordance with the REB approved protocol. Applications submitted by a student (application type “standard by student”) will be sent to the supervisor for approval before submission.

Multijurisdictional Research

TCPS 2 Chapter 8 Multijurisdictional Research

“Research involving humans that may require the involvement of multiple institutions and/or multiple REBs includes, but is not limited to, the following situations:

a) a research project conducted by a team of researchers affiliated with different institutions;

b) several research projects independently conducted by researchers affiliated with different institutions, with data combined at some point to form one overall research project;
c) a research project conducted by a researcher affiliated with one institution, but that involves collecting data or recruiting participants at different institutions;
d) a research project conducted by a researcher who has multiple institutional affiliations (e.g., two universities, a university and a college, or a university and a hospital. See Application of Article 6.1);
e) a research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or X-ray technicians, social workers and school teachers); or
f) a research project that researcher(s) working under the auspices of a Canadian research institution conduct in another province, territory or country.

Research outside of Canada normally requires ethics review by a board or committee within that jurisdiction. Please see https://www.hhs.gov/ohrp/international/index.html to determine what process is in place in the country where the research is to take place.

Indicate whether this study is under review or has received approval from another Research Ethics Board. The project cannot begin until you receive approval from the institutions selected. It remains the PIs responsibility, however, to confirm and/or obtain necessary approvals from these sites.

Some organizations, such as school districts, health regions, etc, may require prior approval for researchers to recruit participants or conduct research through their organization. The researcher is responsible for ensuring awareness of requirements, and coordinating logistical and operational aspects of the research within the organization.

Saskatchewan REB Reciprocity
The Research Ethics Boards (REB) in the province of Saskatchewan have moved to a policy of full reciprocity. If your application has been approved by the REB of the University of Saskatchewan, University of Regina, or Saskatchewan Health Authority, that approval 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. Please note that there are criteria for determining which REB is the one that you must seek approval from (it is not necessarily your home institution), so before you begin preparing your REB application, please check in with the staff at the Office of Research Services.

Saskatchewan Health Authority – Operational Approval
If the study involves Saskatchewan Health Authority staff or facilities, (including projects recruiting participants through SHA clinics/departments) operational approval may be required. For more information about SHA's operational approval requirements and application process, visit: http://www.rqhealth.ca/department/research-and-performance/operational-approval

Please note that operational approval is not the same as REB approval and is required before commencing any research within the SHA. Even if your study is granted an exemption from the REB as being quality improvement or program evaluation, there still may be operational requirements that need to be met (e.g., to ensure compliance with HIPA legislation).If you have questions about SHA's operational approval process, please contact the research approval coordinator at (306) 766-0893 or ResearchApproval@rqhealth.ca<mailto:ResearchApproval@rqhealth.ca>.

TCPS2 Critical Inquiry Article 3.6

In critical inquiry, permission is not required from an institution, organization or other group in order to conduct research on them. If a researcher engages the participation of members of any such group without the group's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.

Funding Detail

Source of funds refers to the agency/sponsor of the proposed research, internal or external, that will be providing the funds needed to undertake the project. Many external funding agencies have requirements whereby the Office of Research Services must ensure that ethical approval is obtained prior to contact with participants. Some funders may have requirements outlined in contracts or funding guidelines that could impact participants (for example sharing of data) which will need to be reviewed with respect to ethical issues such as participant confidentiality or intent to commercialize. Funding related agreements must align with the REB application and all materials provided to participants.

Funding which has been applied for through, or held by the University of Regina is recorded in the Grant Management Module of Converis. If you cannot locate or link the funding, indicate the name of the source of funds, title of the finding program (if available), and whether or not the funds have been awarded. If funding changes, e.g. addition, deletion or change of sponsor, during the course of research, an amendment must should be submitted.

The name of the funding organization and or program must be included on the Consent Form.

Overview of the Research Project

Describe the project, its objectives and potential significance.
Provide a short summary of the research project written in lay language and suitable for REB members from different disciplines or community members. It should include a description of the research being proposed and the potential significance.

Specify the research questions and methodology being evaluated in the project.
Include a description of the target population and/or sample, sample size, sampling method (e.g. randomization), and type of research design (e.g. experimental parallel group or cross-over design).
Include a justification for the use of deception or placebo or for the need to carry out research in emergency health situations, if applicable.
Include a brief description of the intended analyses, and if appropriate, who will be responsible for conducting them. That is, if the statistical expertise is not present on the research team and an external consultant will support the analyses, this should be stated.

Specify which procedures are research-related and how they differ from standard care. This information must be explained in the consent form in such a way that the participant understands how participating in the research may be different from the treatment normally received with standard care.

Methods

Some specific methods are identified as they impose specific ethical considerations or possible alterations or further considerations to the processes of obtaining free and informed consent.

Questionnaire

Provide details regarding the distribution and collection of the questionnaire. If an online survey will be used provide the survey link as well as a PDF of the questionnaire. This allows the reviewers to review factors such as forced responses, collection of identifiable information.

Qualtrics

To collect identifiable information separately from their responses from survey participants in Qualtrics (eg for reimbursement) see the instructions for creating an anonymized raffle.

For Qualtrics surveys with gift cards (not a draw)

Qualtrics provides Captcha support, which is a simple task designed to separate humans from bots: Consider using a captcha verification step previous to the survey to help filter bot responses.

Additionally, researchers can prevent additional online survey responses by requesting respondents not to participate more than once and stating that participants will only be compensated once for their participation.

Surveys that involve a broad sampling or census of a population of current and prospective students, alumni, staff and other stakeholders of the University of Regina may fall under the UofR Survey Policy. Please review the Survey Policy or contact the Office for Resource Planning.

Individual Interviews

If interviews will be recorded, describe how, if they be transcribed and by whom. Will transcripts be returned to participants, and if so, how will this be done in such a way that participant confidentiality is maintained? If software will be used, consider the security of the platform used. This can be further addressed in the "Use of Internet" section of the Application Form.

Describe where the interviews will take place (in person, via telephone, videoconference, including any software platforms that will be used. Include the security measures that will be in place. For example, a closed room with a door for privacy. If you are using zoom, address how you will address the guidance provided in the University of Regina Guidelines for Using Zoom

Group Interviews & Focus Groups

The REB application and consent materials should address limitations to the confidentiality of participants and withdrawal of participant data after it has been collected. Consider using the following language:

Focus Group Data Withdrawal

Your participation is voluntary and you may answer only those questions that you are comfortable with. You may withdraw from the research project for any reason, at any time without explanation or penalty of any sort. Should you wish to withdraw, you may leave the focus group at any time.

Due to the nature of focus groups your data cannot be withdrawn from the study after it has been collected as it forms part of the context for information provided by other participants.

Focus Group Confidentiality

When conducting focus group research, there are limits to which you, as the researcher, can guarantee the discussion will be kept confidential. A disclosure such as the following is therefore appropriate under these circumstances: "The researcher will undertake to safeguard the confidentiality of the discussion, but cannot guarantee that other members of the group will do so. Please respect the

confidentiality of the other members of the group by not disclosing the contents of this discussion outside the group, and be aware that others may not respect your confidentiality."

Video Recording & Audio Recording

If there are any plans to use photography (including digital photographs), video or audio recording in the research, those who will have access to the recordings and the methods used to protect the participant's identity must be described in the consent form. The eventual fate of the records must also be disclosed (i.e. where and for how long they will be stored and whether they will be destroyed, any plans for secondary uses of the recordings). If there are plans to use these materials for any other purpose than the research project (e.g. for teaching purposes) and the participant could be identified, separate consent is required.
If the research includes both audio/visual recording and other methods (e.g., paper-and-pencil questionnaires, interviews), the consent form must specify to which method(s) the respondent is consenting; e.g., some participants may consent to give an interview, but not to having it recorded.

Participant Observation

Naturalistic Observational
TCPS2 Article 2.3
Non-participant observational research is the study of human acts or behaviours in a natural environment in which people involved in their normal activities are observed with or without their knowledge by researchers who do not intervene in any way in the activity (also known as "naturalistic observational research").
REB review is not required for research involving the observation of people in public places where:
a. it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
b. individuals or groups targeted for observation have no reasonable expectation of privacy; and
c. any dissemination of research results does not allow identification of specific individuals.
Participant Observational Research is the study of human acts or behaviours in a natural environment in which people involved in their normal activities are observed with or without their knowledge by researchers who participate in some way in the activity. Participant observational research generally does not meet condition (a) of Article 2.3, as there is interaction with the individuals or group being studied.

Experiment

Physical Measurements

Ethnography

The people being studied have a right to know that they are being studied, what the research is about, what is required of them, and that they have a right not to be researched. Participant observation studies that do not meet the above standard are still possible as long as the relevant group approves the project. For example, visiting a remote indigenous community may require the approval of the community council or appropriate authority rather than the approval of each individual. The REB also acknowledges that in some cases it may not be possible to obtain the appropriate approvals prior to arriving at the research site and establishing relationships with members of the community. Fieldworkers need to be specific in their application by outlining their approach to obtaining approval either prior to, or once in, the field.

The REB recognizes that some anthropological fieldwork is necessarily exploratory in nature. Research methods may need to be altered in the field and information gathered may fundamentally alter the focus of the research. Much anthropological research is based upon long-term relationships developed between researcher and the community being studied, and will therefore evolve over time. Also, the demands of the collaborative research model are such that researchers planning to undertake this type of research cannot have a defined agenda before establishing relationships with the people with whom they intend to work.

The researcher should describe the type of consent process he/she intends to use and explain why it is the most appropriate method. For example, an oral consent process is clearly necessary in non-literate cultures, with illiterate participants, or where participants perceive a request to sign a formal document as a risk, a lack of trust, or an insult. In the application for ethical review the researcher must, where possible, demonstrate knowledge of the community and its expectations regarding consent and the behaviour of the researcher. If this is not possible, the researcher should outline how he/she plans to determine the appropriate form of consent once in the field.

Other

Autobiography

Autobiographical research should consider the personal information of second or third parties that may be mentioned in the narrative. The researcher should consider methods to maintain other individual's confidentiality such as coding or the use of pseudonyms. If there are no other people interviewed or named in the narrative, ethical review is not required.

Photovoice

Photovoice is a participatory action research method that employs photography and group dialogue as means for marginalized individuals to deepen their understanding of a community issue or concern. The researcher should describe plans to establish community relationships, educate participants about camera use, obtaining third party consent, limits to confidentiality, participant involvement in data analysis and the planned use of these materials. The consent and information provided to participants should clearly articulate their roles and responsibilities. Participants will take the role of photographer so they have the responsibility for capturing photos and third party consent of individuals in photos.

Action Research

University of Regina Action Research Guidelines

Action research involves researchers investigating their own practice where dual relationships exist between the researcher and participant. When the relationship involves individuals of lesser power or status than the researcher, such as the researcher's students, employees, inmates or clients, there is a potential for coercion.

Compensation

TCPS2 Article 3.1

Incentives are anything offered to participants, monetary or otherwise, for participation in research, and differ from reimbursements and compensation for injury. Where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks. The onus is on the researcher to justify to the REB the use of a particular model and the level of incentives. In considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and decision-making capacity of participants, the customs and practices of the community, and the magnitude and probability of harms.

The participant should not suffer any disadvantage or reprisal for withdrawing, nor should any payment due prior to the point of withdrawal be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

See the following guidelines:
UofR Procedures for Cash and Cash Equivalents as Compensation to Research Participants
Guidelines for Participant Parking on University of Regina Campuses

As per UofR Gift Giving Policy, gift cards can never be given to employees of the University.

Participants may be duly compensated for time spent participating in the study. When participants represent a particular profession, compensation per time spent may be appropriate.

Entry into a draw is considered an acceptable form of remuneration.

Specify the form and amount of compensation as well as the justification for the amount of compensation to be offered to participants. Include any specific details about the reimbursement of expenses related to transportation and parking and when these will be paid.

Deception

In some studies the quality of the data depends on the participants being unaware of the true research goal. A consent procedure that is not fully informed may be allowed as long as the tasks that the participants will be asked to perform are clearly described and the deception is revealed and explained to participants at the earliest opportunity.
Misleading or misinforming people of the nature, objectives or consequences of research must always be explained and justified.
For such techniques to fall within the exception to the general requirement of full disclosure for consent, the research must meet all the requirements of TCPS2 Article 3.7A Alterations to Consent Requirements:

a. the research involves no more than minimal risk to the participants;
b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
c. it is impossible or impracticable (see Glossary) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
e. the plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article TCPS2 3.7B Debriefing in the Context of Alterations to Consent Requirements

a. Debriefing must be a part of all research involving an alteration to consent requirements (Article 3.7A) whenever it is possible, practicable and appropriate.
b. Participants in such research must have the opportunity to refuse consent and request the withdrawal of their data and/or human biological materials whenever possible, practicable and appropriate (Article 3.1).

Deception by omission: Some part of the purpose of the experiment or nature of the task is not revealed to the participant. For example, a reaction time task that purportedly measures eye-hand coordination but also implicitly measures logical reasoning ability.
Deception by commission: A cover story masking the real purpose of the experiment is given to participants. For example, participants in a study that is investigating the impact of racist attitudes are told they will be involved in testing a new job interview procedure.

Minor deception: Withholding specific points of interest in an attempt to prevent a bias in the results is usually considered minor deception. For example, a study of memory may not reveal to participants that they are specifically being tested on their ability to remember something.

Major deception: Leading participants to believe that they have committed a crime or failed an exam are examples of major deception. Deceptions of this magnitude must be clearly counterbalanced by the benefits of the research and participants must be carefully debriefed.

Deception is considered a risk, as it can negatively impact on a participant's feelings of trust in the study, the researcher, the institution and research in general. Therefore, whenever deception is to be used, it is important that debriefing be done so as to provide the participant with an opportunity for real informed consent. The participant should also be re-consented, or asked whether they wish to have data withdrawn, after debriefing.

Confidentiality

The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and participant, and to the integrity of the research project.
Researchers and REBs shall consider whether information proposed for use in research is identifiable. The following categories provide guidance for assessing the extent to which information could be used to identify an individual:

- Directly identifying information – the information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).
- Indirectly identifying information – the information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).
- Coded information – direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants' code names with their actual names so data can be re-linked if necessary).
- Anonymized information – the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.
- Anonymous information – the information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

Ethical concerns regarding privacy decrease as it becomes more difficult (or impossible) to associate information with a particular individual. These concerns also vary with the sensitivity of the information and the extent to which access, use or disclosure may harm an individual or group.

TCPS2 Article 5.1
Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality.

Include in the REB application any limitations to confidentiality, how they will be mitigated and ensure these are explained clearly through the consent process.

Risk and Benefit

Harm is anything that has a negative effect on the welfare of participants, and the nature of the harm may be social, behavioural, psychological, physical or economic.

Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties. A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk.

- The magnitude or seriousness of the harm
- The probability of occurrence of the harm

TCPS2 Article 2.10 Research Attributable Risk
When describing the foreseeable risks and potential benefits of research involving participants who are also exposed to other risks, researchers should clearly distinguish between the risks that are attributable to the research, and the risks to which participants would normally be exposed.
In their evaluation of risk, REBs should evaluate those risks that are attributable to the research.

Minimal Risk research is defined as 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.

Participant Vulnerability in Research
REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability (TCPS2 Article 4.7)

Possible risks include: clinical diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, and socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of duty to report intent to cause serious harm, subpoena, or breach of confidentiality).

Biomedical Research
Researchers should quantify the foreseeable risks of harms (side effects) or inconveniences (discomfort or incapacity) to the participant associated with each procedure (including radiation risks from x-rays), therapy, test, interview, or other aspect of the project. Include information about the seriousness and consequences of the different types of adverse events that have been observed, as well as the

probability of these events occurring. Quantification of these harms should emphasize the INCREMENTAL risk with the experimental intervention as compared to placebo or no treatment, wherever possible.
The Board requires numerical (usually percentage) quantification of risks wherever possible. Qualitative terms such are "rare", "common", "infrequent" are not acceptable unless quantitative ranges are explicitly attached to them. Quantifiers such as ">5%" are similarly not acceptable since they do little to define the magnitude of risk.

It is helpful to list risks in descending order of frequency and/or group them according to category of risk (e.g., by magnitude, severity, organ system). See the example of categories provided below.

1. Very Common (50% or greater)
2. Common (20% to 50%)
3. Less Common (5% to 20%)
4. Uncommon (2% to 5%)
5. Rare (Less than 2%)

Where no percentages are available, specific discussion about risks encountered in case series/case reports, preclinical projects, or projects involving similar procedures are required. If absolutely no relevant data about harms of the experimental procedures is available (e.g., a Phase I trial), Investigators are required to make their best effort to honestly inform participants about possible risks of participating in the research, even if they can't be quantified. This quantification can be in the form of "for thirty participants, five experienced a particular side effect." This information must always be included in the consent form.

Include an explanation that unanticipated side effects, including severe or irreversible ones, could occur if a novel combination of drugs is being tested, even if the individual drugs are not expected to have these side effects.

Management of Risk
Describe the precautions that have been taken to manage/minimize each risk: (e.g. reporting side effects to the investigator, rescue medication, early withdrawal from the project). If the protocol has the potential to upset, distress or harm individuals, arrangements to mitigate such effects and the provision for support must be described.
The researcher must, at the outset, advise the participant what support services are available (e.g. University Counseling Services, referral to an appropriate agency or medical clinic). Whenever possible, the researcher is urged to determine optional services that may be voluntary (e.g. the family physician, other appropriate government/community based agencies) versus fee-for-service options.

Benefits
Specify the potential benefits to the participants. If there are no benefits, this should be clearly stated to participants in the consent process. If benefits at a community or society level are expected, these should be mentioned. The proportionate approach to ethical review requires that a project have favourable balance of risks and benefits in order to receive REB approval.

Relationship Between Research Ethics Review and Scholarly Review
TCPS 2 Article 2.7 As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research.

Application
The primary test to be used by REBs in evaluating a research project should be ethical acceptability and, where appropriate, relevant disciplinary scholarly standards. The extent of the scholarly review that is required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out. Research in the humanities and the social sciences that poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed.

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.

Peer reviews conducted by granting agencies or by Health Canada, for investigational drugs or devices, are considered to be acceptable types of 'external' peer review. Any review process conducted within a for-profit agency is not considered to be independent. For graduate student research, the approval of the supervisory committee will be deemed sufficient.

If a peer review has not been conducted, and the project involves more than minimal risk to participants, explain why this is the case. Note that the REB may request an independent peer review, which could slow down the REB application process.

Form Part 2 Tab

Use of Internet

TCPS 2 Chapter 5 Safeguarding Information
Research data sent over the Internet may require encryption or use of special denominalization software to prevent interception by unauthorized individuals, or other risks to data security. In general, identifiable data obtained through research that is kept on a computer and connected to the Internet should be encrypted.

Describe all platforms where the interaction, communication, etc will take place. Identify the third party owner and the plans for obtaining permission to use data gathered from the site.
Describe the security provisions of the internet interaction or website to maintain the confidentiality of participants' responses. This may include encryption during storage and transmission, server security, and informing participants to remove "cookies" from the computer. Researchers should check the service provider to understand the type of security provisions that they offer. Any potential security limitations should be described to potential participants so they understand the level of privacy protection. Unless using an encryption device, the researcher should assume mail on the internet is not secure.

A potential statement that may be used to describe limits to confidentiality:
This web-survey company, the host of this on-line research, is located in the USA. This company is subject to U.S. laws that allow authorities access to the records of internet service providers. The web survey company servers record incoming IP addresses - including that of the computer that you use to access the survey. However, no connection is made between your data and your computer's IP address.

If you choose to participate in the survey, you understand that your responses to the survey questions will be stored and accessed in the USA.

Clinical Trials

Investigators conducting clinical trials involving either investigational drug(s), device(s), or natural health products formulated for therapeutic purposes OR involving a drug/device/natural health product used for an indication outside those specified in the Health Canada Drug Identification Number, Notice of Compliance or Medical Device License must submit the appropriate application for regulatory approval to Health Canada before research can begin.

It is the duty of the principal investigator to be certain that Health Canada has issued a No Onjection Letter (NOL) before the project begins enrollment. These regulations apply to clinical trials for both new investigational drugs and some marketed drugs. The use of a marketed drug outside of its approved indication requires Health Canada approval for use in a clinical trial (whether investigator or industry initiated).

All clinical trials, including Phase IV trials, must be conducted in accordance with good clinical practices as specified by ICH Good Clinical Practice Consolidated Guidelines. However Phase IV clinical trials are not participant to the Clinical Trial Application filing requirements with Health Canada.

The International Committee of Medical Journal Editors (ICMJE) require registration for all clinical trials as defined by "Any research project that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes". Health-related interventions include any intervention that modifies a biomedical or health-related outcome (e.g., drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational projects (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.
Assistance with the registration of a clinical trial is provided by the Office of Research Services.

Indigenous Research

Researchers conducting research that meets any of the following 5 criteria must consider and address each article of Chapter 9 of the TCPS 2 Research Involving the First Nations, Inuit and Métis Peoples of Canada

a. research conducted on First Nations, Inuit or Métis lands;
b. recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study;
c. research that seeks input from participants regarding a community's cultural heritage, artefacts, traditional knowledge or unique characteristics;
d. research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data; and
e. interpretation of research results that will refer to Indigenous communities, peoples, language, history or culture.

Research with First Nations People or their data must apply the First Nations Principles of OCAP® and should complete the Fundamentals of OCAP Course.

TCPS 2 Article Timing of the Research Ethics Board Review 10.1
REB review is not required for the initial exploratory phase, which is intended to establish research partnerships or to inform the design of a research proposal, and may involve contact with individuals or communities.

Community Based Participatory Research

Participant Recruitment

TCPS 2 Consent Should Be Given Voluntarily Article3.1
The approach to recruitment is an important element in assuring voluntariness.

TCPS 2 Appropriate Inclusion Article 4.1
Taking into account the scope and objectives of their research, researchers should be inclusive in selecting participants. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age, unless there is a valid reason for the exclusion.

Describe the participants the inclusion, and the exclusion criteria.
Provide the criteria for inclusion and exclusion of participants. Provide a justification if participants are included or excluded on the basis of such attributes as culture, language, religion, race, mental or physical disability, sexual orientation, ethnicity, gender or age.

Provide the number and justification for the number of participant as well as any sex and gender considerations (with rationale).
Indicate what the study's total enrollment will be (i.e., globally across all sites) and how many participants are expected to be recruited at the local site.

Describe how you will obtain contact information for the participants, and if applicable who originally collected the contact information.
Indicate how participants are identified and initially contacted to participate in a research study. In particular, this information should include a description of the source (i.e. its original purpose, if relevant) of the contact information and an explanation of who you will obtain permission from in order to access this information.

Ethical Guidelines for Snowball Sampling

Canada's Anti-spam Legislation
Spam has become a significant social and economic burden in Canada and around the world. The simplest definition of spam is unsolicited email, though it can also include unsolicited text messages and software. The legal definition of spam also encompasses: unauthorized alteration of transmission data; the installation of computer programs without consent; false or misleading electronic representations (including websites); the harvesting of addresses (collecting and/or using email or other electronic addresses without permission); the collection of personal information by accessing a computer system or electronic device illegally

Health Information Protection Act (HIPA)

Identifying and Contacting Prospective Participants from Primary Health Care Provider Records
In some situations, the prospective participant's primary care (i.e. family doctor) physician (or other primary health care provider) holds the participant's personal contact information. In this case, permission to use the contact information must be obtained from the participant by the primary care physician before the Investigator can use the information for recruitment purposes. The primary care physician must either verbally ask the prospective participants' permission to release their names to the Investigator or distribute an introductory letter describing the project to the prospective participants, with details on how to contact the Investigator if they are interested in participating.

Information Held by Disease Specific Registries
Participants who have previously consented to be included in a registry for research purposes and this consent included contact for future research projects must first be contacted by mail vis a vis the contact information included in the Registry. The letter must explain how their contact information was obtained in addition to the purpose of the contact.

Note that private practice physicians fall under the provisions of the Saskatchewan Health Information Protection Act (HIPA). Section 29 of the Act regulates the disclosure by physicians of personal information for research or statistical purposes. Section 29 sets out the rules under which trustees can use or disclose personal health information. It requires all research proposals to be approved by a recognized Government of Saskatchewan research ethics committee, and whenever practicable, the consent of the individual received.

Provide a detailed description of the recruitment process.
Describe how potential participants will be identified.
Describe who will make the initial contact with the prospective participant, how the prospective participant will be initially contacted; when the prospective participant will be initially contacted, and the manner in which it will be done.

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.
Provide a brief description of the research team's experiences and/or ability to conduct the research. This could include your familiarity with the proposed population(s) and the research topic or issues. If the researcher is a student, the degree of supervision, by the faculty supervisor and/or on-site supervisor should be included.

Dual Role of Researchers
TCPS 2 Researchers and Conflicts of Interest Article 7.4
Dual roles of researchers and their associated obligations (e.g., acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures.

The relationship, whether pre-existing, current or future, should be described.

Special care needs to be taken during the initial contact when the Investigator is in a fiduciary relationship with prospective research participants. For example, whenever the relationship between the Investigator and research participant is such that coercion could be perceived to be a factor (e.g.,

when the Investigator is a teacher, or providing medical care to a prospective participant), non-coercive means for inviting participation should be used. A typical example of the latter would be posting notices to invite volunteers from the entire group concerned, for example, in the waiting room of the medical clinic. Or involving a third party in the recruitment and consent process. The physician/care provider must make the distinction between "medical care" and "research".

The REB permits project nurses/co-ordinators who co-ordinate projects out of a medical clinic to make direct initial contact with a prospective participant who is attending that clinic for patient care or for research purposes. The project nurse must identify his/herself and the relationship to the clinic/medical department at the time of contact with the prospective participant.

Recruitment Attachments

The REB will review advertising to assure that it is not unduly coercive and does not promise a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol. This is especially critical when a project may involve participants who are likely to be vulnerable to undue influence.

Any advertisement, e-mail, letters, notices, posters, radio spots, brochures, etc. for purposes of information or recruitment or to advertise a research project and aid in recruitment must be submitted to the REB for review and approval.

Materials must not promise any advantages or benefits of participation that are not supported by the approved protocol and the participant information and consent form material. No claims should be made, either explicitly or implicitly, that any study drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.

Advertisements aimed at recruitment must clearly and concisely state:

i. The nature and purpose of the project, and that it is research

ii. Who is eligible to participate (and who is not)

iii. The time or other commitment required of research participants

iv. An affiliation with a bona fide medical practice or medical research center (e.g., this project is being conducted by "_____" in the Department of "_____").

v. How to obtain further information

4. Advertising for recruitment into investigational drug, biologic or device projects should not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article is investigational. A phrase such as "receive new treatment" implies that all project participants will be receiving newly marketed products of proven worth.

5. Advertisements should not promise "free medical treatment" when the intent is only to say research participants will not be charged for taking part in the investigation. Advertisements may indicate that participants will be reimbursed for certain expenses, and may receive payment at a reasonable level for participation, but these payments should not serve as an inducement to participants to participate in the project.

6. Recruitment materials issued by the sponsor on a global platform (internet, television, radio, national newspapers, etc. should provide contact information for a local investigator whom potential research participants may contact. A copy of the telephone script (if applicable) should be provided. Assurance concerning the protection of individual privacy and data confidentiality must also be provided.

7. Use of the University of Regina Logo Is recommended but not mandatory on all advertisements for those investigators who are affiliated with the University.

E-mail and Letters

E-mail and letters used for initial contact purposes may be followed by a telephone call. In this situation, the letter must explain when the telephone call will occur, such that there is a reasonable length of time between receiving the letter of invitation by mail and the follow up telephone call. It is preferred that the initial contact letter be accompanied by the full consent form so potential participants can be more informed and prepared for the subsequent telephone contact.

Scripts

The first contact prospective project participants make is often with a person who follows a script to determine basic eligibility for the specific project. In some cases, personal and sensitive information is gathered about the individual. The REB should have assurance that the information will be appropriately handled. A simple statement such as "confidentiality will be maintained" does not adequately inform the REB of the procedures that will be used. Examples of issues that are appropriate for REB review are:

- What happens to personal information if the caller ends the interview or simply hangs up?
- Are the data gathered by a marketing company? If so, are names, etc. sold to others?
- Are names of those who are non-eligible maintained in case they would qualify for another project?
- Are paper copies of records shredded or are readable copies put out as trash?

The acceptability of the procedures would depend on the sensitivity of the data gathered, including; personal, medical and financial.

Consent

TCPS 2 Consent Shall Be Given Voluntarily Article 3.1

a. Consent shall be given voluntarily.
b. Consent can be withdrawn at any time.
c. If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

TCPS 2 Consent Shall Be Informed Article 3.2

Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project.

The information generally required for informed consent includes:

a. information that the individual is being invited to participate in a research project;
b. a statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant;
c. a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;
d. an assurance that prospective participants:
    - are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements;
    - will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
    - will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

e. information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors;
f. the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
g. the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
h. the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
i. an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants; a description of how confidentiality will be protected (Article 5.2); a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;
j. information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
k. a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
l. in clinical trials, information on stopping rules and when researchers may remove participants from trial.

Study Results
It is important that participants have access to study findings. For some populations, it may not be appropriate for dissemination of results to only be accessible in a scholarly journal article format. Please describe the format by which participants can access findings (newsletter, website, copy of thesis material, etc.), and how they will be notified of this.

TCPS 2 Consent Shall Be an Ongoing Process Article 3.3
Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

TCPS 2 Incidental Findings Article 3.4
Within the limits of consent provided by the participant, researchers shall disclose to the participant any material incidental findings discovered in the course of research

TCPS 2 Consent Shall Precede Collection of, or Access to, Research Data Article 3.5
Research shall begin only after the participants, or their authorized third parties, have provided their consent.

TCPS 2 Consent Shall Be Documented Article 3.12
Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.

Consent Waiver
TCPS 2 Alterations to Consent Requirements Article 3.7A
The REB may approve research that involves an alteration to the requirements for consent set out in Articles 3.1 to 3.5 if the REB is satisfied, and documents, that all of the following apply:
a. the research involves no more than minimal risk to the participants;

b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants;
c. it is impossible or impracticable (see Glossary) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required;
d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and
e. the plan to provide a debriefing (if any) that may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.

Consent must be obtained in such a way that prospective participants have adequate time between the initial contact and the actual consent phase to consider whether or not they wish to participate. Consider ways that the consent information can be sent in advance, for example a link provided on recruitment materials.

The purpose of a consent process is to provide adequate information to enable a person to make a rational, informed decision as to whether he/she wishes to participate in the research study, or not. Informed consent is an on-going process that starts with the researcher's first contact with the individual and continues through study completion/subject withdrawal, and beyond. Any verbal exchange about the study, the written informed consent form and any other written documentation given to participants should provide adequate information for the participant to make an informed decision about his/her participation
In certain circumstances, signed written consent is not appropriate. Some examples when it may not be appropriate to use written consent are: (a) when it is culturally inappropriate, (b) when the participant is illiterate, (c) there is a potential risk to the participant. The procedures used to seek and confirm consent must be documented.

Renewal of consent may be appropriate in the context of ethnographic research, community-based research or those studies where participants are interviewed or surveyed on multiple occasions.

Telephone Surveys:
If a researcher is conducting a telephone survey, informed consent should take the form of a verbal explanation of the same points covered by written consent. The researcher's name and University affiliation, the purpose of the study, the fact that participation is voluntary, the time commitment being requested, and the manner in which confidentiality or anonymity will be guaranteed should be described.
Any combination of the other items on the consent form that might be relevant should also be included. Respondents can give verbal indication of their consent to participate; this should be documented in the researcher's research records.
For telephone surveys of this type, the "script" that provides the above information must be submitted in the application package.

Implied consent:
Implied consent is sometimes used in circumstances where the research risk is low and the researcher does not physically interact with the participant. This is commonly used in survey research, either internet or paper based. An information section should precede the survey outlining the elements of consent.

COMPETENCE

In Canada, there is no definitive age below which parental/guardian consent is required in order to participate in research. The age of majority in Saskatchewan is age 18. Whenever children (under 18 years of age) are to be included as participants, the researcher must consider the risk of the research, the maturity level of the children, and any potential risks versus benefits associated with parental knowledge of the research (e.g. research looking at drug use in youth).

Adolescents that do not live with their parents can consent for themselves. Similarly, university students are considered to be adults, whether or not they live out of the home.

If an adult participant is not competent to formally consent, a surrogate decision maker can do so. However, the research should be explained to the participant, and they should be given the opportunity to provide assent or dissent.

Assent: Assent means to concur with the decision of another, whereas "consent means to provide permission". Assent, from children or those individuals who lack the capacity to consent for themselves, should also be obtained, as even very young children can be made to understand simple explanations of what the research involves and determine whether they want to participate or not.

Capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. This ability may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought.

TCPS 2 Article 3.9

For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

a. The researcher involves participants who lack the capacity to decide on their own behalf to the greatest extent possible in the decision-making process.
b. The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned.
c. The authorized third party is not the researcher or any other member of the research team.
d. The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research.
e. When authorization for participation was granted by an authorized third party, and a participant acquires or regains decision-making capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

The TCPS 2 states that capacity to consent consists in "the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate. There are thus two thresholds or tests that must be met to establish capacity to consent: capacity to understand, and capacity to appreciate one's decision. Understanding is the ability to discern in significant measure the nature of the research and the consequences of choosing/forgoing participation in it. Appreciation is the ability to give reasons

for participation that reflect, or are consistent with, the prospective participant's own fundamental values. It assumes adequately developed adult capacities for forming and revising personal values.

The Principal Investigator must judge the potential participant's ability to consent to research on his or her own behalf, in all patients, in all research projects, regardless of the prospective participant's age.

Those who lack the capacity to consent on their own behalf should be informed and involved in decision making with respect to their participation to the extent possible. These participants may not be able to participate in research if they dissent or do not assent, even though third party consent has been obtained.

The determination of capacity to participate in research, then, is not a static determination. It is a process that may change over time, depending on the nature of the decision the prospective participant needs to make, and on any changes in the participant's condition. Assessing capacity is a question of determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it. Capacity must be assessed not only at the time of obtaining initial consent but also must be assessed on an ongoing basis throughout the duration of the project. Should an authorized representative of the participant consent on behalf of a participant, the principal investigator or delegated representative is also obligated to assess that representative's capacity to consent.

Types of participants who may fall into this category include:
1.Individuals with permanent or transient cognitive impairments (e.g. participants with Alzheimer's Disease, participants who are sedated/ventilated; participants with a variable/permanent mental illness);
2. Children who do not yet meet the tests for competency.

TCPS Article 4.6 states that for individuals who lack capacity to consent to participate in research, the investigator shall satisfy the REB that:
1."The research question can be addressed only with participants within the identified group;
2.The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
3.Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong."

WITHDRAWAL
What actions constitute withdrawal should be listed. This may include actions of non-compliance by the participant, leading the researcher to withdraw the participant from the study. If participants cannot withdraw after a certain point for any reason (e.g. de-linking of data), this should be explained.

Data Security and Storage

(TCPS2 Articles 5.1 safeguard information, 5.2 describe measures for meeting confidentiality obligations, 5.3 safeguarding information over the full life cycle of information)

Research records must be recorded or preserved in accordance with the highest standard of scientific and academic practice and procedures. Research records are those documents and other records and materials recorded by or for an investigator that are necessary to document, reconstruct, evaluate, and validate research results and the events and processes leading to the acquisition of those results. Research records may be in many forms including but not limited to laboratory notebooks, survey documents, questionnaires, interview notes, transcripts, machine-generated data or performance outputs, recruitment materials, consent forms, correspondence, other documents, computer files, audio or video recordings, photographs including negatives, slides, x-ray films, samples of compounds, organisms (including cell lines, microorganisms, viruses, plants, animals) and components of organisms.

The PI is responsible for the collection, maintenance, privacy, and secure retention of research records in accord with these procedures and applicable privacy legislation. The PI should also ensure that all personnel involved with the research understand and adhere to established practices that are consistent with these procedures.

IMPORTANT NOTE: Unless your data fits the definition of 'anonymity' provided in the TCPS, it is usually more appropriate to promise confidentiality than anonymity.

Personal health information is considered to be any information about an individual's physical or mental health gathered in the course of providing a health service. It includes personal health information on computers, in paper files, on microfilm, on x-ray film, and anywhere the personal health information is stored by a data trustee. Examples of personal health information include health background, health care provider's name, MRN, HSN, medical history, lab test results and X-rays, doctor/nurse notes, or medical diagnosis. Sources of personal health information may include a medical record held by a physician, a patient record held by a hospital, registration information held by the Department of Health to register individuals for insured services, information about lab tests being performed for an individual, or records of prescriptions filled by a pharmacist.

ACCESS TO IDENTIFIABLE PERSONAL HEALTH INFORMATION
Participant Enrolment Logs, documents or databases, which correlate participant names with project code numbers, must be kept on the locked premises of the Principal Investigator or in an appropriately secured electronic form. They should be stored separately from any of the other data. The names of project personnel who are provided with this access must be disclosed.

Personal and health information being used for research purposes may be collected prospectively or gathered retrospectively.

As with all research and other activities, assuring patient privacy and confidentiality is of utmost importance. Privacy risks arise at all stages of the research life cycle, including initial collection of information, use and analysis to address research questions, dissemination of findings, storage and retention of information, and disposal of records or devices on which information is stored. As a result, it is the responsibility of the principal investigators and associated research personnel to maintain patient confidentiality of all information to which they are privy in the context of their research activities. Specifically, this requires that participants not be identified in any way in all research reports and/or documents generated through the research activity (e.g., no names, initials, or unique identifiers). In addition, it is the responsibility of all investigators and research personnel to be familiar with the Freedom of Information and Protection of Privacy Act (FOIPPA) and other relevant legislation and requirements concerning confidentiality.

When it is not possible to anonymize research related records (i.e. anonymity is defined as the removal of all personal identifiers from a participant's records), the use of a unique project code or scrambled initials is considered acceptable by the REB.

The REB expects that research-related documents (except the master randomization schedule, consent forms, or screening logs) do not include information that would allow the participant to be identified.

Information is considered de-identified if the following conditions are met:

- The unique project code is not derived from or related to the information about the individual;
- The unique project code could not be translated to identify the individual; and,
- The investigator or their institution could not use OR disclose the unique project code for other purposes OR disclose the mechanism for re identification.

It is not necessary to use a personal identifier (for example, birthdate) as a secondary identifier in order to confirm the identity of the participants. This can be accomplished by using any two unique identifiers.

Access to Identifiable Project Logs
Participant Enrolment Logs, documents or databases, which correlate participant names with project code numbers, must be kept on the locked premises of the Principal Investigator or in an appropriately secured electronic form. They should be stored separately from any of the other data.

Disclosure of Information
Include information on what measures are taken to prevent unauthorized access to the research data.

Include information on the provisions in place to protect the anonymity of data when it is transferred to other project institutions outside of the local institution (e.g. countries outside of Canada, institutions in other parts of Canada).

Will there be a key linking participant names and numbers?
Documents or files that link de-identified data to their primary source must be stored separately from the project data.

According to TCPS Article 5.7, “Investigators who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information... The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage. Where data linkage involves or is likely to produce identifiable information, investigators shall satisfy the REB that:

1. The data linkage is essential to the research; and
2. Appropriate security measures will be implemented to safeguard information.”

Only a restricted number of individuals should perform the function of merging databases, and investigators should use enhanced security measures to store the merged file. Where investigators seek access to datasets held by another organization, it may be preferable for the data holder to carry out data linkage and remove identifiers beforehand. Legislation and organizational policies may regulate data linkage in specific circumstances. Data holders, such as statistics agencies, may also have policies on data linkage.

Person responsible for data storage.
When an investigator leaves the institution, she or he may take a copy of the research records related to her or his research. If a PI leaves the institution or a project is to be moved to another institution, the institution must be notified of the location of the original research records. In some instances (e.g., where institution intellectual property or other interests are involved), such transfer may not be permitted, and any such agreement may require diligent retention by the recipient and continued access by the institution. The obligations of investigators set out in these procedures continue to apply if an individual takes copies of research material to his/her new institution.

How will data be secured during transportation from collection site (e.g. physical, electronic, downloading from 3rd party platforms)?
Research data sent over the Internet may require encryption or use of special denominalization software to prevent risks to data security, such as interception by unauthorized individuals.

What steps will be taken to ensure the security of data while in use (eg. Password protected, Passwords/screen timeouts, Firewall/virus protection)
For each type of data, outline the security measures that will be used

How will data be securely shared among members of the research team?
The University recommends the use of Filr, if using other platforms please describe the security measures used by the platform.

Describe the means and location of storage of each format (paper, electronic etc) of data (e.g. a locked filing cabinet, password protected computer files, encryption).
In general, identifiable data that is kept on a computer and connected to the Internet should be encrypted.
All research documents must be securely stored in a specified area (e.g., in a locked filing cabinet located in the principal investigator's hospital office.).
Describe how you will limit the number of people who will have access to identifiable data, or keys which would be used to re-identify data.

Time duration of storage (Must be greater than 5 Years).
Research record retention periods will vary depending on the research discipline, research purpose and type of records involved. Research records must be retained for not less than:
•Five (5) years after the end of a research project's records collection and recording period;
•Five (5) years from the submission of a final project report;
•Five (5) years from the date of publication of a report of the project research; or,
•Five (5) years from the date a degree related to a particular research project is awarded to a student. whichever occurs last.

All information collected in a clinical trial must be stored in accordance with C.05.012, which includes the requirement for the sponsor to store records for 25 years. Research records must be retained for longer periods:
- If required to protect intellectual property rights;
- If such research records are participant to specific federal or provincial regulations requiring longer retention periods;
- If required by the terms of a research sponsorship agreement; or,

• If any allegations regarding the conduct of the research arise, such as allegations of academic misconduct or conflict of interest.

For clinical trials, the applicant is referred to the following sources for information on the document retention responsibilities of Investigators.

1. ICH GCP 4.9.5: Refer to: http://www.ncehr-cnerh.org/english/gcp/

Research records may be retained for longer periods if retention is required for the continuity of scientific research or if the research records are potentially useful for future research by the PI or other investigators.

Describe which data will be destroyed so that it cannot be recovered and how. (e.g. confidential shredding, electronic file deletion software)

Destruction of research records must be carried out so that personal information cannot practicably be read or reconstructed. In some cases it may be advisable to document the manner and time of destruction.

Paper documents containing personal information should be burned, pulverized or shredded into very small shreds. Erasing electronic files from a computer will not remove the information in that file from the computer. Applications are available that provide for secure erasure and will remove the records. When a computer is decommissioned, the disks must be erased using a secure disk erasure application or physically destroyed

Destruction of project records should be treated as confidential waste and disposed of in that manner.

If data are held on third party platforms describe the timeline for its removal.

For example, surveys should be removed from qualtrics when the study is complete, ensuring of course that all the data is downloaded, complete, backed up etc before removal.

Will data be archived? And if so in what form and where?

Tri-Agency Open Access

https://science.gc.ca/site/science/en/interagency-research-funding/policies-and-guidelines/open-access/tri-agency-open-access-policy-publications

The Tri-Councils place the following responsibilities on grant holders:

• The Social Sciences and Humanities Research Council (SSHRC) Policy on Data Sharing states that all research data collected with the use of SSHRC funds must be preserved and made available for use by others within a reasonable period of time .

• Canadian Institutes of Health Research (CIHR) grantees must deposit bioinformatics, atomic and molecular coordinate data into the appropriate public database immediately upon publication of research results .

Regulated databanks may also have specific requirements for record retention, which should be adhered to for projects using data from these sources.

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

Be broad and inclusive, and ensure all options are included on the consent form so as to not prohibit a use in the future.

When will participant contact information and email messages related to the study be deleted?

Specify where, how, and for how long the data will be stored. Documents or files that link de-identified data to their primary source must be stored separately from the study data.
1) The principal investigator or the project supervisor should be responsible for the data storage.
2) Describe how data security will be maintained during the transportation of confidential information from the site of data collection to the data storage location. Standard measures include password protecting electronic files and storing hard copies of project materials in a locked filing cabinet. Web-based questionnaires must use encryption software.
3) Data security refers to the physical, administrative and technical safeguards to safeguard information. Standard measures include password protecting electronic files and storing hard copies of project materials in a locked filing cabinet. Web-based questionnaires must use encryption software. Data should be stored within a University facility. Long term storage of student research data after data analysis is complete, should be undertaken by the project supervisor. Normally this would be in the Office of Research Services or research laboratory.
4) Each discipline has guidelines for the retention of original data and materials relating to scholarly activity. In the event your discipline has no formalized policy, the minimum period for data retention accepted by the REB is 5 years after the work is published or otherwise presented. In some circumstances, it may be appropriate to deposit your data with an archive. This cannot be done without the permission of the participants. Take this into consideration when seeking their consent to participate in your research.
5) Describe the final plans for the original data set. In some cases, data will be preserved; plans for preservation of material should be described. Explain whether anonymous data will be archived and the final archival location. If data will be destroyed, explain how electronic data will be destroyed.

Declaration Tab

Personnel

All persons assuming a formal role and or who will have access to participants and their data must be noted on the application. This includes, but is not limited to co-principal investigators, co-investigators, residents, student investigators, and faculty advisors.

All UofR personnel who are associated with a research project and will have contact with research participants must complete the TCPS2 Course on Research Ethics (CORE), online tutorial, before the application is submitted to the REB. This includes (but is not limited to) undergraduate and graduate students, postdoctoral fellows research assistants, research coordinators, etc. The TCPS2 CORE is free and can be completed in about two to three hours in either a single session or series of sessions. https://tcps2core.ca/welcome

Personnel involved in a study should usually have access to view the REB application. There are occasions however that the researcher may argue otherwise, such as individuals with very narrow and limited roles, such as a professional transcriptionist. If you do not wish for an individual to have access to view the application, provide a justification.

Conflict of Interest

The TCPS2 Chapter 7 discusses ethical issues that can arise when research activities and other activities are in conflict. A conflict of interest may arise when activities or situations place an individual(s) in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. Note that "immediate family members" includes a person related by blood, adoption, marriage or common-law marriage to the principal investigator or project personnel. It may also include an individual that they previously had such a relationship. (TCPS2 Article 7.4, researchers and conflicts of interest)
UofR Policy: Conflict of Interest and Conflict of Commitment

Any real, potential or perceived conflict of interest must be identified and disclosed to the REB.

The disclosure of any real, potential or perceived conflict of interest should also be made to any research participants. It may also be appropriate to disclose the conflict of interest to the sponsor, the institution, and any relevant professional body as well. If there is a need for a researcher with a conflict of interest in a research project to be involved in some aspect of the project, the extent of the involvement should be described. When disclosure to the REB is not enough to manage the conflict of interest, the REB, guided by established institutional policies, may require that the researcher withdraw from the research, or that others on the research team, who are not in conflict of interest, make research-related decisions. Where appropriate, disclosure to the sponsor, the institution and any relevant professional body may also be necessary. In exceptional cases, the REB has the discretion to refuse approval of a research project where the REB decides that the conflict of interest has not been avoided or cannot be appropriately managed. (TCPS2 Article 7.4, researchers and conflicts of interest)

Researchers and research students hold trust relationships, either directly or indirectly, with participants, research sponsors, institutions, their professional bodies and society. Although the potential for such conflicts has always existed, pressures on researchers (e.g., to delay or withhold dissemination of research outcomes or to use inappropriate recruitment strategies) heighten concerns that conflicts of interest may affect ethical behaviour.

Researchers' conflicts of interest may arise from interpersonal relationships (e.g., family or community relationships), financial partnerships, other economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm), academic interests or any other incentives that may compromise integrity or respect for the core principles of this Policy. Conflicts may arise from an individual's involvement in dual and multiple roles within or outside an institution. While it may not be possible to eliminate all conflicts of interest, researchers are expected to identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to the REB.