**Guidance Notes**

For Research Ethics Board Application Form

The following Guidance Notes (GNs) are intended to ensure that applicants have the necessary information to be able to fill out the Application for Research Ethics Review correctly and to construct consent forms that meet Research Ethics Board (REB) standards. The guidelines in this document comply with those of the Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans (TCPS 2, 2018) as well as with the ICH Good Clinical Practice Guidelines (ICH GCP E6 2R, 2016).

The purpose of a REB is to determine whether the research question or hypothesis is scientifically, and therefore ethically, valid; and, if so, whether the research is in compliance with the relevant ethical requirements for carrying out research involving human participants. In accordance with TCPS Article 2.1 and ICH GCP Article 3.3.6, the research project cannot begin until the REB issues its written approval of the research proposal. All investigators are responsible for understanding and adhering to the TCPS 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.

These notes are offered as guidance to investigators. They are not intended to apply to every situation. The Board may, under certain circumstances, require different procedures than those described here. Similarly, investigators may request that a process other than that described here be followed for a particular project.

Clinical projects are governed by a number of documents, including clinical-trial agreements, protocols, and consent forms.  To ensure consistency among these documents, a copy of the ethics application and consent document(s) may be disclosed to the Funding office of the institution responsible for reviewing and administering the grant or contract.

**Submitting Your Application**

All applications for ethical approval of research proposals (i.e., those requiring full board review and those qualifying for expedited review) are made by submitting **ONE electronic copy** of the completed application form and all attachments.  *Please submit signature pages either as scanned PDF pages of hand written signatures or a signature that has been created using digital signature technology. Typed text submitted in lieu of a signature will* ***not*** *be accepted.*

Applications must be type written. Hand written applications will be returned.

Theelectronic copy of your application and all related files can be sent to ResearchEthics.Regina@saskhealthauthority.ca.

All signatures requested must be obtained prior to submission to the Board. Applications with missing signatures will be returned to the investigator without review. Applications received at least 14 working days prior to a scheduled meeting will be reviewed at that meeting. The application is recorded and forwarded to the Chair of the Board. Following review by the Committee, the Chair will communicate the decision regarding suitability to the applicant in writing. For REB meeting dates, click (ADD Link to submissions page).

Good Clinical Practice (GCP) and “Health Canada Division 5 – Drugs for Clinical Trials Involving Human Subjects” training (required for all study team members conducting clinical trials).

Principal investigators and all study staff accessing personal health information for studies must complete the McMaster Chart Audit Tutorial, available at <http://ethics.mcmaster.ca/chart/>, prior to submission to the Board.

All personnel who are associated with a research project and will have contact with research participants are expected to have completed the TCPS online tutorial before the application is submitted to the REB. This includes (but is not limited to) undergraduate and graduate students, medical residents, research assistants, research coordinators, etc. The TCPS Tutorial is free and can be completed in about three to four hours, and does not need to be completed in one sitting. A copy of the *TCPS Certificate of Completion* should be attached to the application. The TCPS tutorial can be found at the following address: <https://tcps2core.ca/welcome>.

* **Approval**: The Certificate of Approval will be issued for a term of one year.
* **Conditional Approval**: The REB endorses the study with some changes and authorizes the Chair to grant approval when the concerns addressed to the researchers in the Notice of Ethical Review (i.e., the provisos) have been satisfactorily addressed.
* **Deferral or Resubmission**: Based on the documentation provided, the REB is unable to make a final decision. The decision is deferred for full board review at such time as the researchers submit the supplementary information or documentation as specified by the REB in the Notice of Ethical Review. In some cases the REB may request the entire application be resubmitted with updated documentation in clean and track changes versions.
* **Not Approved**: The REB does not authorize the conduct of the research in the SHA.

This decision will be forwarded to Administration for information and to the applicant with an outline of the requested changes, if any. Research projects must not be initiated until "Approval without changes" is granted.

**How to Use the Guidance Notes With the Application Form**

The GNs are numbered and correspond to the same numbered box in the Application Form. It is the responsibility of the investigator(s) to ensure that the information contained in each GN is applied in a manner appropriate to each individual project for both the Application Form and any accompanying documentation. The REB requires a complete response to each question in the Application Form.

|  |
| --- |
| PART 1: Identification\* |

**GUIDANCE NOTE 1.1:****PROJECT TITLE**

The title of the project should accurately reflect the nature of the project.

The title given in Box 1.1 of the Application Form and the title of the protocol submitted should be the same and correspond to the title of any consent form(s) also submitted. If applicable, include the protocol number in brackets at the end of the title.

**GUIDANCE NOTE 1.2: PRINCIPAL INVESTIGATOR**

The "principal investigator" is the individual who is ultimately responsible for the actions of those acting with delegated authority. He/she is the person responsible for the conduct of the project at a research institution or the responsible leader of the team.

The Principal Investigator (PI) must notify the REB office in writing when this responsibility is going to be assumed by a different investigator. Principal Investigators 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 University or Saskatchewan Health Authority affiliated position and the project remains ongoing.

Unless noted otherwise in Section 1.5, the REB office will send all *Notices of Ethical Review, Acknowledgements*, and *Certificates of Approval* to the address provided for the Principal Investigator.

Home mailing addresses are not acceptable.

**GUIDANCE NOTE 1.3: AFFILIATION REQUIREMENTS**

The Principal Investigator bears the overall responsibility for the conduct of the project, including the activities of sub-investigators, who are assumed to be acting under the delegated authority of the Principal Investigator. All research being conducted by a University and/or Saskatchewan Health Authority affiliated investigator must receive REB approval.

For research being conducted within the Saskatchewan Health Authority (SHA), the Principal Investigator of the project must hold a staff appointment within a SHA affiliated institution. Projects being conducted by residents, students, or Out-of-Region investigators must appoint a local Principal Investigator who will be responsible for the conduct of the project at that institution.

**GUIDANCE NOTE 1.4:****PROJECT PERSONNEL**

All persons assuming a role within the project that are to be listed on the *Certificate of Approval* must be noted on the application. This includes, but is not limited to sub-investigators, residents, student investigators, and faculty advisors.

For each person noted in this section, the particular position/role they serve in the project should be identified. Typical positions may include statistician, research assistant, study/project coordinator, sub-investigator, transcriptionist, or student researcher.

**GUIDANCE NOTE 1.5: PRIMARY CONTACT PERSON**

Include the name and contact information for anyone who, in addition to the PI, should receive a copy of all REB-related correspondence.

**GUIDANCE NOTE 1.6:****INSTITUTIONS WHERE THE RESEARCH WILL BE CARRIED OUT**

Enter the names of locations/institutions/institutions where the research will be carried out under this Research Ethics Board approval. The project cannot begin until you receive approval from the institutions specified (i.e., Operational Approval). It remains the PIs responsibility to assure departments are aware of research projects prior to submitting REB applications to assure that departments are aware of any impact on their resources and are willing to have research occur that may have resource impact for the departments.

**Note Regarding Operational Approval:**

Once an REB file number is issued the Research Approval process can be initiated please see the Operational Approval page for information on this process and for forms (Add link to OA page please).

**GUIDANCE NOTE 1.7:****PROPOSED PROJECT PERIOD**

Enter the estimated start date and end date of this project. In order to extend the proposed end date of a project, an amendment must be submitted to the REB. Also indicate if there are extenuating circumstances that the REB should be aware of that necessitate the delegated/expedited review of this project.

**GUIDANCE NOTE 1.8:****PROJECTS BEING SUBMITTED FOR REB APPROVAL AT OTHER INSTITUTIONS**

Indicate whether this project is under review OR has received approval from another REB in Saskatchewan and/or a REB outside of Saskatchewan. Projects that have received approval from another REB may be eligible to receive an expedited/delegated review.

For projects being conducted in multiple sites within Saskatchewan or that require REB approval from multiple institutions, the research ethics review process can occur simultaneously at all of these sites, provided the PI informs the REBs at the time of submission.

**GUIDANCE NOTE 1.9:****PROJECT RISK**

The process used to review new applications is proportionate to the level of risk that the participant could experience as a result of the research procedures employed. *Minimal risk* projects do not get submitted to the Full Board for review. They are reviewed by the Research Ethics Specialists or Chair of the REB and/or a sub-committee of REB members. This is referred to as an expedited or delegated review. *More-than-minimal-risk* projects are reviewed at the next meeting of the REB if they are submitted by the submission deadline. Please click here for the submission deadlines for Full Board reviews: Add link to submissions page

After reviewing the criteria below, decide whether your project falls under the category of “minimal risk” (and therefore eligible for delegated/expedited review).

**Submission Criteria**

Minimal Risk is defined in the TCPS as: *“… research in which 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*.” [TCPS 2, 2018 Chapter 2B]. Risks of daily life mean those risks encountered in the daily lives of the participants of the research, considering their actual life situations, as opposed to the daily life of “normal persons” or “healthy volunteers” as the case may be.

**Types of Minimal Risk Research Projects Qualifying for Delegated Review**

Projects that may meet the criterion for minimal risk include research that is *limited* to the following sources of data and may undergo expedited review by the REB Chair:

*Primary Sources of Data Obtained for Prospective Research*

* Collections of hair, nail clippings, deciduous teeth, excreta, salivary secretions, additional swabs, or other external secretions that have been collected in a non-invasive manner and that may also be collected as part of routine clinical care;
* Placenta or amniotic fluid collected as a consequence of childbirth, or fetal tissue collected as a consequence of therapeutic abortion or miscarriage;
* Data recorded using non-invasive procedures (e.g., EEG, EKG, MRI, ultrasound, or x-rays not exceeding radiation exposure equivalent to one return transcontinental air flight);
* Blood samples collected by venipuncture or a central line installed as part of clinical care;
* Output data obtained as a result of moderate exercise undertaken by healthy volunteers;
* Output data obtained as a result of maximal exercise undertaken by healthy volunteers who are less than 40 years old;
* Clinical data collected prospectively as part of clinical care;
* Interventional studies that involve minimal risk for participants;
* Observational research on standard treatment(s) where the treatment(s) is/are determined clinically and not assigned by research methodology (e.g., randomization);
* Interview or filling in a questionnaire for a fully competent adult participant.

All projects that do not meet the criteria described above must be submitted for full board review. The REB Chair also reserves the right to refer any project for full board review for any reason and will notify the applicant of a change.

**Delegated Review Not Allowed**

* Projects with greater than minimal risk to the participant;
* Interventional studies with new therapeutics or devices;
* Research on a sensitive topic that could cause distress to the participant;
* Collection of tissue/blood for the purpose of creating or adding to a tissue bank or for the purpose of genetic research;
* Projects whose purpose is the derivation of stem cell lines from human somatic tissue, umbilical cord or placenta OR research involving the grafting of stem cell lines into humans;
* Payments/gifts-in-kind of value more than $50 per research participant;
* Research involving vulnerable populations (e.g., prisoners, children, cognitively impaired, etc.) which deal with sensitive issues and/or entail greater than minimal risk;
* Open label extensions.

**GUIDANCE NOTE 1.10:****SOURCE OF FUNDS**

Source of funds refers to the agency/sponsor of the proposed research that will be providing the funds needed to undertake the project.

Note that research receiving its funding from an industry sponsor (i.e., pharmaceutical/medical devices company or an agent thereof) is participant to the fee for ethical review. Add link to REB Fees page.

The ethics review fee is waived for the following projects:

1. Projects that have received a grant-in-aid (normally an investigator-initiated project with partial funding-e.g., supply of drugs or devices or a very limited amount of funding from an industry sponsor);
2. Projects that are funded by not-for-profit agencies;
3. Projects that receive internal grants from an affiliated institutions or are self-funded;
4. Projects funded by non-profit agencies such as SHRF, CIHR, NSERC, CHSRF, and NIH (including NIH Institutes), and;
5. Projects without external funding.

**GUIDANCE NOTE1.11:****FUNDING STATUS**

Indicate whether or not the funds have been awarded yet. Investigators must send a letter to the REB office informing them of any changes or additions to the funding source(s).

**GUIDANCE NOTE1.12:****NAME OF SPONSOR**

“Sponsor” refers to an individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of a clinical trial. For unfunded/investigator-initiated projects, the sponsor could be the principal/qualified investigator. The sponsor is usually responsible for applying for regulatory approval with the Health Protection and Food Branch of Health Canada.

|  |
| --- |
| PART 2: REGULATORY REQUIREMENTS  |

**GUIDANCE NOTE 2.1: OBTAINING REGULATORY APPROVAL**

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 OBJECTION 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).

The Sponsor is usually responsible for applying for regulatory approval with the Health Protection and Food Branch of Health Canada. For unfunded/investigator-initiated projects, the sponsor could be the principal investigator.

The Clinical Trial Application (CTA) for drugs/radiopharmaceuticals/natural health products or the Investigational Testing Authorization (ITA) for devices must be filed with the appropriate directorate within the Health Protection and Food Branch of Health Canada:

1. Clinical trials for either drugs or devices - refer to the Therapeutics Product Directorate
2. Clinical trials for either biologics or radiopharmaceuticals - refer to the Biologics and Genetic Therapies Directorate
3. Clinical trials involving natural health products formulated for therapeutic purposes - refer to the Natural Health Products Directorate

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.

**Industry Sponsored Clinical Trials**

Specify the date of the application to Health Canada and the Health Canada control number for all clinical trials. The control number must be submitted once obtained if not available at the time of submission to the REB.

**Investigator-Initiated Clinical Trials**

Specify the date of the application to Health Canada.

Applications to the REB and Health Canada may be concurrent. However, only a conditional Approval from the REB will be issued until Health Canada Regulatory Approval is received and a copy of the NOL is submitted to the REB.

**GUIDANCE NOTE 2.2: COMPLIANCE WITH U.S. REGULATION FOR RESEARCH ETHICS**

If this project is sponsored or monitored by one of the agencies below, the PI is responsible for ensuring that the project complies with the applicable US regulations.

* Office of Human Research Protections (US Department of Health and Human Services)
* Food and Drug Administration (FDA)
* US National Cancer Institute (NCI)
* National Institutes of Health (NIH)

**GUIDANCE NOTE 2.3: REGISTRATION FOR PUBLICATION OF CLINICAL TRIALS**

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.

**GUIDANCE NOTE 2.4: ACADEMIC VALIDITY/SCIENTIFIC 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.

Peer review is considered independent when experts in the field, who are not affiliated with the institutional department carrying out the project or who are not affiliated with the company sponsoring a clinical drug/device trial, have evaluated the project for its scientific appropriateness.

An independent peer review may be either 'internal' or 'external'. The appropriate type of review is dependent on the nature of the project.

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.

**GUIDANCE NOTE 2.5: CURRICULUM VITAE OF THE PRINCIPAL INVESTIGATOR**

Good Clinical Practices (Section 3.1.2) requires that the REB be provided with the PI’s current curriculum vitae to provide further evidence of his/her qualifications to conduct the project. If the PIs CV has not been submitted within the past 5 years or has been recently updated, please attach.

|  |
| --- |
| PART 3: BRIEF OVERVIEW OF THE RESEARCH PROJECT\*  |

**Guidance Note 3: SUMMARY OF RESEARCH PROPOSAL**

Provide a short summary of the research project written in lay language and suitable for the non-scientific REB members. Do not exceed two pages and do not cut and paste directly from the protocol.

**Guidance Note 3.1: RESEARCH QUESTION/HYPOTHESIS**

This specifies the precise research questions being evaluated in the project. It is the main reason that the project is being conducted (e.g., to determine efficacy, equivalence, safety, dosage levels, effectiveness).

**Guidance Note 3.2: ACADEMIC VALIDITY**

Include background information that leads up to the specific project being proposed. This includes background evidence that explains the need for the project. For clinical trials, this information should provide evidence of clinical equipoise, which is defined as *"...a genuine uncertainty on the part of the expert medical community about the comparative therapeutic merits of each arm of a clinical trial.*" The justification must include the differences between what is considered the current standard of care and the experimental intervention.

**Guidance Note 3.3: RESEARCH DESIGN/METHODS**

This should 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). It should also include a justification for the use of deception or placebo or for the need to carry out research in emergency health situations, if applicable.

**Guidance Note 3.4: STATISTICAL ANALYSES**

A brief description of the intended analyses, and if appropriate, who will be responsible for conducting them, should be provided. 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.

**Guidance Note 3.5: POTENTIAL SIGNIFICANCE/JUSTIFICATION**

Explain what is unique about the project in order to support the ethical tenet that the proposed research has value. In particular, this section should explain what new research questions can be answered. Some projects are conducted in order to satisfy requirements for Health Canada or FDA approval: this is not a sufficient ethical justification for the project. Ensure that a more precise justification is provided which explains why additional projects are needed and warranted.

|  |
| --- |
| \*PART 4: PARTICIPANT RECRUITMENT  |

**GUIDANCE NOTE 4.1: NUMBER OF PARTICIPANTS**

Indicate what the project’s total enrollment will be (i.e., globally across all institutions/sites) and how many participants are expected to be recruited at the local institution.

**GUIDANCE NOTE 4.2: INCLUSION CRITERIA**

Provide all inclusion criteria as described in the protocol. Otherwise, indicate how these criteria differ from that in the protocol.

The selection of participants must be considered equitable and should strive to achieve a demographically representative sampling, subsequent to the constraints of the research.

Note that the inclusion of legally incompetent participants must meet the requirement of TCPS 2, 2018 Article 4.6, which states that the investigator shall satisfy the REB that *“...the research does not expose the participants to more than minimal risk without the prospect of direct benefits for them, or, 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*."

Special consideration must be given to the potential for inclusion of vulnerable participants who are not competent to give a legally or ethically valid consent or who have relatively little social or economic power. The research should not intentionally nor inadvertently increase or exploit this vulnerability, nor should these types of populations be excluded from research, which is potentially beneficial to them as individuals, or to the group that they represent.

**GUIDANCE NOTE 4.3: EXCLUSION CRITERIA**

Provide all exclusion criteria as described in the protocol. Otherwise, indicate how these criteria differ from that in the protocol. Ensure that a justification is provided if participants are excluded on the basis of such attributes as culture, language, religion, race, mental or physical disability, sexual orientation, ethnicity, gender or age.

**GUIDANCE NOTE 4.4: METHOD OF RECRUITMENT OF POTENTIAL PARTICIPANTS**

Provide a detailed description of the method of recruitment. Describe how potential participants will be identified, who will contact them and the manner in which it will be done.

In some projects, the Investigator requires information from a third party's records in order to invite prospective participants to participate in a research project. Details of how initial contact vis a vis third party records will be accomplished and copies of any letters sent to either the third party or to the participant via the third party must be provided for review by the REB. In addition, any recruitment materials, such as letters, advertisements, flyers, radio or television scripts, or Internet messages must be included with your application as attachments in an appendix.

Specifically, the REB requires information on how participants are identified and initially contacted to participate in a research project. In particular, this information should include a description of:

1. The source of the contact information *(e.g., clinic, hospital, or office records*);
2. Who will make the initial contact with the prospective participant (*e.g., study coordinator, primary caregiver*)
3. How the prospective participant will be initially contacted *(e.g., by letter, telephone, verbally*)
4. When the prospective participant will be initially contacted *(e.g., one week after discharge)*; and,
5. The Investigator's relationship, if any, to the participants (*e.g., treating physician*).

The following procedures for identifying and making initial contact with prospective participants are acceptable to the REB:

**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.

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.

**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.

**Initial Contact with Prospective Participants under the Investigator’s Care or Authority**

*Ensuring Non-coercive Contact*

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 also 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 in the waiting room of the medical clinic. The physician/care provider must make the distinction between “medical care” and “research”.

*Direct Initial Contact by Project Staff (e.g., nurses, coordinators, etc.)*

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.

*Initial Contact by Mail*

Prospective participants under the Principal Investigator's care may also be contacted by mail via an initial contact letter, which can be followed up by a telephone call within a reasonable length of time. The letter should stipulate who will make the follow-up phone call and when this will occur. The SHA REB prefers that the follow-up telephone contact be made by a project nurse/co-ordinator in order to minimize the possibility of coercion, perceived or otherwise. The Principal Investigator must sign the initial contact letter unless a compelling reason why someone else should sign is provided.

**Initial Contact with Prospective Participants Who Provide Personal Data to Sponsors’ Call Centres**

Participants may choose to contact a Call Centre directly to indicate that they would like to participate in a clinical trial and to provide their contact information. The local project centre, upon receiving this information from the Call Centre, may contact the prospective participant directly by phone, explaining how their name and phone number was obtained. A description of this procedure must be included in Box 4.4 of the Application Form along with the script used by the Call Centre to receive calls and all screening scripts.

The REB is concerned about how personal information (including contact information) given to central screening agencies is handled by these agencies. Investigators are required to describe the planned disposition of the information by the Call Centre. For example, the REB would not permit this information to be provided to the sponsor for possible use in marketing or for contacting patients for reasons unrelated to the research project.

**Identification and Contact of Participants by Third Parties**

The SHA REB does not permit investigators to ask their participants to invite other people (e.g., family members) to participate in a proposed research project. While recruitment of participants by participants may be methodologically desirable and convenient, it may put the index participant and the people they contact in a variety of potentially uncomfortable and coercive situations and is therefore not permitted. At no time should there be any obligation placed on the participant to recruit participants for the investigator. In some situations (with REB approval) it is permissible for participants to be asked to provide the investigators with names of other potential participants, with their permission, (e.g., a sibling who might consider participating as a participant), but no further obligation may be placed on the participant.

**Advertisement Requirements**

The REB will review all the research documents and activities that bear directly on the rights and welfare of the participants of proposed research, including the methods and material that investigators propose to use to recruit participants. 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. No claims should be made, either explicitly or implicitly, that the 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 should be reviewed and approved by the REB as part of the package for initial review. However, when the clinical investigator decides at a later date to advertise for participants, the advertising may be considered an amendment to the ongoing project. When such advertisements are easily compared to the approved consent document, the REB chair, or other designated REB member, may review and approve by expedited means. When the REB reviewer has doubts or other complicating issues are involved, the advertising will be reviewed at a convened meeting of the REB.

Generally, any advertisement to recruit participants should be limited to the information the prospective participants need to determine their eligibility and interest. The minimum requirements for research recruitment materials are:

1. Any advertisement, notices, posters, radio spots, brochures, etc. which are intended to advertise a research project and aid in recruitment must be submitted to the REB for review and approval. Copies of letters to research participants, for purposes of information or recruitment, must also be submitted to the REB.
2. The ad 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 the 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.
3. Advertisements aimed at recruitment must clearly and concisely state:
4. The nature and purpose of the project, and that it is research
5. Who is eligible to participate (and who is not)
6. The time or other commitment required of research participants
7. An affiliation with a bona fide medical practice or medical research center (e.g., this project is being conducted by “\_\_\_\_\_\_\_\_\_\_” in the Department of “\_\_\_\_\_\_\_\_\_”)
8. How to obtain further information
9. 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.
10. 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.
11. 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.
12. Use of the University of Saskatchewan Logo will be allowed on all advertisements for those investigators who are affiliated with the University. The use of the logo is not mandatory.
13. Use of the Saskatchewan Health Authority logo is mandatory on the advertisements and consent forms being used within the SHA.

**Media Advertising**

Direct advertising methods are intended to be seen or heard by prospective participants to solicit their participation in a project (e.g., newspaper, radio, TV, bulletin boards, posters, flyers, etc.). Not included are:

1. Communications intended to be seen or heard by health professionals, such as "dear doctor" letters and doctor-to-doctor letters (even when soliciting for project participants);
2. News stories, and;
3. Publicity intended for other audiences, such as financial page advertisements directed toward prospective investors.

Direct advertising for project participants is considered the start of the informed consent and participant selection process.

The REB will review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcast, investigators should obtain REB approval of message text prior to taping, in order to avoid re-taping because of inappropriate wording.

**Letters**

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 non-eligibles 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.

|  |
| --- |
| PART 5: CONSENT PROCESS |

**Guidance Note 5.1: Consent Requirements**

Consent should, in most cases, be obtained after a face to face discussion with the participant/authorized representative has taken place. The information included in Box 5.1should include details of the following:

* Who would approach the participant to obtain consent [note that this contact should occur a minimum of 24 hours after initial contact, except in the case of emergency situations];
* Who would inform and take the consent from the participant;
* What is relationship of the person obtaining consent to the participant?

Written evidence of the participant/authorized representative’s informed consent/assent must be obtained and documented before participation in the project begins.

The requirements for seeking consent are participant to federal and provincial privacy legislation and investigators are responsible for compliance with these laws that relate to their research. The REB does not have the authority to authorize any procedure which contravenes these laws.

**Use of Mailed/Faxed Consent Forms**

Consent forms with an introductory letter may be mailed or faxed to potential participants who live in areas outside of the geographical catchment area for a project. In these circumstances, the Principal Investigator or designate can sign the consent form after receiving the signed consent form back from the participant, or after having obtained telephone consent (see telephone consent procedures).

**Questionnaires/Interviews Conducted by Telephone**

Consent forms with an introductory letter (indicating that a follow up phone call will be made) may be mailed or faxed to prospective participants when the project involves questionnaires/interviews that must be conducted by telephone. A follow up telephone call can then be made after a reasonable period of time to the participant to obtain their verbal consent in order to proceed with the interview or questionnaire. The complete written consent form or phone script should be read to participants over the phone and their verbal consent documented prior to proceeding with the interview/questionnaire. The participant’s signed written consent form must be returned to the investigator as evidence that written consent has been obtained. The investigators must maintain a verifiable record detailing when and who obtained verbal consent by phone. In some situations, the REB may request that signed consent forms be returned to the Principal Investigator.

**Initial Contact by Telephone for Obtaining Consent in Emergency Situations**

Any proposal to make initial contact with a potential participant by telephone should include a detailed description of the procedure and provide adequate justification. Contacting potential participants by telephone is generally unacceptable and should be avoided, except under unusual circumstances, such as research being conducted in a hospital emergency department.

1. This consenting procedure may be used only when the next-of-kin or legal representatives have not arrived with the potential project participant and are not expected at the hospital within the time limit of the project initiation.
2. The principal investigator or designate will present the information in the consent form over the phone and provide any clarification required.
3. Once the next-of-kin or legal representative of the patient has been fully informed of the patient's medical condition by the attending physician, the project will be discussed by one of the Investigators. The Principal Investigator or Sub-investigator will read the entire consent form over the telephone and provide any clarification requested by the next-of-kin or legal representative.
4. When all questions have been answered to the satisfaction of the next-of-kin or legal representative, the call will be terminated to provide an opportunity for the next-of-kin or legal representative to consider the project. In approximately (but not before) 30 minutes have passed, the Investigator (and witness) will again contact the individual for their decision (This is done so the family does not have to bear the costs of long distance charges).
5. A witness to the telephone consent, in addition to the Investigator reading the consent form, will be on the telephone line to hear the reading of the consent form and the verbal granting or refusal of consent by the next-of-kin or legal representative.
6. The identity of the witness will be disclosed to the next-of-kin or legal representative prior to the reading of the consent form.
7. The date and time that the telephone consent is obtained, the names of the next-of-kin or legal representative, the Investigator (reader), and the witness will be entered into the original consent form.
8. Whenever possible the consent form will be faxed to the next-of-kin or legal representative prior to the reading of the form, enabling them to follow along as it is read to them. If the next-of-kin or legal representative agrees to participate, she or he will be instructed to sign the form and fax it back to the principal investigator.
9. Written evidence of consent will be subsequently obtained in a timely manner after obtaining verbal consent.

**Projects Using Questionnaires Only**

The returned questionnaire may be taken as evidence of implied consent. Note that participant ID number should only identify the questionnaire.

**GUIDANCE NOTE 5.2: ALLOWING SUFFICIENT TIME FOR PROSPECTIVE PARTICIPANTS TO CONSIDER PARTICIPATION**

Consent must be done in such a way that prospective participants have adequate time between the time of initial contact to the actual consent phase to consider whether or not they wish to participate. For example, prospective participants who are attending a clinic for elective or scheduled procedures should not be approached and asked to consent to participate in a project at that time. They may be invited to participate in the project and if interested, given the consent form, which they can return, should they decide to participate.

**GUIDANCE NOTE 5.3: CAPACITY**

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.

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 2, 2018, 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*."

**Substitute Decision Makers**

TCPS 2, 2018, Article 3.9 specifies the following minimum conditions that must be met for research involving incompetent participants:

1. "*The investigator involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process.*
2. *The investigator seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned.*
3. *The authorized third party is not the investigator or any other member of the research team.*
4. *The investigator 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 investigator 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.*
5. *When authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the investigator shall promptly seek the participant’s consent as a condition of continuing participation*.”

TCPS 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*." [TCPS 2, 2018, Chapter 3C, emphasis added]. 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.

**Obtaining Assent from Participants who Lack Capacity, Including Children and the Mentally Impaired**

According to TCPS, participants who lack legal capacity may be ineligible to participate in research unless they assent to participation. The procedures that the investigator plans to adopt for obtaining assent must be described in Box 5.3b of the Application Form.

**GUIDANCE NOTE 5.4: REMUNERATION**

Where investigators plan to provide remuneration to participants, the REB will assess the value of the remuneration on a project-by-project basis. In general, remuneration should not be so substantial as to induce participants to trade accepting potential risks for financial gain.

For most projects, remuneration that is considered reasonable is within the $25.00 to $100.00 range for participation. Randomly provided monetary remuneration (e.g., via entry into a draw) is considered an acceptable form of remuneration. This does not include reimbursement of any expenses incurred by the participant during participation in the research.

Include any specific details about the reimbursement of expenses related to transportation and parking and when these will be paid.

If the participant will not be paid for participation or reimbursed for expenses, this should be stated in the consent form.

Participants must be eligible for remuneration according to their actual amount/duration of participation with no rewards for completing the project or withholding of owed remuneration from those who withdraw.

The monetary value of the remuneration for participation should preferably not be disclosed at the time of recruitment. The promise of remuneration in the recruitment materials may unintentionally mislead some prospective participants into thinking that they will automatically be enrolled into the project.

**GUIDANCE NOTE 5.5: PARTICIPANT FEEDBACK**

Regardless of the type of project, all participating participants should be offered access to the project’s findings. Depending on the type of project, the way in which this requirement is accomplished will vary. Some acceptable methods for providing participant feedback include:

* Attaching a separate ‘sign up’ sheet to the consent form for participants to indicate their interest in receiving a copy of the findings. Note, providing participants with a copy of the scientific summary is not considered suitable feedback. As such, any summaries intended for the participant should be written in lay terms. The list of interested participants should be stored separate from the consent form, and when the project is completed, a summary should be mailed.
* An invitation to review the project findings with the participant upon completion of the project (e.g., during their next office visit).
* Placing posters in the waiting room to indicate that the project results are in and inviting participating participants to request a copy from the receptionist.
* Host a public presentation of the findings and invite all participants.

Note that whatever method providing participant feedback is chosen, it is to be disclosed in the Participant Project Information/Consent Form.

|  |
| --- |
| PART 6: PROCEDURES AND RISKS  |

**GUIDANCE NOTE 6.1: RESEARCH PROCEDURES**

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.

**GUIDANCE NOTE 6.2: RISKS**

Information on risks of the project procedures must be included. For pharmaceutical projects, this information must be consistent with the information on harms provided in the protocol and Investigator's Brochure (IB)/Product Monograph. If information is not available from the protocol or IB, indicate the source of the risk data provided.

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.

Quantification should 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. Please do not use symbols such as >, as not all participants may understand the symbol, it would be better to say “greater than”.

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.

Box 6.2, as well as the consent form, should 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.

**GUIDANCE NOTE 6.3: MINIMIZING HARMS**

The information provided here should include an explanation of any strategies put in place to minimize and/or manage the harms for participants and other affected individuals (e.g., reporting side effects to the investigator, rescue medication, early withdrawal from the project).

In projects where the interaction with other drugs is unknown, disclose whether the research necessitates that certain medication or treatments not be administered during the project so participants can evaluate this in the context of their current health.

For projects with **wash-out periods** or requirements for stopping medication,the symptoms/signs that participants could experience from being taken off of any medication need to be noted as well the procedures that will be followed to minimize potential harm.

**Provision for Special Counseling**

The REB expects to see evidence of measures taken to ensure that counselling services are made available to research participants if the project tests could lead to information which would have serious consequences for that individual and/or their family.

Some projects (e.g., genetic tests) may provide results to participants, which identify them as belonging to a high-risk group on the basis of the result (e.g., genetic status, biochemical test result). In the case of research involving families and groups in genetic research, the investigators must "*reveal potential harms to the REB and outline how such harms will be dealt with as part of the research project*." In this regard, TCPS Article 13.4 requires that "*Where investigators plan to share results of genetic research with participants, the research proposal should make genetic counselling available at that time, where appropriate*."

*Harms Related to Testing for Reportable Diseases*

Pre-test counselling for participants tested for reportable diseases includes the implications, some of which may be life-altering, of having a positive test. These may include the legal obligation for mandatory reporting by the investigator, medication implications for sexual partners as well as the impact of a positive test on a participant’s insurance policies. The implications of research related tests should be clearly explained to participants in the consent form and this should be outlined in 6.3.

**GUIDANCE NOTE 6.4: PROVISIONS FOR BREAKING THE CODE FOR DOUBLE BLIND PROJECTS**

Please have a clear process for breaking the study code in the event of an emergency. There should be detailed information on who has the code and a 24 hour contact number to assure participant safety, a participant wallet card with this information is recommended.

|  |
| --- |
| PART 7: DATA SECURITY AND STORAGE |

According to TCPS 2, 2018 Chapter 5A,, “*Security refers to measures used to protect information. It includes physical, administrative and technical safeguards. An individual or organization fulfills its confidentiality duties, in part, by adopting and enforcing appropriate security measures. Physical safeguards include the use of locked filing cabinets, and the location of computers containing research data away from public areas. Administrative safeguards include the development and enforcement of organizational rules about who has access to personal information about participants. Technical safeguards include use of computer passwords, firewalls, anti-virus software, encryption and other measures that protect data from unauthorized access, loss or modification*.”

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.

**GUIDANCE NOTE 7.1: SOURCES OF PERSONAL AND HEALTH INFORMATION**

**Personal information** is defined in the TCPS 2, 2018, Chapter 5A as being “*information that may reasonably be expected to identify an individual, alone or in combination with other available information*”. Such information may include name, address, age, birthdate, ethnicity, social insurance number, educational background, employment history, life experience, religion, or social status.

**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.

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

Please be sure to check all applicable data sources and please note that eHealth data may require a data sharing agreement with the Ministry of Health. The eHealth viewer cannot be used for research purposes. Please note that the Saskatchewan Cancer Agency (SCA) has a separate process for data access and that information can be found here: <http://www.saskcancer.ca/research-article/data-access-requests>. SCM access will require a research specific account and this should be requested through the SHA Research Approval Process. Clinical SCM accounts should not be used for research data collection. If private office data is being used please specify in the “other” section what data sources will be used (EMR, Accuro etc.)

**GUIDANCE NOTE 7.2: CONFIDENTIALITY OF PARTICIPANTS**

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).

**GUIDANCE NOTE 7.3: STORAGE AND FINAL DISPOSITION OF PROJECT DATA**

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.

Applications require a statement outlining the procedures investigators will use to securely store research records including the length of time the research records will be stored, the location of storage, the identity of the person responsible for storage of research records, and the procedures that will ensure secure storage.

**Storage Requirements**

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.). Documents or files that link de-identified data to their primary source must be stored separately from the project data.

**Retention Requirements**

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[[1]](#footnote-1) 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.

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.[[2]](#footnote-2)

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[[3]](#footnote-3).
* 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[[4]](#footnote-4).
* CIHR grantees must retain original data sets arising from CIHR-funded research for a minimum of five years after the end of the grant. This applies to all data, whether published or not[[5]](#footnote-5).
* Collections of animal, culture, plant or geological specimens, or archaeological artifacts (“collections”) collected by a grantee with Tri-Council grant funds are the property of the University5.

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

1. ICH GCP E6 R2 4.9.5: Refer to: <https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>
2. Health Canada's Food and Drug Act Division 5 C.05.012 (4): Refer to: <https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/compliance-enforcement/establishment-licences/directives-guidance-documents-policies/guidance-drugs-clinical-trials-human-subjects-gui-0100/GUI-0100-v1-EN-version.pdf>

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

**Destruction of Records**

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

Destruction of project records should be treated as confidential waste and disposed of in that manner. The exact length of time the records will be stored (e.g., 5 years, 25 years) must be disclosed and adhered to.

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.

**Leaving the Institution**

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.

**GUIDANCE NOTE 7.4: 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.

**GUIDANCE NOTE 7.5: PRIVACY RISK ASSESSMENT/SOLUTIONS**

According to TCPS 2, 2018 Article 5.3, *“Investigators shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal... Measures for safeguarding information apply both to original documents and copies of information. Factors relevant to the REB’s assessment of the adequacy of the investigators’ proposed measures for safeguarding information include:*

1. *The type of information to be collected;*
2. *The purpose for which the information will be used, and the purpose of any secondary use of identifiable information;*
3. *Limits on the use, disclosure and retention of the information;*
4. *Risks to participants should the security of the data be breached, including risks of re-identification of individuals;*
5. *Appropriate security safeguards for the full life cycle of information;*
6. *Any recording of observations (e.g., photographs, videos, sound recordings) in the research that may allow identification of particular participants;*
7. *Any anticipated uses of personal information from the research; and*
8. *Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records*.”

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. In general, identifiable data that is kept on a computer and connected to the Internet should be encrypted.

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.

|  |
| --- |
| PART 8: CONFLICT OF INTEREST |

**GUIDANCE NOTE 8.1: CONFLICT OF INTEREST**

According to TCPS 2, 2018, Chapter 7, “*A conflict of interest may arise when activities or situations place an individual or institution in a real, potential or perceived conflict between the duties or responsibilities related to research, and personal, institutional or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the institution and/or the individual, their family members, friends, or their former, current or prospective professional associates... Prospective participants need to know about real, potential or perceived conflicts of interest in order to make an informed decision about whether or not to participate... It is preferable to avoid or prevent being in a position of conflict of interest, if possible. When it is not possible to avoid a conflict of interest, then it shall be disclosed to the appropriate people and steps taken to minimize or manage the conflict*.”

**Institutional Conflict of Interest**

Institutions involved in research hold trust relationships with participants, research sponsors, researchers and society. These institutions may have financial or reputational interests that conflict with the institution’s obligations to protect and respect human dignity. Institutions must ensure that the ethical conduct of research is not compromised by real, potential or perceived conflicts of interest.

Institutions may be in conflict of interest, for example, when they:

1. Sponsor a research project;
2. Manage the intellectual property that forms the basis of a research project or stand to benefit from intellectual property resulting from the research;
3. Hold equity in companies and/or receive major donations; or
4. Have conflicting roles carried out by one institutional official.

Acting in a professional role within the institution, individuals (e.g., institution president, dean of a faculty, department head) are in a conflict of interest when they are subject to competing incentives or functions. These may significantly interfere with the impartial exercise of duties, including legal and ethical obligations within the institutional structure.

**REB Member Conflict of Interest**

The REB, as an entity, or in the persons of the members who make up the board, also hold trust relationships with participants, research sponsors, researchers and society. REB members are in a conflict of interest when their own research projects are under review by their REB, when they are a sub-investigator, or when they are in a supervisory or mentoring relationship with a graduate student applicant.

Conflicts of interest based on collaborations or disputes with colleagues, students or others may be ongoing or of limited duration. REBs have an obligation to ensure that the fairness and transparency of research ethics review is not compromised by real, potential or perceived conflicts of interest.

**Researcher Conflict 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.

**Clinical Trials Conflict of Interest**

Section 54 of FDA Regulations states that “*The reliability of the data generated by clinical projects may be considered inadequate if, among other things, appropriate steps have not been taken in the design, conduct, reporting, and analysis of the projects to minimize bias. One potential source of bias in clinical projects is a financial interest of the clinical investigator in the outcome of the project because of the way payment is arranged (e.g., a royalty) or because the investigator has a proprietary interest in the product (e.g., a patent) or because the investigator has an equity interest in the sponsor of the covered pr*oject.”

Clinical trials can be affected by all types of conflict of interest: personal, professional and/or institutional. TCPS 2, 2018, Article 7.4 deals specifically with financial conflicts of interest that are of concern for sponsored clinical trials: “*Researchers and REBs should be aware of and consider the possibility of financial conflicts of interest. They should ensure that clinical trials are designed to meet appropriate standards of participant safety in accordance with the core principles of this Policy. Financial considerations shall not affect these standards or the scientific validity and transparency of trial procedures*.”

“Payment provisions should be scrutinized to ensure they do not create ethically inappropriate incentives to recruit quickly, at the expense of a careful review of the suitability of prospective participants. Unreasonable payments or undue inducements may place the researcher, and sometimes the institution, in a conflict between maximizing financial remuneration on the one hand and protecting participants and meeting the scientific requirements of the project on the other. Disclosure of the kinds and amounts of payments and other budgetary details encourages the researcher to identify and appropriately manage potential conflicts of interest and helps the institution to assess them. Management by institutions may include prohibiting certain forms of payment.”

The rights of sponsors with respect to the analysis of data, interpretation of results and publication of findings, and ownership thereof, are typically described in sponsor-researcher contracts (often referred to as clinical trial agreements), which are reviewed by the institution. These contracts may seek to place restrictions on the publication of findings, either directly or through provisions that seek to protect, in favour of the sponsor, the intellectual property of research procedures, data or other information.

With respect to research findings, TCPS 2, 2018 Article 4.8 states that: “Researchers shall disseminate, through publication or otherwise, the analysis of data and interpretation of research results, including those that do not support the research hypotheses. The dissemination shall take place in a timely manner without undue restriction.”

Researchers and institutions have an ethical responsibility to make reasonable efforts to publicly disseminate the findings of clinical trials in a timely manner by publications and by the inclusion of raw data and results in appropriate databases. In publications, they have the obligation to report trial details (for example, method, all planned outcomes, and harms as defined by the Consolidated Standards of Reporting Trials[[6]](#footnote-6)).

However, negative findings of research are not always published or otherwise disseminated. Failing to publish negative findings could lead to publication bias and thus contribute to a series of risks, including misinformed clinical decision making practices and injury to health, needless and wasteful duplication of research with associated risks to participants, fraud or deception in the clinical trials process, and erosion of public trust and accountability in research. Both negative and positive findings should be published.

Institutions and REBs require the satisfactory amendment or removal of any confidentiality clauses or publication restrictions that unduly limit either the content of the scientific information that may be disseminated or the timing of dissemination. Contracts should ensure that principal investigators have the necessary access to original trial data and the opportunity to analyze them, to ensure that they can report trial findings fairly and accurately, particularly with respect to both efficacy and safety. Sponsors’ legitimate interests should be reasonably balanced against the researcher’s ethical and legal obligations to participants and to the scientific and public good to disseminate data and research findings. It shall be understood that the welfare of participants takes precedence over the interests of both researchers and sponsors.

Clinical trial research contracts should ensure compliance with institutional policy standards and do all of the following [TCPS 2, 2018, Article 6.24]:

1. *“It is the responsibility of institutions to review clauses in sponsor-researcher contracts related to confidentiality, publication, and access to data. They shall require that any clauses related to confidentiality and publication be consistent with the researchers’ duties to:*
	1. *disclose new information that may affect participant welfare or consent to REBs and participants; and*
	2. *report research findings in a timely manner without undue restriction.*
2. *Institutions shall also ensure that sponsor-researcher contracts:*

*a. stipulate that researchers, primarily the principal investigator, should assume he primary role and responsibility for the analysis, interpretation, and preparation of the findings for publication;*

*b. permit principal investigators to access all study data;*

*c. permit researchers to access all study data collected at their respective sites; and*

*d. permit all researchers to access all study data in cases where no principal investigator is named.*”

In the review process, the onus to justify restrictions on dissemination or access to data should lie with the one seeking such restriction, usually the researcher or sponsor. The reasonableness of restrictions on either the content or timing of dissemination should be measured against the written institutional policies (e.g., some existing institutional policies deem unacceptable any publication restrictions that exceed a time limit of three to six months after the close of the trial). Restrictions on information that participants would reasonably consider relevant to their welfare, or that are required to give appropriate context to a manuscript or other publication, are seldom, if ever, justified.

|  |
| --- |
| PART 9: DECLARATION BY PRINCIPAL INVESTIGATOR\* |

**GUIDANCE NOTE 9.1: DECLARATION BY PRINCIPAL INVESTIGATOR**

Applications will not be accepted without the original signature of the Principal Investigator, Student Investigator (if applicable) and the Department Head.

|  |
| --- |
| PART 10: ATTACHMENTS |

**GUIDANCE NOTE 10.1: Department/OPERATIONAL Approval FOR RESEARCH BEING CONDUCTED IN THE SHA**

Research Approval for research using SHA facilities, accessing SHA patients or involving SHA staff or other resources requires a Letter of Authorization to Conduct Research at SHA, please see the Operational Approval (OA) page for OA information and forms ADD OA link. The OA form must also be completed for internally funded projects that do not involve a direct exchange of money, but rather, are funded through ‘donations-in-kind’ from various departments. Signatures are necessary to ensure that prior to commencement of the investigation, department heads and unit managers have had an opportunity to assess the impact of the proposal on their area.

Please be sure that all required documents are submitted for studies.

2

1. For example: Canada’s Food and Drug Regulations require certain clinical trial records to be stored for twenty-five (25) years and research conducted in provincial hospitals may be subject to The Hospital Standards Regulations, 1980 (Saskatchewan). [↑](#footnote-ref-1)
2. Future use of research records may be subject to the provisions of applicable privacy legislation and/or the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) https://ethics.gc.ca/eng/policy-politique\_tcps2-eptc2\_2018.html [↑](#footnote-ref-2)
3. http://www.sshrc.ca/site/apply-demande/policies-politiques/edata-donnees\_electroniques-eng.aspx [↑](#footnote-ref-3)
4. http://www.cihr-irsc.gc.ca/e/34846.html#8 [↑](#footnote-ref-4)
5. http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/Responsibilities-Responsabilites\_eng.asp [↑](#footnote-ref-5)
6. CONSORT Statement: www.consort-statement.org/consort-statement (accessed April 19, 2010). [↑](#footnote-ref-6)