

GUIDELINES FOR WRITING PROPOSALS AND CONSENT FORMS

The following are some points which may be helpful in preparing a proposal and consent form. While all points will not be applicable for every study they represent some of the areas considered when reviewing a proposal.

RESEARCH PROTOCOL

Identification:	<ul style="list-style-type: none"> Title of project, principal investigator(s) and department
Background/rationale:	<ul style="list-style-type: none"> Brief review of current, relevant scientific data Reasons for study - current treatments commonly used - pros and cons of present standard treatment
Purpose:	<ul style="list-style-type: none"> Hypothesis, objectives, research questions
Population:	<ul style="list-style-type: none"> Description and reason for interest Inclusion/ exclusion criteria Study design e.g. placebo, groups Method of sample selection Sample size and calculation
Procedure:	<ul style="list-style-type: none"> Description of procedures and information to be collected Procedures specifically for research purposes Study time Data sources
Intervention or treatment:	<ul style="list-style-type: none"> Dosages and treatment schedule Alternative treatment Side effects and risks Conditions for withdrawal Departure from usual treatment Experimental aspects of intervention Tests, measurements: Number and frequency Description of any side-effects and risks Copy of instruments, questionnaires used

Risks and benefits:	<ul style="list-style-type: none"> • Any risks from the treatment, study design and tests • Must be clearly stated without minimizing effect • Benefits should not be exaggerated
Proposed data analysis:	<ul style="list-style-type: none"> • Provide a description of the proposed data analysis
Implications of research:	<ul style="list-style-type: none"> • Describe the implications of the research study
Ethical issues/concerns:	<ul style="list-style-type: none"> • Special population issues -competency, age • Risks versus benefits • Method of sample recruitment (free of coercion, written and verbal explanations, time to consider) • Confidentiality safeguards • Data security

CONSENT FORM

A consent form should provide, to the extent that it is possible, all the information needed for an individual to make an informed decision. Although written information is provided, a verbal explanation should also be given as well as the time to consider and ask questions. The invitation to participate in a research study should be presented in a way that avoids coercion or undue influence. Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research participant. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

The guidelines (to be used in conjunction with the CTO Sample Consent Form template) below outline some points that may be considered when drafting a consent form.

<p>Introduction:</p>	<ul style="list-style-type: none"> • An introductory statement regarding the consent process is recommended • See the CTO Sample Consent Form template for standard language
<p>Consent form should:</p>	<ul style="list-style-type: none"> • Be submitted in its final form (i.e., as it will be seen by the patient/subject), including letterhead • Be in a language the subject understands • Use simple, clear language for technical and medical terms • Define short forms and abbreviations • Use meaningful comparisons to describe amounts or risks • Use large print if older subjects are involved • The information should be worded in second person • Number the pages of the consent, i.e., 1 of 5, 2 of 5, etc • Consent should be identified by version number and date (i.e., Version 1, dated Nov 12, 2023)
<p>Identification:</p>	<ul style="list-style-type: none"> • Title of study, name of investigator • If there is a sponsor, add their name, address, phone or website
<p>Background and Purpose:</p>	<ul style="list-style-type: none"> • Provide background information on what prompted the need for this study • Refer to standard of care, knowledge to date etc. • Describe the primary reason for the study and draft a paragraph that provides basic information about it • Define any concepts that may not be well understood outside of the research setting (e.g. efficacy) • Samples of the type of detail that should be included in the purpose can be found in the bulleted sentences below. • Explain why individual is asked to participate • State number of participants

Study Design:

- Describe the approach to conducting this research study including if it is randomized, blinded, multi-centre, if a wash-out is required, and other details as appropriate
- If subjects are to be randomized to 2 or more conditions, the chance of being in any 1 condition needs to be clearly specified by ratio and/or percentage (e.g., 50:50, 1 in 2, 33% [1 in 3], etc.) It might also be specified if the chance of receiving study drug is different from the chance of being in a condition – for instance, if there are 5 conditions, the chance of being in 1 condition is 1 in 5 but if 4 of the conditions involve study drugs then the chance of receiving study drug is 4 in 5.
- If a placebo condition is used, participants should clearly understand that they may not receive any study drug or that they may not receive any medication
- Include the duration of participation

<p>Study Visits and Procedures:</p>	<ul style="list-style-type: none"> • Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues) • Name each procedure that the participant will be involved in and explain each one in lay terms. Verify that the consent form and protocol are consistent. It is helpful to include the purpose of the visit and separate the phases of the study under specific headings (e.g. Screening, Baseline, Randomization, Follow-up, etc.). • Include how long each visit and procedure will take. If similar tests are done on multiple visits, try to minimize redundancy by grouping visits together, e.g. “on Visits 1, 2, 4, 6, and 10 the following tests will be done”. • Describe all tests, measures, questionnaires, procedures, interventions, or treatments that are outlined in the research protocol • Make the distinction between research-related procedures and standard-of-care procedures clear. The consent should focus on research-related procedures and discuss standard-of-care where necessary • Describe the type of information that will be asked in the questionnaires. If responses to the questions are of a sensitive nature, e.g. HIV, illicit drug screen, depression testing, pregnancy, the subject should be forewarned and a sample of the type of question should be provided. If the response necessitates further action, describe what will happen (e.g. Report to public health, refer for counseling, etc). Subjects should also be told they can refuse to answer any questions
<p>Eligibility:</p>	<ul style="list-style-type: none"> • Inclusion/exclusion criteria - specific exclusion criteria should be addressed

<p>Risks, inconvenience:</p>	<ul style="list-style-type: none"> • Include a list of all study related side effects. Separate side effects by study drug or study intervention as appropriate. Use lay language to describe or explain. • Address the frequency and severity of side effects. Sometimes risks need to include side effects that have not been clearly linked to the study drug, e.g. increases and decreases in blood pressure have been noted in some patients receiving the study drug but it is not clear whether these effects are truly related to the study drug. • Address reversibility of side effects, long term side-effects as applicable and any treatments, interventions or precautions that may be taken to address these risks • Address psychological risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues (e.g. mental health, sexuality) • Who to call if an adverse event occurs
<p>Risks to fetus/infant:</p>	<ul style="list-style-type: none"> • Women who are of childbearing potential should be warned if there are potential risks to the fetus. If so, they should be advised not to become pregnant or breast feed during the study. They or their partner should use a medically acceptable form of contraception. The acceptable forms of contraception should be described and the length of time following the trial that they should continue with birth control. • A pregnancy test before entering the study will be necessary and possibly repeated during the study. • Similar warnings may be required for male subjects for they or their partner to use effective birth control during the study period.

<p>Benefits:</p>	<ul style="list-style-type: none"> • For subject, for society • Note that the hypothesis being tested is not a benefit therefore statements should be avoided that suggest that a potential benefit is this proposed new treatment (e.g. Statements such as “A benefit of this study is that Drug X may help your medical condition” should be avoided). • Avoid overstating the benefits. When there is no intended medical benefit or personal benefit to the subject, the subject should be made aware of this. • Do not include monetary reimbursement in the benefits section.
<p>Alternative treatment:</p>	<ul style="list-style-type: none"> • Include a disclosure of appropriate procedures or courses of treatment that may be an alternative or standard of care alternative • If the participant can receive the same medications or study intervention without participating in research this must be stated • Address palliative care or non-treatment as alternatives, where applicable
<p>Withdrawal:</p>	<ul style="list-style-type: none"> • Right to withdraw at any time • Guidelines for participant being withdrawn from study and implications for treatment/care • Rules for stopping study
<p>Confidentiality:</p>	<ul style="list-style-type: none"> • Describe how data and personal health information will be treated • Possible access to records by the REB, sponsor, Health Canada (not TPD), Food and Drug Administration (FDA) • Please contact the HRH REB office for Confidentiality language

<p>Rights as a volunteer:</p>	<ul style="list-style-type: none"> • Participation is voluntary • Refusal to participate does not affect care • Right to withdraw without penalty and implications for treatment/care • Information on their rights to request the withdrawal of data or human biological materials, including any limitations on the feasibility of withdrawals
<p>Compensation:</p>	<ul style="list-style-type: none"> • If any and what it covers - in non-legal language. The following standard clause is recommended. “If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.”
<p>Conflict of Interest:</p>	<ul style="list-style-type: none"> • 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 • Note that the most common form of conflict of interest is the professional benefit gained by the Investigators.
<p>New findings:</p>	<ul style="list-style-type: none"> • Participant will be informed of any new findings which develop during the course of study which may relate to their willingness to continue in the study
<p>Expenses:</p>	<ul style="list-style-type: none"> • Include whether participants will incur any expenses as a result of their participation in the study. Include any remuneration, gifts in-kind, vouchers, etc to participants and how reimbursement will be pro-rated if subjects withdraw early from study

<p>Clinical Trial Registration:</p>	<ul style="list-style-type: none"> • A statement indicating where applicable clinical trials will be registered and publicly accessible on the Web. • For <i>applicable</i> clinical (drug) trials subject to FDA regulations, the following statement must be included on the ICF: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”
<p>Questions/concerns:</p>	<ul style="list-style-type: none"> • Names and phone numbers of contacts who can explain the scientific aspects of the research • For any questions about rights as a research participant, name Dr. Vibhuti Shah, Chair of HRH Research Ethics Board as contact (416) 242-1000 ext. 46011
<p>Consent:</p>	<ul style="list-style-type: none"> • The consent section should repeat some of the key points that the subject should understand to participate • Statement should include that participation is voluntary and that they will receive a copy of the signed informed consent
<p>Signatures:</p>	<ul style="list-style-type: none"> • The consent should be signed and dated by the subject and by the person who has explained the study and obtained the consent • The person obtaining consent should: <ul style="list-style-type: none"> ○ be knowledgeable about the study protocol in order to answer questions that the prospective participant may have; ○ be able to obtain information from the investigators to address issues raised by the prospective participant; ○ ideally not be in a treating relationship with the prospective participant.

Date of Consent:

- The consent should have a version number and version date (on each page) for easier tracking of consent versions in the future.