

THE UNIVERSITY OF WESTERN ONTARIO
RESEARCH ETHICS BOARD FOR THE REVIEW OF HEALTH SCIENCES RESEARCH
INVOLVING HUMAN SUBJECTS
(HSREB)

INFORMATION AND CONSENT DOCUMENTATION GUIDELINES

All sections are marked as to whether they are a requirement in the Information and Consent Documentation. Any requests to alter or omit a required section or phrase must be included in the protocol submission form.

Once the Informed Consent documentation has been approved, any subsequent changes require the review and approval of the HSREB before they are implemented.

INSTRUCTONS – INFORMATION & CONSENT DOCUMENTATION		
SECTION	RATIONALE & COMMENTS	PHRASING
	<ul style="list-style-type: none"> The participant must receive a copy of the Letter of Information or combined Information/Consent document 	
Title of the research REQUIRED	<ul style="list-style-type: none"> The formal title of the study heads this section. The form should include the exact title of the research protocol (i.e. Section 1.1 the title under which the research was approved and funded). When the title is cumbersome, a short simplified title may be added. 	
Identity of researchers & sponsors REQUIRED	<ul style="list-style-type: none"> Identity of researchers and sponsors must be included on the form. The name(s), degree(s) (and affiliation if other than the institution where the research is being conducted), and contact telephone number(s) If a researcher is a student this must be explicitly stated and the identifying information of the supervisor included This information should be listed below the title of the project The investigators should refer to themselves as the 'study investigator(s)' or 'study doctor(s)' to avoid confusion with the patient's usual physician 	EXAMPLE: The drugs in this study are provided by XXX Company, who are also providing the funds to conduct this study, as their future interest in developing and arranging for the sale of these drugs is dependent, in some part, on the results of this study.

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Invitation to participate in research REQUIRED	<ul style="list-style-type: none"> Information that informs the individual that they are being invited to participate in <i>research</i>. Provide a brief description of the study, indicating that it is a research study or clinical trial, as appropriate. 	EXAMPLES: You are being invited to participate in a research study looking at ... This is a clinical trial (a type of research study), which includes patients who choose to take part. Please take your time to make a decision, and discuss this proposal with your personal doctor, family members and friends as you feel inclined. The purpose of this letter is to provide you with the information you require to make an informed decision on participating in this research and to help us talk to you about your illness and its treatment. This letter contains information to help you decide whether or not to participate in this research study. It is important for you to understand why the study is being conducted and what it will involve. Please take the time to read this carefully and feel free to ask questions if anything is unclear or there are words or phrases you do not understand. We are asking you to take part because you have...

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To whom the Consent Form should be directed REQUIRED	<ul style="list-style-type: none"> Use the pronouns “you” and “your” rather than “I” and “mine”. If there are competent and incompetent participants or if the participants are minors, the letter should be written and read as referring to the participant rather than the parent/guardian who is signing the consent form for the participant. Avoid the use of “you/the participant” or “your/the participant’s” phrasing in the documents. 	<i>(if applicable insert at beginning of letter/questionnaire/instructions etc)</i> The pronouns ‘you’ and ‘your’ should be read as referring to the participant rather than the parent/guardian/next of kin who is signing the consent form for the participant.
Summary explanation of research Purpose of study REQUIRED	<ul style="list-style-type: none"> The document should be written in language which can be understood by the research participant. It may be necessary to have the letter translated into another language if it is known that the subjects are unlikely to be fluent in English A brief description of the purpose of the research should explain what hypothesis is being tested and what the research is supposed to demonstrate. 	<ul style="list-style-type: none"> Use lay language and grade 8 reading level. Possible need for translations See Glossary of Alternative Words
Number of participants REQUIRED	<ul style="list-style-type: none"> Indicate the number of participants that will participate and if a multi-site study indicate number at local site and number nationally/internationally. 	
Participant inclusion and exclusion criteria REQUIRED IN SPECIAL CIRCUMSTANCES	<ul style="list-style-type: none"> Include inclusion/exclusion criteria if the recruiter would not know if a participant was eligible or if there could be consequences to a non-eligible person’s participation in the study. 	EXAMPLES: If you are pregnant or breastfeeding you must not participate in this study. If you become pregnant during the course of the study you must notify the study doctors immediately. If you are allergic to milk or milk products you must not participate in this study.

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Description of the research REQUIRED	<ul style="list-style-type: none"> • Provide a clear understanding for the participant of how s/he will be involved in the research • Identify any procedures which are not part of normal care. Make a distinction between procedures that are part of standard medical care for the disorder in question and those that are mandated by the study design. • Explain if any current therapies or treatments are being altered or discontinued • Thoroughly describe all of the study procedures. • Identify any drug(s), intervention(s) ,device(s), testing procedure(s) that will be used. When procedures are repeated, list the frequency and intervals concerned. This is often best enumerated in the form of a table. • If any of the study procedures, drugs, or devices are experimental, they must be identified as such. • If the participant will be interviewed or asked to complete a questionnaire, describe the types of questions that he/she will be asked to answer. • If radiation is involved, indicate the level of radiation to which the participant is exposed • If blood testing is involved indicate the amount of blood to be taken • If a person’s (health) record will be reviewed this too must be explained 	EXAMPLES: If you take part in this study, you will have the following tests and procedures : These procedures are part of regular cancer care, and may be done even if you do not participate in the study... The following are standard medical procedures that will be done because you are part of the study... The following are experimental procedures that are being tested in this study...
Experimental procedures REQUIRED		

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Specific Research Techniques REQUIRED <ul style="list-style-type: none"> • Randomization • Blinding • Sequential Assignment 	<ul style="list-style-type: none"> • Specific research techniques must be explained to the participants. 	EXAMPLES: The participants in the study will be assigned at random, that is, by a method of chance, to one of the groups. You will have a (1 in 2 ; 3 in 4 etc) chance of being in a placebo group or an active drug group. Neither you nor your study doctor will know which group you are in. However, in the case of an emergency the code can be broken.
Magnetic Resonance Imaging	<ul style="list-style-type: none"> • see HSREB Guideline 2-G-0004 (formerly Appendix 3) for more details 	REQUIRED: see HSREB Guideline 2-G-0004 (formerly Appendix 3) for required wording
Placebo-control studies REQUIRED IN SPECIAL CIRCUMSTANCES	<ul style="list-style-type: none"> • If the trial involves a placebo rather than an active comparator, this section must inform the potential subject about (1) any therapy that may be withheld or withdrawn for the purposes of the study; (2) the possible consequences of withholding or withdrawing this therapy; and (3) the reasons why the use of the placebo is considered necessary 	EXAMPLES: This is a placebo controlled study. There will be two (or more) groups of subjects; one or more groups will receive the active drug which is being studied; the other(s) will receive a placebo. A placebo is an inactive substance which will have no direct effect on your illness.
Estimate of participant's time REQUIRED	<ul style="list-style-type: none"> • An estimate of the total amount of time required on the part of the participant (number of sessions, frequency of testing, etc.). 	EXAMPLES: You will be asked to complete six questionnaires, one at each of the office visits. The questionnaire at the first visit will take approximately 30 minutes to complete, the other five questionnaires will only take 5 minutes each. You will have to go to Dr. Smith's office at 9 am every Friday morning for the next 4 weeks to have your eyes checked. The eye examinations will take approximately 15 minutes to complete.

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Location REQUIRED	<ul style="list-style-type: none"> Indicate where the research will be conducted. 	EXAMPLES: The testing will take place in Room 155 at the Board of Education offices on Main Street. The nurse will come to your home to take your blood pressure and collect the food diaries. The interviewer will call you at home and ask you the questions over the phone.
Risks / Harms REQUIRED	<ul style="list-style-type: none"> Describe all risks and discomforts (physical and psychological) and any reasonably foreseeable risks or discomforts to the participant. It is not necessary to describe, in detail, the risks of the standard procedures the participant would undergo even if he was not a research subject -- concentrate on those risks associated with the investigational aspects of the protocol. Describe how serious the potential harm is Describe how likely it is to occur List the risks in categories that describe frequency and severity : e.g. likely and less likely – quantify with percentages or frequency when relevant. What will be done to prevent or minimize the probability of occurrence Acknowledge the possibility of unforeseen harms <p>If there is a risk of injury to the participant(s) the participant must be told:</p> <ul style="list-style-type: none"> who will be responsible for providing emergency medical treatment in the event of injury 	EXAMPLES: While on the study, you may experience side effects. Known side effects are listed below, but other effects may occur that we cannot predict. Most side effects go away when you stop taking the drugs, but others may be long-lasting or permanent. The following mild side effects are likely, occurring in more than 5% of people taking the drug: The following severe side-effects are less likely, occurring in less than 5% of people taking the drug: The treatment or procedure may involve risks, which are currently unforeseeable, to you or to the foetus, if you are or become pregnant.

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	<ul style="list-style-type: none"> • who will be responsible to pay for this treatment. • an explanation and description of any compensation and any medical treatments that are available if research participants are injured; • where further information may be obtained • whom to contact in the event of a research-related injury. <ul style="list-style-type: none"> • If there are no known risks include a statement to that effect. <ul style="list-style-type: none"> • Consent forms originating in the US must be adapted by the Canadian investigators to remove/alter clauses which are only appropriate to the American health care system 	<p>This study is covered by an insurance policy and if during the course of the study any injury should occur to you as a result of the administration of the study medication, not due to your fault or negligence, all medical expenses necessary to treat such injury will be paid provided: a) you comply at all times with the investigator's instructions b) you promptly report any such injury to the study doctor conducting the study, and c) the expenses are not otherwise covered by your provincial health care. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available.</p> <p>There are no known risks to your participation in this study.</p>

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Risks involved with pregnancies REQUIRED IN RELEVANT CIRCUMSTANCES	<ul style="list-style-type: none"> • If applicable, include a statement that the treatment or procedure may involve risks, which are currently unforeseeable, to the participant or to the foetus or child, if the participant is or may become pregnant or is breastfeeding. • If appropriate it may also be necessary to warn male participants or partners about the danger of fathering a child while involved with the study • In many instances if a woman becomes pregnant or a man fathers a child while in a study the pregnancy should be monitored to ascertain the health of the mother and child. In some cases it may be necessary/prudent to monitor the child once it has been born 	EXAMPLES if you are or become pregnant the treatment or procedure may involve risks, which are currently unforeseeable, to you or to the foetus. Because we do not yet know very much about the safety of this drug in pregnancy, we want to know what happens if any of the participants become pregnant (father a child) while taking the drug. If you get pregnant (father a child) during this study you must inform your study doctor right away. We would then appreciate it if you'd allow us to get information about the outcome of the pregnancy (the child's health etc.) This will involve asking you to allow us to contact you annually for the next five years to ask about the health of your child.
Benefits REQUIRED	<ul style="list-style-type: none"> • Identify benefits to participant • If treatment is involved no beneficial effects are to be guaranteed • If no direct benefit to participant is anticipated include a statement to that effect • If there are potential benefits, describe as completely as possible, • how important are they and how likely are they to occur • An additional sentence/paragraph about possible benefits to society or science may also be inserted. This should be separate from the specific benefits. • N.B. Monetary compensation is <u>not</u> a benefit. 	EXAMPLES: There are no known benefits to you associated with your participation in this research. You will not benefit directly from participation in this research. You will not get a personal medical benefit from participating in this study but your participation may help us get new knowledge that may benefit future patients with your disease.

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<p>Voluntary participation</p> <p>Refusal to participate</p> <p>Discontinuing Participation</p> <p>Withdrawal from study</p> <ul style="list-style-type: none"> • By participant • By investigators or sponsor <p>REQUIRED</p>	<ul style="list-style-type: none"> • The participants must freely consent to participate; participation is voluntary; participants may choose not to participate at all, may refuse to participate in certain procedures or answer certain questions or may discontinue the experiment at any time without penalty or loss of benefits to which the participant is otherwise entitled. • Emphasize that the decision to participate, or not participate, is solely up to the participant. • In those instances when it is not possible for a participant to withdraw from the research (e.g. partway through a surgical procedure), this should be explained. • It is also important to advise participants that withdrawal of their participation does not necessarily include withdrawal of any data compiled up to that point. • When applicable, participants should be informed of circumstances under which their participation may be terminated by the investigator without the participant's consent. • Participants should also be informed of procedures for safe and orderly termination should they decide to withdraw from the study before it is completed 	<p>REQUIRED WORDING:</p> <p>Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future (care/ academic status/ employment etc).</p> <p>EXAMPLES OF ADDITIONAL STATEMENTS:</p> <p>You have the right to be given all important information about your treatment, the study and what you will be asked to do. You should only agree to take part if you feel happy that you know enough about these things. You do not have to take part in the study if you do not want to.</p> <p>You may withdraw at any point in the study up until the time the implant has been put in place. Once the implant is in place it will not be possible to remove it for 48 hours without serious complications.</p> <p>The investigator may decide to take you off the study at any time if he feels your continued participation would seriously impair your health. He will take you off the study if any of the following events occur:...</p> <p>You may be withdrawn from the study by the doctor or sponsor if you develop a or do not take the medications as directed.</p> <p>If you decide to withdraw from the study, or if you are withdrawn from the study before it is completed you</p>

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		may be asked to (e.g. return all unused medications; return to the clinic for a final evaluation etc)
Participation in concurrent or future studies REQUIRED	<ul style="list-style-type: none"> It is important to determine if participants are already part of an ongoing study and may be compromised by participation in this study. <i>Some clinical trials prohibit participation in more than one study even though there is no risk or medical contraindication.</i> If you discover that a person is already participating in another study you should contact the other study's principal investigator to ensure that enrolment in your study will not disadvantage the participant. On occasion, participation in a study will knowingly involve the participant with a predictable chance for involvement in further studies If this is the case participants should be provided with this information and told they will have the opportunity to decide if they want to participate at a later date Concurrent studies for tissue or blood banking will require a separate consent form 	EXAMPLES: If you are participating in another study at this time, please inform the study doctor or nurse right away to determine if it is appropriate for you to participate in this study.

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Biological Specimens, Blood or Human Tissues REQUIRED IN RELEVANT CIRCUMSTANCES	Indicate <ul style="list-style-type: none"> • what the sample(s) are to be used for <ul style="list-style-type: none"> - Current study only - Future unknown research (banking) • where and how the samples will be stored • whether or not the participant will receive the results of the testing • if they will be linked to the participant • how long they will be stored • how they will be disposed of • describe the possibility for commercialization of research findings and what the subject may expect in way of compensation • <i>Consent for future unknown research and/or general banking of blood or tissues must have a separate Information/consent document.</i> 	EXAMPLES: Any specimen(s) (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the researchers/sponsors and once you have provided the specimens you will not have access to them. The specimen(s) will be discarded or destroyed once they have been used for the purposes described in the protocol. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the researchers/sponsor. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens.
New Findings RECOMMENDED REQUIRED IN CLINICAL TRIALS	<ul style="list-style-type: none"> • Participant must be given continuing and meaningful opportunities for deciding whether or not to continue participation. • The inclusion of this statement is mandatory in clinical trials. 	REQUIRED WORDING: If, during the course of this study, new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the investigator.

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Anonymity REQUIRED IN RELEVANT CIRCUMSTANCES	<ul style="list-style-type: none"> Assurance of anonymity can only be given when the researcher will have no way of connecting data to individuals. Names or other easily identifiable elements should not be noted directly on questionnaires or documents that would be sent to sponsors (e.g. patient reports) 	
Confidentiality REQUIRED	<ul style="list-style-type: none"> Describe the protection of the participant's privacy, method of storing research data, and who may have access to study records. The documents should not contain language that may be construed as requiring the participant to consent to unfettered access to his or her medical records by third parties. The monitor(s), the auditor(s), the REB and regulatory authority(ies) will be granted direct access to the participant's original (medical) records for verification of clinical trial procedures and /or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations. The participant or the participant's legally acceptable representative, by signing a consent form is authorizing such access NB use the term Health Canada to describe the Canadian regulatory agency Access may have to be granted to ensure the integrity of the study, to ensure participant health and welfare and maintenance of high standards Since there are situations in which a researcher may be compelled to break the confidentiality of 	<p>REQUIRED WHEN THE PARTICIPANT'S IDENTITY IS KNOWN AND ACCESS TO THE RECORDS BY THE REB IS POSSIBLE: Representatives of The University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.</p> <p>REQUIRED IF INITIALS AND DATE OF BIRTH INFORMATION BEING SENT OFF-SITE While we will do our best to protect your information there is no guarantee that we will be able to do so. The inclusion of your initials and your date of birth may allow someone to link the data and identify you.</p> <p>ADDITIONAL SAMPLE PHRASES: Your research records will be stored in the following manner: locked in a cabinet in a secure office; video tapes will be viewed only by members of the research team and they will be destroyed after 2 years.</p> <p>If the results of the study are published, your name will not be used and no information that discloses</p>

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	<p>(e.g. in response to a subpoena), absolute guarantees are not possible.</p> <ul style="list-style-type: none"> • Participant’s privacy will be protected to the maximum extent allowable by law • If the REB wants to contact the research participants they will do so via the investigator. Usually this will be done by asking the investigator to give the participant a letter from the REB that asks for permission to contact them or invites them to contact the REB, 	<p>your identity will be released or published without your explicit consent to the disclosure.</p> <p>Your confidentiality will be respected. No information that discloses your identity will be released or published with your explicit consent to the disclosure. However, it is important to note that the original signed research consent form and the data which will follow will be included in your health record.</p> <p>Representatives of (research team, REB, authorized study personnel, the study sponsor (identify), and regulatory bodies (identify) may require access to your records for the purpose of monitoring the research.</p> <p>If we find information we are required by law to disclose, we cannot guarantee confidentiality.</p> <p>We will strive to ensure the confidentiality of your research-related records. Absolute confidentiality cannot be guaranteed as we may have to disclose certain information under certain laws.</p> <p>As the study involves the use of a new drug, the records may be reviewed by the sponsoring company; by the Canadian regulatory agency, Health Canada; any by the US Food and Drug Administration.</p> <p>Thus, by agreeing to participate in this research trial, you consent to give representatives of the following entities access to your research-related medical</p>

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		<p>records to ensure the proper conduct of the research and verify the accuracy of the collected data :</p> <p>If the research-related records are kept in your hospital medical record, only those portions will be provided to these representatives, who will preserve your confidentiality.</p>
<p>Alternative treatments</p> <p>REQUIRED IN RELEVANT CIRCUMSTANCES</p>	<ul style="list-style-type: none"> • Include applicable information on alternative procedures or courses of treatment that may be available to the potential participant if he/she chooses not to participate or withdraws from the study. It is not enough just to indicate that there are alternatives, they must be described. • Particularly in the case of therapeutic interventions identify the care to be provided if the participant declines to participate. Include a summary of the nature of the alternative and potential harms and benefits. • If a treatment is involved, no beneficial effects are to be guaranteed; in the case of experimental treatment, participants are to be informed of alternative or standard treatments available and their record of success. 	<p>EXAMPLES:</p> <p>If you decide not to participate or if you withdraw from the study before it is completed, the alternative procedures or course of treatment will be the usual palliative care. Palliative care concentrates on providing you with control of your symptoms and advice and assistance. It is an active treatment with a focus on enabling you to live with your illness in as much comfort as possible.</p> <p>Regardless of your decision to participate you can still receive continuing care through this clinic.</p> <p>(If no alternative treatments) An alternative to the procedures described above is not to participate in the study and continue on just as you do now.</p>

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Contact person(s) for participants REQUIRED	<ul style="list-style-type: none"> • Instructions on whom (name and phone number) to contact regarding any questions or concerns that may be raised by participating in the study. The identity of the qualified designated representative who can explain scientific or scholarly aspects of the research. • The form should contain contact information other than the research team for participants with questions regarding the conduct of the study and/or their rights as research participants. 	REQUIRED: See application for names of the contact persons for participants who have questions regarding their rights and the conduct of the research. The correct person must be inserted into this sentence and this phrase included in the Letter of Information. <i>"If you have any questions about your rights as a research participant or the conduct of the study you may contact..."</i> ----- If participants are recruited from within the LHSC / SJHC system or research is taking place at LHSC / SJHC sites Dr. David Hill, Scientific Director, Lawson Health Research Institute (519) 667-6649 ----- If participants are recruited from sites other than LHSC or SJHC and research not taking place at LHSC or SJHC sites. The Office of Research Ethics (519) 661-3036, email ethics@uwo.ca.

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Compensation & Costs to Subjects RECOMMENDED BUT REQUIRED WHEN COMPENSATION IS PROVIDED AND/OR SUBJECTS WILL INCUR COSTS	<ul style="list-style-type: none"> • If participants will be compensated for their participation or reimbursed for costs (e.g., parking), describe in detail the type of payment, amount, and terms. • If participant does not complete the study compensation should be prorated. • If there is to be no compensation include a statement to that effect. • Specify any additional costs to the participant that may result from participation in this study that will not be reimbursed. • See above for compensation for injury. • If participants have to pay a fee for service and there is a need to distinguish fees for ordinary care or service from such fees as might result from the participant's participation in research. Include a statement to that effect. 	EXAMPLES The study medication will be given to you at no cost. You will not be paid to take part in the study; however, you will be reimbursed for your expenses such as parking for visits required as part of this study. In the event you are not able to complete the study your compensation will be pro-rated accordingly. You will not be compensated for your participation in this research study. Additional costs you may incur as a result of your participation are: (e.g. parking, drug costs, child care etc) Your participation in this research project will not involve any additional costs to you or your health care insurer. Your participation in this research project may involve additional costs to you for (indicate source of cost, e.g., drugs, device, diagnostic procedure, therapeutic procedure). Your health care insurance probably will not pay for all of these additional costs. It is estimated that the additional, unreimbursed costs to you will not exceed (\$). If actual costs exceed this estimate, you are still responsible for them.

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Private medical or life insurance REQUIRED FOR CLINICAL TRIALS & EXPERIMENTAL THERAPIES	<ul style="list-style-type: none"> Private medical and life insurers are becoming concerned that they are being asked to assume costs for deaths or injuries resulting from a person's participation in a clinical trial Participation in a trial may also affect a person's ability to utilize certain diagnostic and treatment technologies e.g. MRI It may also be necessary to explain to the participant what would happen if a medical condition was detected of which they were unaware. E.g. high blood pressure, HIV 	REQUIRED FOR CLINICAL TRIALS OR THERAPEUTIC INTERVENTIONS THAT ARE NOT PART OF USUAL CARE: If you have private medical or life insurance, you should check with your insurance company before you agree to take part in the study to confirm that participation in this study will not affect your insurance coverage and/or access to benefits.
No waiver of rights REQUIRED	<ul style="list-style-type: none"> There should be <u>no exculpatory language</u> whereby the participant waives or appears to waive, any of his/her legal rights, including any release of the sponsor, institution or its agents from liability for negligence. Alternatively you may explicitly state that they do not waive their rights. 	EXAMPLE You do not waive any legal rights by signing the consent form.

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Research-related injury clauses REQUIRED WHEN PRESENT	<ul style="list-style-type: none"> There should be <u>no exculpatory language</u> whereby the participant waives or appears to waive, any of his/her legal rights, including any release of the sponsor, institution or its agents from liability for negligence. 	<p>REQUIRED: INCLUDE A STATEMENT ADJACENT TO CLAUSES DEALING WITH RESEARCH RELATED INJURIES.</p> <p>EXAMPLE This study is covered by an insurance policy and if during the course of the study any injury should occur to you as a result of the administration of the study medication, not due to your fault or negligence, all medical expenses necessary to treat such injury will be paid provided: a) you comply at all times with the investigator's instructions b) you promptly report any such injury to the physician conducting the study, and c) the expenses are not otherwise covered by your provincial health care. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. You do not waive any legal rights by signing the consent form.</p>
No statement of institutional approval REQUIRED	<ul style="list-style-type: none"> There must be <u>no indication</u> that the REB, UWO or its affiliated institutions have approved the research as this may unduly influence a potential participant's decision to participate 	
Publication of results REQUIRED	<ul style="list-style-type: none"> The ways in which the research results will be published, And if appropriate, how the participants will be informed of the results. 	<p>EXAMPLES If the results of the study are published, your name will not be used.</p> <p>If you would like to receive a copy of the overall results of this study please put your name and address on a blank piece of paper (separate from the questionnaire) and give it to the technician.</p>

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Copy of information/consent documentation REQUIRED	<ul style="list-style-type: none"> The participant must be provided with a copy of the Letter of Information/Consent documentation and this should be stated in the Information part of the Information/Consent documentation 	EXAMPLES: This letter is for you to keep. You will be given a copy of this letter of information and consent form once it has been signed.
Conflict of Interest REQUIRED WHEN PRESENT	<ul style="list-style-type: none"> When appropriate, a statement concerning an investigator's or an institution's potential financial or other conflict of interest in the conduct of the study. If the investigator has a significant financial interest in the outcome of this particular study or research program, a statement to that effect should be inserted. This would include shares in the sponsoring company and remuneration for the recruitment of the participant. 	
Use of Letterhead REQUIRED	<ul style="list-style-type: none"> All letters and consent forms should be printed on letterhead when they are presented to potential participants The HSREB will accept draft versions of the documentation not on letterhead for review and comment but before final approval can be released the Office of Research Ethics must receive the final version on letterhead. 	
Use Appropriate Language Level REQUIRED	<ul style="list-style-type: none"> Lay language and no jargon Simplified explanations of complex procedures or concepts Grade 6-8 level recommended for general public 	See Glossary for possible alternative words

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Formatting REQUIRED	<ul style="list-style-type: none"> • Use simple declarative statements. • Write short sentences/ use short paragraphs • Use of “you <i>understand</i> that” is not permitted as it could be interpreted as suggestive and can constitute coercive influence over a subject. 	
RECOMMENDED	Type: <ul style="list-style-type: none"> ▪ Size ▪ Font ▪ Emphasis 	<ul style="list-style-type: none"> • 12 point recommended but larger type may be needed for elderly or visually compromised participants • Avoid italics or ornate type
RECOMMENDED	Page layout	<ul style="list-style-type: none"> • Use bullets, tables, charts • The use of ‘white space’ makes the document easier to read.
RECOMMENDED REQUIRED FOR CLINICAL TRIALS	Page header or footer <ul style="list-style-type: none"> • Keep the footers simple and short • Ensure they do not run into the footers preprinted on letterhead. • The version number, date etc should refer only to the current version. 	<ul style="list-style-type: none"> • Number each page – use Page # of # format • Study title or reference or version • Date • Place for participant to initial each page

INSTRUCTONS – INFORMATION & CONSENT DOCUMENTATION		
SECTION	RATIONALE & COMMENTS	PHRASING
RECOMMENDED	Use headings and subheading frequently	<p>Examples of Headings</p> <ul style="list-style-type: none"> • Introduction • Purpose of this study • Research tests or procedures for this study • Research drugs or treatments you will receive in this study • Voluntary Participation • Compensation • Privacy & Confidentiality • Risks and discomforts to you if you participate in this study • The benefits to you if you take part in this study • What other choices you have besides taking part in this study • What will happen to the samples or information that are collected • Other pertinent information • What costs are there to you if you enter this study • What to do if you want to withdraw from this study • Specific things you should know about confidentiality • Concerns about pregnancy or fertility or childbearing in the future • How long will this study last and how many people will be enrolled.

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Consent Statement REQUIRED ALSO SEE SECTION ON 'REQUIREMENT FOR WRITTEN CONSENT'	<ul style="list-style-type: none"> • The Letter of Information and Consent Form may be combined as one document • The consent statement should be at the end of the combined Information/Consent document • The subject must receive a copy of the Letter of Information or Information/Consent document • All substantive information should be in the Letter of Information do not include extra statements to Consent form 	REQUIRED WORDING I have read the Letter of Information (or Information/Consent document), have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction. IF CONSENT IS TO BE KEPT SEPARATE FROM LETTER OF INFORMATION THEN CONSENT FORM MUST INCLUDE : <ul style="list-style-type: none"> ▪ STUDY TITLE ▪ INVESTIGATOR(S) NAME

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Signatures REQUIRED SEE ALSO SECTION ON 'REQUIREMENT FOR WRITTEN CONSENT'	<ul style="list-style-type: none"> • Include a “Legally-Authorized Representative” signature line only if participants cannot consent on their own behalf. • The signature of a witness is optional but it is <u>not</u> required by law. A “Witness” signature line may be required by the Sponsor. However, the inclusion of a Witness is not recommended by the HSREB as the use of an impartial person unrelated to the protocol, may compromise the confidentiality of the participant. • Form should be co-signed by the person responsible for obtaining informed consent • Children over 7 are encouraged to sign their name – alternatively they may sign an Assent form. (see Guidelines - Children Assent forms) • Participants should initial each page <p>Blind, illiterate or non-English speaking subjects</p> <ul style="list-style-type: none"> • When consent is given following reading/translating of the information/consent documents by someone other than the participant, that person should sign the consent form indicating their role in the consent process 	REQUIRED: <i>Provide space to Print the person’s name for all persons signing the consent.</i> <ul style="list-style-type: none"> • Research participant or legally authorized representative • Person responsible for obtaining informed consent REQUIRED: <ul style="list-style-type: none"> • Person translating or reading document

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Requirement for written consent WRITTEN CONSENT IS REQUIRED FOR CLINICAL TRIALS & EXPERIMENTAL THERAPIES	<ul style="list-style-type: none"> • In some cases, such as a survey or questionnaire, it is not necessary to have the subjects sign a consent form as the act of completing the questionnaire is taken to be the consent. • The investigator must incorporate the elements of a Letter of Information in a cover letter or face sheet to a written questionnaire. • Written consent is required for clinical trials and experimental therapies 	EXAMPLES Completion of the survey is indication of your consent to participate. You indicate your voluntary agreement to participate by completing and returning this questionnaire. You indicate your voluntary agreement to participate by responding to the questions.