Prince Edward Island
RESEARCH ETHICS BOARD

Guidelines for Preparation of a Consent Form

These guidelines are designed to conform with the Tri-Council Policy Statement: Ethical Conduct for Research in Humans (TCPS) and the ICH Good Clinical Practice: Consolidated Guideline (GCP).

1. GENERAL ADVICE

Delays in approval of application are often caused by inadequate or inappropriate consent forms. The submission of a properly completed standard consent form will expedite the processing of your application.

It is ethically and legally necessary to explain the research study and obtain consent from any person prior to an invasion of their person or their privacy, no matter how minor such an invasion may be.

A written consent form is usually required for all but the most trivial of procedures.

A verbal explanation of the research is ALWAYS required.

The standard consent form combines a written explanation with the actual consent statements. The written explanation allows the participant to consider participation and to discuss it with family or advisors prior to consent. It does not excuse an investigator from verbal explanation nor from answering any questions from the participant. Thus, a participant's signature alone is not a guarantee that informed consent has been obtained.

A participant must be given sufficient time to read and reflect upon the information in the consent form. If appropriate, time should be allowed to seek advice from a third party. Consideration of the consent form should be at the participant's leisure and should not take place in the presence of the investigator/staff.

In certain cases the Research Ethics Board may designate a disinterested third party to obtain the consent or to assess competence to give consent following a verbal explanation from the investigator/designate.

2. ADMINISTRATIVE REQUIREMENTS:

The consent form for all studies must conform to a Grade 8 level of readability and should not contain unnecessarily complex and technical jargon. Consent forms should be in 12point Times New Roman font.

Consent forms that do not conform to this standard are considered unacceptable by the REB, and will not be approved until they are revised to conform to this standard.
(Consent Forms for expedited review studies should be at an appropriate level of readability for the population at which they are targeted.)

The first page of any consent form should be on the most appropriate letterhead (eg. QEH, PCH, UPEI). Please contact the Research Ethics Board office for guidance.

- Consent Forms should have pages numbered consecutively with an indication of the total number of pages included (e.g. "Page 3 of 4" or "Page 1 of 1")
- An abbreviated trial or study title should appear as a running header on the top left-hand corner of each page of the consent form.
- The full trial or study title must appear on the first page of the consent form, as well as the signature page.
- The version number and date of the consent form should be included on the bottom left-hand corner of each page of the consent form.
- The consent form must include all required sections. Additional sections may be required, depending on the design and requirements of the research study.

3. CONSENT FORM REQUIRED ELEMENTS

All consent forms must include:

- the purpose of the study;
- explanation of randomization (if applicable);
- what is expected of the participant (procedures, tests, interviews, filling out questionnaires, examinations, etc.) including the time and period of commitment;
- explanation of possible risks and discomforts;
- a statement which explains that participation is voluntary and can be withdrawn without prejudice;
- a statement which promises availability to answer questions throughout the study;
- a statement that there is no guarantee of benefit;
- the standard liability statement

Wording for required statements are given in the consent templates.

Clinical trials will also include:

- a statement which describes the usual treatments for persons not in the study;
- a statement promising communication about any new discovery which might influence
- continued participation in the study;
- a statement which promises medical treatment for any illness or injury which occurs as a
- direct result of taking part in the study;
- a statement which informs the participant that the family doctor will be informed of their
- participation in a trial (if participant agrees);
- a statement which provides contact information;

Wording for these statements are given in the consent templates.

4. WORDING REQUIREMENTS FOR CONSENT FORMS

Randomization

If randomization is to be employed, an explanation of the process should be included, in lay terms.

For trials or studies where participants will be randomized to one of two groups (arms), randomization should be described as "like the flip of a coin" (e.g. - "You will than be randomized (assigned by chance, like the flip of a coin) to one of two groups." {Then include a description of each group.]

For trials or studies where participants will be randomized to one of three or more groups (arms), randomization should be described as "like the roll of a dice" (e.g. - "You will then be randomized (assigned by chance, like the roll of a dice) to one of ___ groups." [Then include a description of each group.]

Placebo Use

If a placebo or inactive control is to be used, a statement must be included indicating that trial participants may receive a substance that is likely to have no active effect. The anticipated consequences of withdrawing or withholding any standard therapy and reasons why investigators deem a placebo-controlled (or inactive-controlled) trial to be necessary should also be stated, in lay terms.

When a clinical trial involving a placebo control is undertaken, the researcher should consult the Tri-Council Policy Statement Article 7.4, regarding the nature of the information that the subject should receive. Please note that giving no control (e.g. - Treatment A versus Treatment A plus B [add-on treatment]) follows the same principles as outlined above, and also requires justification under Article 7.4 of the Tri-Council Policy Statement.

For clinical trials of investigational drugs or natural health products, please refer to a placebo as an "inactive substance" (e.g. - "If you are assigned to the "placebo" group, this means that you will receive an inactive substance instead of the study drug.").

For clinical trials of medical devices involving a sham procedure or sham device comparison arm, please refer to the sham device as an "inactive device" (e.g. - "If you are assigned to the "sham device" group, this means that you will receive an inactive device instead of the study device. You will not know whether you have received the study device or not." OR "If you are assigned to the "sham procedure" group, this means that you will have a similar procedure done but will not receive the study device. You will not know whether you have received the study device or not."

Blinding

For trials or studies where participants and/or investigators (or evaluators), in the case of surgical or medical device interventions) will be blinded.

Single-Blinded Trials/Studies
For clinical trials investigational drugs or natural health products, please explain single-blinding as follows: "You will not know whether you are receiving the study drug or the inactive substance".

For clinical trials of medical devices being compared to participants receiving no device, please explain single-blinding as follows: "You will not know whether you received the study device or not."

For clinical trials of medical devices being compared to participants receiving sham devices, please explain single-blinding as follows: "You will not know whether you received the study device or the inactive device."

For clinical trials of medical devices being compared to standard of care or 'best practice' devices, please explain single-blinding as follows: "You will not know whether you received the study device or the device you would have received as part of normal care for your condition."

For clinical trials of surgical techniques or procedures (where blinding is possible), please explain single-blinding as follows: "You will not know which type of surgery you received."

For Expedited Review research studies, please adapt the above examples accordingly, to suit your study (e.g. – "You will not know whether you are receiving the standard questionnaire or the study questionnaire").

Double-Blinded Trials/Studies
For clinical trials of investigational drugs or natural health products, please explain double-blinding as follows: "Neither you nor the Principal Investigator will know whether you are receiving the study drug or the inactive substance".

For clinical trials of medical devices being compared to participants receiving no device, please explain double-blinding as follows: "Neither you nor the _____ who evaluates your progress will know whether you received the study device or not." (filling in the blank as appropriate for your trial).

For clinical trials of medical devices being compared to participants receiving sham devices, please explain double-blinding as follows: "Neither you nor the _____ who evaluates your progress will know whether you received the study device or the inactive device." (filling in the blank as appropriate for your trial).

For clinical trials of medical devices being compared to standard of care or 'best practice' devices, please explain double-blinding as follows: "Neither you nor the _____ who evaluates your progress will know whether you received the study device or the device you would have received as part of normal care for your condition." (filling in the blank as appropriate for your trial).

For clinical trials of surgical techniques or procedures (where blinding is possible), please explain double-blinding as follows: "Neither you nor the _____ who evaluates your progress will know which type of surgery you received." (filling in the blank as appropriate for your trial).

For Category B research studies, please adapt one of the above examples accordingly, to suit your study.

The above issues regarding randomization, placebo use and blinding should be explained in the "How Is The Trial Being Done?"(Full Board Review studies) or the "How is the Study Being Done?" (Expedited Review studies) section of the consent form.

5. ADDITIONAL SECTIONS THAT MAY BE REQUIRED FOR CONSENT FORMS:

Conflicts of Interest
Describe any actual or potential conflicts of interest on the part of the researchers and/or the institutions and/or the persons recruiting participants.

Commercialization of Research Results
Describe any potential profit that may be expected by the sponsor or researchers from commercialization of the results of the research and what, if any, plans have been made to share these profits with the research participants.

Continued Access
State whether the service/drug/intervention/device/program will be available to the participant once the research is complete and, if so, under what conditions.

Blood/Tissue Storage and Genetic Testing
Please see the REB Guidelines for Studies involving Genetic Research and/or Blood or Tissue Storage. **(Not Available - Currently being written.)**

Future Contact/Future Research/Other Use
If the researcher would like to be able to contact the participants again in the future to seek their involvement in subsequent research projects, he/she should seek explicit consent to future contact.

If the researcher would like to keep the information/samples gathered during this trial/study for future research, he/she must seek explicit consent for such future use. Please note that the future research that the researcher wishes to undertake must clearly be explained (eg. If a sample is obtained for breast cancer research and is to be kept for future research on other types of cancer, but may be used later for diabetes [or other] research, the consent form should state clearly that the participant's sample may be used for purposes other than those originally intended, or for any purposes whatsoever without consulting them, if they choose to provide a sample) as well as any additional risks to participants.

If the researcher would like to use the information/samples gathered at some time in the future for purposes other than research (e.g. teaching), he/she must seek a separate explicit consent for such use.

6. SPECIAL SITUATIONS TO CONSIDER REGARDING THE CONSENT PROCESS

Problems in Communicating Information
This applies to subjects who are blind deaf, illiterate, or those whose fluency is in languages other than English. Precautions must be taken in fulfilling the necessary criteria for a valid consent process to ensure that communication is made in a manner that these special subject populations can understand. The consenting process should be detailed in the "Recruiting and Consenting Step-By-Step Process".

In cases where a potential participant cannot read, the witness to the participant's signature should observe the entire consent process to ensure that the information in the consent form is accurately relayed to the potential participant. In these instances, the signature line may be revised by hand to say "Witness to Consent Process and Participant's Signature" rather than simply "Witness to Participant's Signature". Such a revision should be initialed and dated by the person making the revision to the consent form signature page.

Communication in these instances should be documented and confirmed in writing by third parties aiding the investigator. Family members should not be enlisted as translators for the consent process if at all possible, as they are likely to be biased either in favour or against their family member participating in the research. For this reason an impartial, professional translator should facilitate the consent process, if possible.

Witnesses
In situations where a person is able to provide informed consent on their own behalf, the individual signing the "Witness to Participant's Signature" field on the consent form signature page is attesting only that they witnessed the person sign the consent form.

Minors
There is no legal "age of consent" in PEI. PEI Law provides that a minor may give valid consent if he/she is capable of appreciating fully the nature and consequences of the treatment or procedures. If the research involves subjects primarily under 17 years of age, the IWK Research Ethics Board in Halifax may be consulted to provide an ethical review for the study.

Mentally Incapacitated Adults
This applies to individuals rendered unconscious or who are otherwise not mentally competent to make decisions on their own behalf.

Third party authorization must be sought when individuals are incapable of providing consent to participate in research. However, should the competency of the individual change while participating as a research subject, their informed consent (or renewal thereof) must be sought as soon as possible.

Legally Accepted Representative

If the legally accepted representative is consenting to the enrollment of the participant into the study, then their signature is acceptable. However, if the legally accepted representative is also being asked to provide information or samples that will be used as part of the research, they should provide a separate consent on their own behalf in order to participate.

7. ADDENDUMS TO CONSENT FORM

Consent Form Addendums should be used with participants when:

- there are amendments to the protocol that alter the study procedures (e.g. a change in the length of study visits, additional follow-up visits are added, or an additional blood draw at each of the study visits is added);
- there are updates to the risks of the study (e.g. the risks are updated after a new version of the Investigator's Brochure, Product Monograph or Device Manual is released);
- new information has become available that might alter participant's willingness to continue their participation in the trial.

8. CASE REPORT CONSENT FORM TEMPLATE

If you wish to present or publish a case report of de-identified information about a particular patient, you must first obtain consent from the patient in question (if he/she is capable of providing consent) or the patient's legally accepted representative if he/she is incapable of providing consent.

Please fill in the blanks in the template accordingly when drafting your Case Report Consent Form, filling in the patient's name, the name of the person doing the case report, and providing the name and full contact information for the person doing the case report (work address, contact telephone number, pager number [if applicable] and e-mail address).

IMPORTANT: In instances where a patient is incapable of providing consent on his/her own behalf for the presentation or publication of his/her de-identified health information for these purposes, and efforts have been unsuccessful to obtain the consent of the patient's legally accepted representative (e.g. – when a legally accepted representative does not exist, or is unreachable after repeated efforts to contact him/her) the Board will accept proof of due diligence in attempting to obtain consent. However, please note that refusal of a patient's legally accepted representative to provide consent is <u>not considered to constitute proof of due diligence</u>. In situations where a patient's legally accepted representative refuses to provide consent, a patient's information may not be presented or published for case report purposes.

9. WAIVER OF INFORMED CONSENT REQUIREMENT

The REB may waive the requirement to obtain informed consent provided that it is shown that:

- The research involves no more than minimal risk to the subjects

The waiver is unlikely to adversely affect the rights and welfare of the subjects

- The research could not practicably be carried out without the waiver
- Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation.
- The waived consent does not involve therapeutic intervention.

- For chart review studies (whether retrospective or prospective) please indicate a request for waiver of the informed consent requirement for human subjects research under Section 2.1 c) of the Tri-Council Policy Statement in your cover letter to the REB.

10. VERBAL CONSENTS

Please note that verbal consents (in person or over the phone - or covering letters/information sheets which accompany mailed questionnaires) must include the required elements of the consent. In some cases the benefit and liability sections may be omitted but the investigator should check with the Research Ethics Office.

11. TYPICAL ERRORS OR OMISSIONS

- Not updating version number and date on all pages of revised versions of the consent form
- Not omitting irrelevant sections or wording that do not apply to your study/site
- Not modifying wording for special situations
- Not using the term "Principal Investigator" consistently, and using terms like "your doctor", "the doctor" and "study doctor" instead
- The stated numbers of local and global (total) subjects does not match the protocol
- Unnecessary repetition of information.
- Confusing or grouping together usual care with research
- Use of overly complex language. Consent forms provided to you from elsewhere and even consent forms that have been approved for use elsewhere will almost always be too complex in wording.
    - Avoid complex sentences. Any sentence with more than one comma, and any punctuation marks other than a comma or period, is complex.
    - Avoid uncommon words. Remember that as a health professional many words that are common to you, like "IV" or "catheter", are meaningless to much of the general population.
    - Avoid difficult words (a good rule of thumb is to use no more than 1 or 2 words with more than 3 syllables in each sentence)
    - Avoid long, or run-on sentences
    - Avoid long paragraphs
    - Don't believe that "our population is well informed and different - they understand complex words and jargon". Many don't understand complex words and jargon, but may pretend that they do.

12. TIPS FOR WRITING IN PLAIN LANGUAGE

- Use the active voice.
- Write directly to the research participant "you".
- Use the positive wherever possible - "will" versus "will not/won't".
- Use common words rather than technical jargon.
- Use short words and short sentences.
- Make bulleted or numbered lists of important points.
- Test the consent form on lay people who are unfamiliar with the content of the study.

13. TIPS FOR DESIGNING A CONSENT DOCUMENT

Justification:
Use only left justification, not full justification.

Fonts:
Use a font with serifs (e.g. Times Roman, not a sans serif font like Arial)
Serifs - the curls on letters - help readability

Space:
The margins and white space between paragraphs guide reading.
Bulleted lists are easier to read than series with commas.
Headings/subheadings in bold except in major headings.

Also view the website for the Fog Index and Keep it Simple:
http://www.fpd.finop.umn.edu/groups/ppd/documents/information/writing_tips.cfm

14. TEST THE READABILITY

i) Both WordPerfect and MSWord have a way to test readability of any document. The following instructions apply to the latest versions of the word processors and may be slightly different from other versions. If all else fails you could read the online help files.

WordPerfect	**MSWord**
1. Click **Tools** ➡**Grammatik**. 2. Click **Options** ➡**Analysis** ➡**Readability**.	1. Click **Tools** ➡**Options** ➡ **Spelling and Grammar**. 2. Select **Check grammar with spelling** check box. 3. Select **Show readability statistics** check box and then click **OK**. 4. On the standard toolbar click **Tools** ➡ **Spelling and Grammar** When MS Word finishes checking spelling and grammar, it displays information about the reading level of the document
Read off the Flesch-Kincaid Grade level. You should aim for a grade less than 10 to ensure maximum comprehension.	
Replace the Medical Jargon!	

ii) SMOG is another widely used method. It allows you to keep the really critical "long words" - a drug name, for example, and calculate the reading level around it by skipping that word in the counts. This method takes about five minutes to do on a standard length consent form.

How to Use the S.M.O.G. (Simple measure of gobbledegook) readability formula:

If the text has 30 or more sentences:

1. Count off 30 sentences within the document - 10 consecutive sentences at the beginning, in the middle and near the end of the text. Do not include titles or headings and treat a bulleted list as a sentence.
2. Mark all polysyllabic words (words with 3 or more syllables) in the sample.
3. Count the total number of polysyllabic words.
4. Find the nearest square root of this number.
5. Add 3 to the square root. This gives you the reading level the person must have to understand the text.

If the text has less than 30 sentences:

1. Count the polysyllabic words in the text.
2. Count the number of sentences in the text.
3. Find the average number of polysyllabic words per sentences:
   total number of polysyllabic words divided by the total number of sentences.
4. Subtract the total number of sentences from 30 and multiply the remainder by the average number of polysyllabic words per sentence.
5. Add this figure to the total number of polysyllabic words.
6. Find the square root and add 3.

Additional guidelines for using SMOG

1. Hyphenated words are considered one word.
2. Numbers in numeric forms should be pronounced to determine if they are polysyllabic (the number 337 has 8 syllables).
3. Proper nouns are counted.
4. Abbreviations should be pronounced to determine if they are polysyllabic (PEI = Prince Edward Island 5 syllables.
5. Include all repetitions of the word, no matter how often used.
6. Read bulleted lists as a single sentence.

The grade level is accurate to +/- 1.5 grades.