UNIVERSITY OF OTTAWA
HEART INSTITUTE
INSTITUT DE CARDIOLOGIE
DE L'UNIVERSITÉ D'OTTAWA

Guidance Document for Writing the 'Participant Information Sheet and Consent Form'

This guidance document seeks to assist researchers and their staff by outlining what information to include in each section of the Participant Information Sheet and Consent Form (PIS&CF). This document is structured with the same sections as the PIS&CF template, and according to TCPS2 guidelines, specifically Article 3.2: "*Researchers shall provide to prospective participants, or authorized third parties, full disclosure of all information necessary for making an informed decision to participate in a research project*". It is also in compliance with Institutional SOPs. This guidance document and the consent template have been created primarily targeting patients as participants in clinical trials. Please revise accordingly for other groups, ie: healthy volunteers, trainees, etc.

If, after reading this guidance document and the PIS&CF template, you still have questions, please contact Debra Warren, Protocol Officer for the University of Ottawa Heart Institute (UOHI) Human Research Ethics Board (HREB). She can be reached at 613-798-5555 ext. 19865, or dewarren@ohri.ca or Sharon Finlay, Clinical Research Administrator, Research Services at ext. 18686 or sfinlay@ottawaheart.ca

General Guidelines

- Make sure information in the PIS&CF is consistent with the research protocol and the application form. The Board specifically reviews the documents for consistency.
- Write the consent form as though you are verbally explaining the study to a prospective participant using simple laymen language at a grade 8 reading level. Copy and pasting from the protocol or application is not recommended.
- Use second person ("you/your") throughout the PIS, and use first person ("I") for the Consent to Participate signature page.
- Define or explain all required technical terms the first time they appear in the document, avoiding the frequent use of parenthesis.
- Define acronyms the first time they appear in the document.
- Be consistent with technical terms by using the same one throughout the document (e.g., if you define CTA, then use this acronym throughout the document; do not later switch to CT Angiogram).
- Avoid bolding text aside from section headings.
- Use a consistent font style and size throughout the document; a minimum of 11 is recommended, 12 is preferable.
- The document should not exceed 8-10 pages.
- The first page and the final signature page must be on institutional letterhead; and if more than one logo will be on those pages (ie: a collaborating site's logo), the UOHI logo must remain in the upper left corner.
- The other pages should contain the study title in a header; and page X of Y and the version date of the document in the footer; and the "valid until" date must be added to the final page, once HREB approval has been granted.

For templates provided by sponsoring sites:
Template PIS&CFs are often provided by the sponsoring site (either industry sponsored or from another academic institution). These templates must be modified to meet the UOHI requirements outlined in this guidance document and the UOHI PIS&CF template. For industry sponsored trials, the sponsor must approve the document before the study is submitted for ethical review. Please consult with your sponsor for exact processes. Be sure to contact the HREB office if you encounter difficulty with a sponsor approving a particular section of the PIS&CF.

For translating HREB-approved English PIS&CFs into French:
Researchers must have HREB-approved English PIS&CFs translated by: (1) the UOHI Translation Services; or (2) a third party (i.e., sponsor or translation company) so long as the documents submitted are accompanied by a certificate of translation or verified by UOHI Translation Services; or (3) for investigator initiated protocols only, a bilingual Principal Investigator may do the translation independently, but must agree to assume responsibility in writing for the accuracy of the translation. Refer to the OHRI SOP OH1000 v2 for further details.

Introduction

In this section inform participants why they are being approached. For example, is it because they have a particular disease, or are they being approached as normal, healthy volunteers?

- Be as specific as possible but use everyday language. Do not use technical language or list the inclusion/exclusion criteria.

Background, Purpose and Design of the Study

In this section state the purpose of the study and provide the rationale for performing the study (e.g., results of previous studies, etc.), as relevant to the participant.

- State whether the study is a continuation of a previous study, increased dosage, changing administration of a drug, new patient population, etc.).
- Indicate if the study drug, device or procedure is deemed experimental; has been approved by Health Canada, FDA or other regulatory authorities; and the testing that has been completed.
- List the number of centres participating (for multi-centre trials), the total number of participants to be recruited from all centres, and the number to be recruited from UOHI.

Study Duration

Inform the participant how long the study is expected to continue, and the length of their expected study participation.

Study Procedures

In this section provide a clear description of what the patient should expect with participation in the study, and the type of study ie: randomized, double-blinded, etc.

- Make a distinction between research-related procedures and standard-of-care procedures. If the study includes procedures that the participant would undergo in the

course of standard diagnosis or treatment, then these procedures do not need to be explained/described in-depth. The PIS&CF should focus on describing research-related procedures and only discuss standard-of-care where really necessary.

- Explain if the participant's current therapies or treatments will be altered or discontinued.
- If a drug is to be given, indicate the dosage, the route of administration, and the duration of administration.
- If a placebo is to be used, explain why that is necessary and provide definition (as per template)
- Describe randomization and blinding (see template for details).
- Describe all tests (blood, x-rays, PET, etc), measures, procedures, interventions, treatments or questionnaires that are outlined in the research protocol, chronologically if possible.
- Consider the use of subheadings to help organize this section and increase readability (e.g. Screening, Baseline Visit, Randomization, Follow-up).
- Indicate the frequency of each procedure and the length of time taken to complete it. The use of tables is recommended to describe procedures, particularly if they will be repeated at several visits (see PIS&CF template for an example). The table should be printed on one page.
- Inform the participant where he/she will take part in the study, whether it will be at the hospital, at home, how many visits their participation may involve, how long each visit will take, and whether any follow-up will be required for the study, etc.

For specific procedures:

- If blood will be drawn, indicate the amount in teaspoons/tablespoons and milliliters for each sample, as well as the total amount of blood to be drawn. (Conversions: 1 tsp = 5 ml; 1 tbsp = 15 ml)
- If there are questionnaires, inform the participant what type of questions they will be asked; how many times they will be asked to complete the questionnaires; provide an estimated time to complete them; and inform them that they may skip any questions that they do not feel comfortable answering.

Responsibilities of the Participant

In this section list what the participant must do to comply with the study requirements; particularly if they need to abstain from the use of certain meds or foods, and reporting symptoms/adverse events, etc.

Potential Risks and Discomforts

In this section list all potential risks or discomforts of each/test procedure that are research related. **You do not need to include the risks or discomforts for procedures performed as standard of care**.

- For studies involving drug therapies indicate all risks listed in the investigator's brochure, being sure to define medical terms.
- Quantify the side effects and risks in percentages or group them in categories whenever possible.
    -- Very Likely (21% or more patients).
    -- Less Likely (5% to 20%).

-- Rare (1% to 4%).
-- Very Rare but serious (less than 1%).

- Always write out terms such as “less than” or “greater than” as some people may not understand symbols such as “<” or “>”.
- Address the reversibility of side effects and long term side-effects as applicable.

Radiation Risks

If your study involves procedures that will expose participant to radiation, please fill out the appropriate forms and include an appropriate statement about the risk.

Pregnancy Risk

ONLY include this section if pregnancy is an exclusion criterion **OR** if the study poses risks to those who are pregnant, become pregnant or are nursing mothers (as per TCPS2 Art. 4.3 and ICH GCP s. 4.8.10 (g)).

Potential Benefits

In this section identify the specific direct benefits to subjects if he/she participates in the study.

- Do not include monetary/expense reimbursements in the “Benefits” section; this should be indicated in the “Study Costs” section.
- Ensure statements are not coercive but realistically provide an appreciation of the scientific knowledge anticipated.

Alternative Treatments Available

In this section describe any approved and/or standard treatments that are available for participant’s disease and/or condition. These options should be presented to the participant so he/she is fully informed. Participant should also be informed if no alternative treatments are available. For non-clinical studies this section may not be necessary.

Withdrawal from the Study

In this section, explain that participant may withdraw from the study at any time without an impact on their care. Participants should also be given the choice of having their data withdrawn from the study completely, or be provided with the reasons why this option might not be possible. Participant is also informed of foreseeable circumstances and/or reasons under which his/her participation in the trial may be terminated (ICH-GCP 4.8.10(r)).

- State if withdrawal is impossible. For example, the well functioning experimental artificial hip cannot be removed, but participation in the study assessments may be withdrawn.
- Specify if the request to withdraw from the study must be in writing, a sample letter must be provided to the research participant. (A sample is available on the OHRI REB website, under ‘Consent Forms’).

Compensation

In this section indicate that treatment in the event of injury will be covered by the sponsor and/or UOHI.

- Use one of the two required language paragraphs.

Study Cost Coverage

In this section describe any monetary compensation and/or expense reimbursements for the study.

- Explain that the study product (drug(s)/device) will be provided at no cost to them for the duration of the study.
- Indicate if participant will be reimbursed for direct study related costs, such as parking, meals, babysitting, transportation, accommodation, etc.
- Indicate if participant will be compensated for his/her time in a study.
- If income is given to participant, then include required language in PIS&CF template that income may be taxable. Include this language even if income is less than $500 for this study, because subject may be participating in multiple studies.
- If the Investigators will receive payment for enrolling participants (rare) into the trial, this must be disclosed (specific fee to him/her, not as part of per patient budget).

Conflict of Interest

Research staff must declare any perceived or real conflict of interest related to the study.

Possibility of Commercialization

In this section you must explain if there is a plan for the investigational product to be marketed following the study (ie: new drug, device, software, etc.)

Confidentiality

In this section describe how participant's personal health information will be protected, stored, and at the appropriate time, destroyed.

- Make sure, as stipulated in the PIS&CF template language, that all information that leaves UOHI and/or TOH is stripped of all personal identifiers and only identified with an independent study number. Initials and date of birth (DOB) are considered personal identifiers. If DOB is required, only the year and month may be used.
- Indicate how the Master List will be maintained and safeguarded, electronically and in hard copy – stored securely and separately from study data.
- Electronic records must be stored on the UOHI secure server, not on a computer's C drive. Files must be password protected. No portable devices may contain PHI.
- Explain who will have access to the records; include Health Canada and/or FDA only for trials regulated by them.
- Include the appropriate number of years for storage depending on the nature of the study. For interventional studies regulated by Health Canada, and for all CIHR funded trials, files must be kept for a minimum of 25 years. For non-regulated studies, files must be kept for 10 years. Secure storage must be maintained for this period.

- Explain the hope/plan for specific publications and presentations, if known.
- For clinical trials with U.S. ties (FDA oversight, NIH funding, etc.), the FDA required language, regarding registering the study, must be included exactly as recorded in the PIS&CF template.
- For clinical trials in Canada, the requirement is more flexible, only requiring the study team to register the trial with a "recognized and easily accessible public registry." (Art 11.3). The default required language is the same as for the US, however if the sponsor wishes to register on another publicly available registry, please notify the HREB.

Voluntary Participation

In this section it is reiterated that participation is voluntary. The inclusion of this statement is mandatory in clinical trials. Participant must also be provided any new information that becomes available during the course of the study; and be given continued and meaningful opportunities to choose whether to continue in the study. The required language covers these concerns.

Study Contacts

In this section provide the participant with the names and phone numbers of the local investigators, and/or the research assistants/nurses that he/she may call with questions about the study.

- Provide an alternate 24-hour phone number if the nature of the study is such that the participant might need to contact the local investigators and/or the research assistants/nurses after regular business hours due to unusual side effects or symptoms. Participant should be told to contact them immediately if side effects or symptoms arise.
- Keep in mind that staffing changes will result in a revision of the consent, so provide adequate contact information, but don't list the entire research team.

Consent Form Signature Page

- The "Consent to participate in research" section should be in one electronic document with the Participant Information Sheet, but on its own separate hard copy page on Institutional letterhead.
- **The consent form should be personally dated by the participant, or their representative, and by the person who obtained consent.**