

Preparing Participant Information and Consent Forms (PI&CF)

Delays in the approval of research projects are often due to inadequate Participant Information and Consent Forms. Please ensure these documents are well prepared. Good communication is the key to recruitment and compliance, as well as serving to reduce the likelihood of complaints.

The Participant Information and Consent Form is a set of documents comprising two discrete sections. The first section of the document is the Participant Information. Some form of written Participant Information is usually required for research projects in which informed consent will be obtained. The second section includes a variety of Consent Forms.

Participant Information

The purpose of the Participant Information section is to ensure participants understand the risks and benefits of participation (compared with not participating) to both themselves and others. Remember that a document that is too long and too detailed is less likely to be read and properly understood than a document that is concise and brief.

The principal researcher is responsible for providing information about the project to the participant and/or the participant's parent, guardian or advocate. Use clear and plain language without technical terms or jargon. As a guide, pitch it at the reading level of a 12-year-old. Include sufficient information about the purpose, procedures, demands, benefits, risks, inconveniences, discomforts and possible outcomes (*National Statement* 1.7). The Participant Information must always include the contact details of the researcher and the fact that participation is voluntary. If relevant, participants must be given the choice whether they wish to remain anonymous.

If there are circumstances in which confidentiality may be broken, for example, mandatory reporting of child abuse observed during a home interview, this must be disclosed in the Participant Information (see *National Statement*, Chapter 18, Appendices 2 and 3).

The Participant Information must clearly identify the Institution, preferably on Institution letterhead. However, a heading at the top of the page that clearly identifies the Institution is acceptable.

The Participant Information should include the version number and date; any modifications to the document (either as requested by the reviewing HREC or during the course of the project) should be reflected in a change to the version number and date.

Where appropriate, the researcher must provide the Participant Information translated into relevant language(s) for the participants and their parent, guardian or advocate. Statements need to be sensitive to cultural diversity and accessible to those with disability, low literacy or those whose first language is not English.

In some cases it may be more appropriate to use a letter of invitation rather than Participant Information, for example, when using a mail-out questionnaire. In these cases, the letter of invitation must contain the information normally included in a Participant Information and Consent Form. A returned and completed questionnaire implies that consent has been given.

If the research involves video or audio taping, this must be made clear to participants. If tapes are to be destroyed, participants must first be shown a transcript to confirm accuracy.

The Participant Information must also contain certain statements required by State and/or Commonwealth privacy legislation, whenever any personal, health or sensitive information about the participant will be collected, used or disclosed. These statements include (where relevant):

- The identity of the organisation collecting the information and how to contact it;
- The purpose for which the information is being collected;
- The period for which the records relating to the participant will be kept;
- The steps taken to ensure confidentiality and secure storage of data;
- The types of individuals or organisations to which the Institution usually discloses information of this kind;
- How privacy will be protected in any publication of the information;
- The fact that the individual may access the information;
- Any law that requires the particular information to be collected;
- The consequences (if any) for the individual if all or part of the information is not provided.

Consent Forms

The second section of the PI&CF document contains a number of Consent Forms, including:

- a Consent Form for individuals giving consent for their own participation;
- a Consent Form for Tissue Sample Storage and Use (if applicable; only included in the template kit for clinical drug trial projects)
- a Third Party Consent Form for those cases where someone is giving consent for another person to participate (for example, parents who must give consent for minor children);
- a Person Responsible Consent Form for those cases where the participant is incapable of giving consent and a 'person responsible', as defined by the *Guardianship and Administration Act 1986* (Vic), provides consent for the person's involvement in a medical research project;
- a Participant Continuation Consent Form to be used for participants who are involved in medical research and who regain capacity to consent for themselves;
- a Revocation of Consent Form.

Some of these forms will not be relevant to certain types of research project and do not need to be included with the application. For example, if there are no minors participating in the research, you may have no need to include a Third Party Consent Form; if none of the participants will be suffering incapacity, no Person Responsible Consent Form is required; if consent to participate will be indicated through completion of a survey or questionnaire, then only a Revocation of Consent Form need be included.

If you anticipate recruiting participants who do not speak English as their first language, it is useful to organise a translated copy of the Consent Form and include this in the application to the HREC. If it is not practicable to have the information translated, you may need to show access to the Institution's interpreting service for the project.

The Consent Form must be signed by the project participant and by the member of the research team who explained the project to the participant. All parties signing the Consent Form must also put the date next to their own signature.

It is generally expected that a witness will also sign the Consent Form. The witness may be anybody who can certify that a person they believe to be the named project participant has actually signed the Consent Form.

The signature of the researcher explaining the project implies they certify that they followed the research protocol for explaining the project and obtaining informed consent from a prospective project participant. Although any member of the research team may give the information as part of the consent process, the legal responsibility for the adequacy of the explanation lies with the principal researcher and the Institution approving the project. The principal researcher must ensure the adequacy of this explanation of the project either personally or by their delegate.

Legally effective consent implies that the participant understands the proposed research and is willing to participate, as well as giving a signature on paper. It is recommended that the researcher who gives the explanation also records this information by making detailed written notes and placing a copy in the participant's file or clinical record. The written notes should include a description of the explanation given, details of benefits and risks explained, and a list of questions raised and answers given. Also record that the consent and signature were obtained and the place, date and time together with a list of all people present.

Participants can withdraw from a study at any time, and it may be appropriate for them to sign a **Revocation of Consent** form which is to be stored with study records.

Template Forms

Two Participant Information and Consent Form templates are provided. These templates are intended to provide guidance to you in preparing forms that are relevant to your project.

- **PI&CF (non-clinical)** is for projects that **DO NOT** involve clinical drug or device trials or collection of tissue.
- **PI&CF (clinical)** is for projects that **DO** involve clinical drug or device trials or collection of tissue.

The main difference between the two templates is that the forms for use in projects involving clinical drug or device trials or tissue collection include additional statements, specially worded to fulfil the requirements of the Victorian Managed Insurance Authority (VMIA). This additional material is not required in projects that don't involve these types of projects.

If you decide to use the template provided for your Participant Information and Consent Form, the format, layout and wording of the template should be followed as closely as possible to ensure that basic requirements are included. **However, you should modify the template according to the circumstances of your project.** Change word usage where necessary and use appropriate terms for the project and the participants. Remember to **delete sections in the template that don't apply** and then re-number the following sections accordingly. Please also **delete any Consent forms not required**. For example, if the Third Party Consent Forms are not required for your project, please do not include the unmodified template Third Party form in your submission, as its inclusion will be confusing to the reviewing HREC.

To use the template for the Participant Information, it is recommended that you copy the contents from the position indicated on Page 1 of the template ("Copy from here") to the position indicated on the last page of the template ("Copy to here"). Similarly, for each

Consent Form you need to use, copy the text below the text box for the Institution's name or letterhead. Paste the text onto letterhead or onto a page showing the name of the Institution. All recommended text is presented in plain type (headings are the same font in bold), while instructions, suggestions for optional statements and prompts to the researcher are presented in bold, italic type. As you work your way through the document, delete the comments, prompts and instructions, replacing them with appropriate words or statements, where required.

You do not have to use the template for your Participant Information and Consent Form and you should always check with your Institution to determine whether there are any site-specific requirements for inclusion in these documents.