Australian Government
Department of Defence
Department of Veterans' Affairs

DDVA HREC Participant Information Sheet and Consent Form

User Guide

When developing your Participant Information Sheet and Consent Form (PICF), thoughtfully consider both your project and its participants. While the template is helpful as a starting point, it's essential the PICF meets the needs of your target audience—particularly if they have distinctive communication needs related to culture, literacy, or age.

This template offers a helpful foundation for creating a straightforward and clear PICF. While it includes useful guidance, you should tailor it to suit your specific requirements. It is highly recommended to use consistent terminology in your PICF.

For most research projects, the participant should be referred to as 'you' in the PICF, even if they are unable to give consent themselves, such as in studies involving young children.

In this template, the default form of address is "the participant." However, we recommend selecting a form of address that best suits your project's requirements—for example, "your child" or "your partner"—as alternatives to "the participant."

Think carefully about how relevant and thorough your information needs to be for both your project and your audience. For example, a Participant Information Consent Form (PICF) for a brief online survey doesn't require as much detail as one created for a clinical trial. It's important to consider what people already know, too.

Following the instructions in the template

The templates demonstrates 3 text formats to help you use the template:

Plain black text serves as template content relevant to most research projects. You may use it as is, adapt it for your participants, or delete it if it does not apply.

<Orange text> - needs your attention. This may be relevant to your project, but you will often need to adapt it to suit your participants. Choose a scenario or add project-specific details as needed.

[Blue text] - These are template instructions. Remove this text after reading; do not include in the final PICF.

After you've completed your drafting, check for any <> and [] to spot and delete stray prompts or instructions.

Key principles for drafting PICFs

Principle 1 - Know your likely participants and be inclusive - Knowing your audience, including potential participants, lets you tailor content and make your PICF relevant.

Principle 2 - Write the same way you talk - When you use simple language and speak informally, it's easier to connect with your audience.

Principle 3 - Use the active voice and be direct - When you use active voice and personal pronouns such as 'you' and 'we', it is easier to identify who is responsible for each action.

Principle 4 - Keep your message relevant, short and simple - A clear message makes it easier for potential participants to grasp what you expect from them.

Principle 5 - Be consistent - Maintaining consistency facilitates clear communication with potential participants, particularly when presenting new concepts.

Principle 6 - Make the layout easy to navigate - A well-organised document with a distinct information hierarchy enables potential participants to efficiently locate and comprehend important details.

Principle 7 - Use visual aids that add meaning - Visual aids like images and tables make content clearer and prevent information overload.

Principle 8 - Involve consumers - Consumers can help draft your PICF or review it for clarity and completeness.

Layered consent

The template uses layered consent to create a clearer, shorter PICF. Layered consent separates information into two types:

- **Key information:** what participants need to know to decide about joining research.
- **Supplementary information:** extra details some may find useful, but which could distract from key points.

This approach physically divides essential and additional content, ensuring potential participants have enough to make an informed decision without reading further. Layered consent lets people access relevant information as needed.

The template helps you provide the key information relating to your research project. If needed, supplementary information should be provided in ways that are suitable for you and your potential participants.

What do I provide as supplementary information?

Not all research projects will require supplementary information. If all relevant information is covered by the key information, the PICF you create from the template can be sufficient.

For other research projects, supplementary information might include:

- Information that is important during participation, but is less relevant at the time of consent, such as detailed schedules and practical information like travelling options and how to get there.
- More detailed information about the project including non-material risks (those that do not meet the threshold for inclusion in the PICF), data retention and sharing, or the project's Data Management Plan.
- Links to external resources such as ANZCTR or clinicaltrials.gov.

Further Information in regards to filling out each component of the PICF template can be found here