Participant Information Sheets and Consent Forms

The Participant Information Sheet and Consent Form (PICF) is a fundamental project document for communicating information about your project to potential participants. It outlines the aims and objectives of the project, what is required of participants, and informs of any risks and/or benefits to participating. Importantly, it provides potential participants the mechanism to document their consent to participate in your project.

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How to Write a PICF

The PICF must be written in a format that ensures understanding for potential participants who may not hold knowledge in the projects area of interest. It must not include any technical language or jargon, while informing the potential participants what the project is about.

The National Health and Medical Research Council website offers resources including PICF templates for a variety of research. These templates can be customised to meet the requirements of your project.

Please note: In relation to Person Responsible/Next of Kin consent, the Guardianship and Administration Amendment (Medical Research) Bill 2020 was passed by WA parliament, in effect from 7 April 2020.

As a result, the WA Guardianship and Administration Act 1990 now provides an avenue for the inclusion of incapacitated adults in research.

Guidelines are being developed by the Research Development Unit, Department of Health, WA.

Please consider the following points to include in your PICF:

- As previously mentioned, the PICF must be written in easy to understand language, aiming at a Year 8 (13 years old) reading level.
- It is important to proof read your PICF, checking for any spelling and typographical errors and ensuring correct grammar and punctuation.
- If using the NHMRC templates, consider removing aspects of the templates that do not apply to your project. A PICF must be informative yet succinct and not long winded.
- The overall presentation of the PICF must be easy to read. Utilise clear and informative headings and review the document to ensure consistent use of fonts and headings.
- The introductory paragraph should be written such that it:
    - invite's the individual to participate in the research
    - clearly specifies the institution or persons involved and outlines the funding arrangements for the research (if funding is obtained).

    - references the HREC providing ethical oversight for the project. For
    - see the NHMRC PICF templates for examples on how the above points can be written into the introductory paragraph.
- The PICF must clearly detail what will be expected of participants if they choose to participate. Consider including the number of visits/or activities, when they will occur, what will happen and an estimated participation time. This can be displayed in a table or written out in sentence format depending on the level of information.
- Ensure any risks associated with participation are clearly explained, including the level of risk and frequency. Consider how any distress from participation will be managed. For example, 'counselling services will be provided free of charge if during the interview the participant becomes distressed'.
- If the project involves collection of participant data, be clear and transparent regarding what specific data will be collected e.g. data variables. Explain how the data will be collected and used, how it will be transferred, who will have access to the data and where the data will be stored.
- If the research involves collection of data or biological samples (e.g. blood, tissue) for other research purposes, information should be provided in the PICF, clearly stating the purpose of the investigations or future research and whether it is optional. If the additional research is optional, participants should be informed that they do not need to agree to take part in the optional components to be part of the main study and the consent form should provide clear options for the participant to consent only to the main study or to the main study and the optional components.
- Please list the version number, title of the project and date in the footer of the PICF. This is explained in further detail at Standard, Master and Site Specific PICF's

Example PICF wording related to approving HREC and complaints wording

Note: Please include the WACHS Research Governance (RG) Office contact details for any complaints that may arise throughout the study. Please do not refer to the HREC Chairperson or Ethics Coordinator. Example below can be added to the PICF.

This study has been approved by (insert name of HREC) Human Research Ethics Committee.

Complaints contact person

For matters relating to research at the site at which you are participating, if you have any complaints or concerns related to the study please contact:

Position	Clinical Research Manager, WACHS Research Governance Unit
Telephone	(08) 6553 0982
Email	WACHS.ResearchGovernance@health.wa.gov.au

Standard, Master and Site Specific PICF's

The PICF and all other project documentation must include a version number, and date in the footer on each page. This ensures the document is identifiable from other versions of the document, and allows the document to be tracked over time. The version and date will need to be updated each time an amendment is made.

NHMRC PICF Templates

WA Health investigators are encouraged to use the standard National Health and Medical Research Council's PICFs, available from the NHMRC Human Research Ethics Portal (HREP) which provides guidance in the formulation of PICFs for human research projects. These documents should be used as a minimum starting point for consent forms. Project specific information should be added as necessary and sections that are not applicable to the research project may be removed as required.

Standard PICF

If the project will be delivered only within WACHS and one Principal Investigator will be responsible for the research at all involving WACHS sites, inclusion of a 'master' and site specific PICF's are not necessary, and a standard PICF can be used. The standard PICF should be submitted for approval by the WACHS HREC and RG Office for use at all sites. The standard PICF will not contain any placeholders e.g. [insert institutional header] as its original content is applicable across all involved sites.

Master PICF

If a project is undertaken across multiple sites and health services, as in the case of a project operating under National Mutual Acceptance Scheme, it is appropriate to have a master PICF and additional site specific PICF's. This will depend largely on whether there is variability between how a project will be delivered across sites.

The master PICF should be un-badged, and include no site-specific details. Use placeholders for the site specific details e.g. [insert institutional header], [insert PI name]. The master PICF is submitted for approval by the reviewing HREC for use at all sites.

Example Master PICF

The **footer** of the Master PICF should look something like this:

RGS1234 | Main PICF | Master version 1.0 | dated 1 April 2020	Page x of y

Each component of the above is described below:

- RGS1234 - *Study identifier*
- Main PICF - *PICF type e.g. Main PICF / Carer PICF etc*
- Master version 1.0 - *Updated every time there is a revision*
- dated 1 Apr 2020 - *Date document last amended*

Site Specific PICF

As the name suggests, the site specific PICF will detail the site specific information that the Master PICF does not contain. The site specific PICF will include:

- Site Principal Investigator details
- Site name and logo or letterhead
- The site complaints contact person; as referenced previously must include:

Position	Clinical Research Manager, WACHS Research Governance Unit
Telephone	(08) 6553 0982
Email	WACHS.ResearchGovernance@health.wa.gov.au

- A site specific identifier in the footer

The site specific PICF is submitted to the RG office for approval and is based off the Master PICF approved by the overseeing HREC. In addition to the above dot points, the site specific PICF also includes the below in the footer.

Example Site Specific PICF

[RGS 1234] *[WACHS Region and name of Hospital Site]* [Version 1 dated 14 April 2020 based on Master Participant Information Sheet/Consent Form Version 1 dated 01-April-2020 Page x of y

If there is a sponsor they will usually have already created an Australian master version for submission to a lead HREC as part of the National Mutual Acceptance. They will then forward the Master version to you so you can utilise it to create a Site Specific PICF to submit to the overseeing Research Governance office and HREC.

Save either format of the PICF (e.g. Standard, Master or Site Specific) with a naming convention such as: Study Title (can be acronym) _Main or Site Specific PICF_WACHS_VX_YYYYMMDD_tracked or clean. Then submit on RGS for WACHS RG review, and to overseeing HREC where applicable.

Amendments to the PICFs

When amendments are required, the changes must be tracked into the standard or master PICF and then submitted to the HREC and RG office, using RGS where applicable, for approval. The version number and date of the PICF must also be updated.

Once the PICF is approved by the HREC, if there is a site specific PICF, the appropriate changes need to be made to the site specific PICF/s and submitted to Research Governance Office via RGS for site approval. The version number and date of the site specific PICF must also be updated.

Guidelines for the use of the WACHS logo and Government badging

WACHS' Government badge must be visible on all WACHS' research partnership projects (Option 1 below). This demonstrates to the community that WACHS carries ownership and/or sponsorship to the project.

As a general guideline, you must use the WACHS' Government badge if:

- WACHS is providing funding for the initiative
- WACHS has developed/co-developed the initiative, including the documents produced for use in the project.
- WACHS staff will deliver the initiative

Use of the State Government Badge and Co-badging

In some instances, the research project will be collaboration between WACHS and other government departments and/or external institutions. Therefore the PICF may display co-badging with the Government of Western Australia Department of Health Logo (Option 2 below), WACHS' logo, and/or external institutions. In such instances, the State Government Badge should be the visually more prominent logo. Please refer to the Department of the Premier and Cabinet for co-badging requirements. Approval for co-badging must be sought by the Common Badging Committee.

In instances where a research project is not delivered or produced by WACHS staff, but WACHS is supporting the project; the PICF must include a statement of endorsement on the top left hand corner of the first page as follows:

'WACHS has reviewed this project and authorised its operation in WACHS subject to compliance with WACHS' research monitoring and the continued ethical approval from [insert HREC].'

How to place and use WACHS' Logo

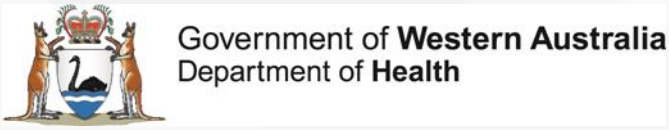
The State Government badge should always be placed in the top left hand corner of any page, signage or electronic document. It must not be stretched, distorted or altered in anyway.

Option 1:

Site specific letterhead logo for WACHS:

Option 2:

One logo for all WA public health organisation's (if the project will occur across WA Health Services)



Option 3:

For co-badging with other departments and/or external institutions, please read co-badging requirements.

To provide feedback on this publication email WACHS.ResearchGovernance@health.wa.gov.au