



# Participant Information Sheets and Consent Forms

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The Participant Information Sheet and Consent Form (PICF) is usually one of the most important project documents as it communicates information about the project to potential participants. It is used to outline the aims of the project, what would be required of the participants as well as any risks or benefits to participating. The document should form just one part of the recruitment discussion.

## How to write a PICF

Writing PICFs can be difficult as they shouldn't contain the technical language used on a regular basis by healthcare staff in the workplace. If you need any additional assistance with writing a PICF please contact the Education Officer at [SMHS.RGO@health.wa.gov.au](mailto:SMHS.RGO@health.wa.gov.au) or on 6151 1126.

The [National Health and Medical Research Council](#) provides a number of PICF templates on its website. Please feel free to use these templates and customise them for your project. Please note that Person Responsible/Next-of-Kin consent forms cannot be used in Western Australia as there is no provision for next-of kin consent to research in the WA Guardianship and Administration Act 1990.

When writing a PICF you should consider the following points:

- The language used in PICFs should be simple enough that it can be easily understood by someone with no medical education. It should be aimed at a Year 8 (13 years old) reading level.
- It is important to check for spelling and typographical errors as well as ensuring that the grammar/punctuation is correct.
- The overall presentation of the PICF should be neat and easy to read. Fonts and headings should be consistent throughout the document. Utilise clear and informative headings.
- The opening paragraph should be written such that it:
  - invites the individual to participate in the research
  - makes clear the funding arrangements for the research (who is sponsoring the study or providing funding) if relevant
  - mention which HREC has approved the research

For example: “We invite you to participate in a multicentre clinical research study sponsored by (*insert name of sponsoring company if relevant*) comparing different ways of controlling diabetes in the setting of a suspected heart attack or unstable angina. The local sponsor at this site is ..... This study has been approved by the (*insert name of HREC*) Human Research Ethics Committee.”

- The PICF should clearly outline to the potential participant what will be expected of them if they decide to participate. A schedule of visits which includes the number of visits, when they will occur, what will happen at the visits and how long they will take should be presented in a table.
- The PICF should clearly explain any risks associated with participation in the research project. These risks should include both the severity of the risk and the frequency. Please use X in 100, 1000, 10000 etc rather than percentages.
- When communicating volumes of fluid taken as samples please provide a comparison to teaspoons/tablespoons.
- If the research involves collection of biological samples (e.g. blood, tissue) for other research purposes (e.g. a pharmacokinetic or genetic sub-study), information should be provided in the main study PICF, clearly stating the purpose of the investigations and whether it is optional. If the additional investigations are 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 include the HREC contact details for any complaints that may arise throughout the study (Do not refer to the HREC Chairman or Ethics Executive Officer/Ethics Coordinator).
  - South Metropolitan Health Service Research Ethics & Governance Unit
  - Phone 6151 1180
  - Email: [SMHS.HREC@health.wa.gov.au](mailto:SMHS.HREC@health.wa.gov.au)

## Master and site specific PICFs

All documents, such as PICFs, need to include a version number and date in the footer. This is to ensure that changes to the documents can be tracked over time and it is easy to know which documents should be used. This information should appear in the footer of the document on each page. The version and date will need to be updated each time an amendment is made. Further information about insertion of versions in footers can be found below.

If a project is being conducted at more than one site it may be appropriate to have a master PICF accompanied by various site specific PICFs. This allows PICFs to be specific to the site at which it is used while reducing the number of approvals required.

If a project is conducted at a single WA Health site, there is no need for a master PICF. The PICF submitted to the HREC should be appropriately adapted for your site, including the correct letterhead/logo, PI contact details and Ethics and Governance contact details.

<b>Master PICF</b>	<ul style="list-style-type: none"> <li>PICF approved by a HREC <b>for use at multiple sites</b> e.g. the SMHS HREC is approving a study for conduct at two or more WA Health sites.</li> </ul>
<b>Site-specific PICF</b>	<ul style="list-style-type: none"> <li>local site version of HREC-approved Master PICF</li> <li>only needs review and approval from the site (via the research governance office)</li> </ul>

## Master PICFs

The master PICF should be un-badged with no site-specific details at all – use place holders in the PICF instead e.g. [insert institutional header], [insert PI name] etc.

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

BX1234 Main PICF Master version 1.0 dated 28 Apr 2016	Page x of y
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Where:

- BX1234 - *Study identifier*
- Main PICF - *PICF type e.g. Main PICF /Genetic PICF / Pregnant Partner Data Release Form*
- Master version 1.0 - *Updated every time there is a revision*
- dated 28 Apr 2016 - *Date document last amended*

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 this to you so you can submit to a WA Health HREC. Example:

BX1234 Australian Master Participant Information Sheet/Consent Form Version 1 dated 01-Jan-2016 based on Amendment 1 Global ICF Version 2 dated 20-Nov-2015  <i>(Complete if required) [Site Name] Site Master Participant Information Sheet/Consent Form [Date]</i>  Local governance version <i>[Date]</i> (Site PI use only)	Page x of y9
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Adapted for submission as an un-badged version to a WA Health HREC for use at multiple WA Health sites:

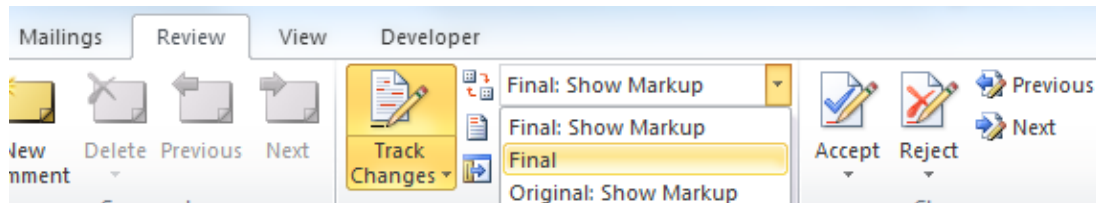
BX1234 Main PICF [Hospital] Version [version number] dated [dd mmm yyyy]  BX1234 Main PICF WA Health Master Version 1 dated 28 Apr 2016 based on Amendment 1 Global ICF Version 2 dated 20-Nov-2015	Page x of y
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## Site-specific PICFs

Single Ethical Review in WA public health means – All WA public health organisations must accept the ethics approval from any Lead WA Health HREC. Therefore, the PICF that was approved by the HREC can be used at any accepting site.

However, since the logos and contact details in the Master version are either not there or different across the sites, each site can adapt the Master version for use at their own site:

1. Get the HREC-approved Master PICF from the CPI
2. Turn on “Track Changes” and choose “Final” from the drop-down menu (changes will be tracked but you won’t see them – makes it easier to see what you’re doing)



3. Insert your site’s logo/letterhead (refer [Instructions for placement](#))
4. Insert an **additional site specific identifier** into the footer for version control and tracking

<b>BX1234 FSH Main PICF version 1.0 dated 15 Jun 2016</b> based on BX1234 Main PICF WA Health Master version 1.0 dated 28 Apr 2016	Page x of y
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Or, as we saw in the Master PICF example earlier, there may already be some kind of placeholder in the footer:

BX1234 WA Health Master PICF Version 1 dated 28 April 2016 based on Amendment 1 Global ICF Version 2 dated 20-Nov-2015  Local governance version <i>[Date]</i> (Site PI use only)	Page x of y
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Adapt for use at your site

<b>BX1234 FSH Main PICF version 1.0 dated 15 Jun 2016</b> based on BX1234 Main PICF WA Health Master Version 1 dated 28 April 2016 based on Amendment 1 Global Main ICF Version 2 dated 20-Nov-2015	Page x of y
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5. If the reviewing HREC’s office is different to your site’s research governance office (e.g. RPH HREC approved the study but your site is FSH), insert your site’s research governance office contact details for complaints related to the conduct of the study at your site.

**EMHS sites:** If you have any complaints related to the conduct of this study at [site] contact the East Metropolitan Health Service Research Ethics and Governance Unit by email [EMHS.REG@health.wa.gov.au](mailto:EMHS.REG@health.wa.gov.au) or phone 9224 3604.

**SMHS sites:** If you have any complaints related to the conduct of this study at [site] contact the South Metropolitan Health Service Research Ethics and Governance Unit by email [SMHS.RGO@health.wa.gov.au](mailto:SMHS.RGO@health.wa.gov.au) or phone 6151 1180.

6. Save as e.g. PRNX\_MainPICF\_FSH\_vX\_YYYYMMDD\_tracked

7. Submit local PICFs to Research Governance office for site approval.

### **Amendments to the PICFs**

When amendments are required, the changes must be tracked into the Master PICF and then submitted to the HREC for approval. The version number and date of the Master PICF must be amended when changes are made to an existing PICF.

Once approved, the appropriate changes need to be made to the site specific PICFs and submitted to [SMHS.RGO@health.wa.gov.au](mailto:SMHS.RGO@health.wa.gov.au) for site approval. The version number and date of the site specific PICF must be amended when changes are made to an existing PICF.

## Guidelines for the use of the FSH logo and Government badging

- If the template is used with the Fiona Stanley Hospital (FSH) logo and State badge in the header:
  - No other logos from non-government organisations are to be used in the header or the footer.
  - Logos may be used only within the content of the document next to the sponsor's name if desired under the 'Sponsor' section. These logos should be smaller than the logos in the header.
  - The document must be reviewed and approved by a senior FSH staff member, who must be aware of the style guidelines of the Department and FSH, and approve the content. Any queries or doubts regarding the FSH style or branding should be addressed immediately to the FSH Communications Manager.
  - Please use the Main sponsor template FSH Research document.
- No co-badging or co-branding is allowed without permission from the Department of the Premier and Cabinet (DPC) via the FSH communications team. This means that you cannot use a third party logo from a non-government organisation with the State badge (above left in the header) without DPC permission. As the FSH logo must always appear together with the State badge in any external publication, it follows that you cannot use a third party logo from a non-government organisation with the FSH logo, without expressed permission. Anyone wishing to use their logo alongside the FSH logo must contact the FSH Communications Manager to start an official process for approval.
- Research application forms and similar documents for joint ventures with FSH may use the name Fiona Stanley Hospital, Department of Health, Western Australia if they wish to use one or more logos from non-government organisations in the header or footer.
- Where FSH is one of several sponsors, please use the multiple sponsor template FSH research document. No logos are permitted in the header.
- Please refer to the State Government State Badge Style Guide on use of the State Badge and minimum size (1.5cm for the crest alone) and spacing required etc.  
<http://www.commonbadge.dpc.wa.gov.au/Documents/Style%20Guide%20December%202012.pdf>

# Instructions for placement of logos

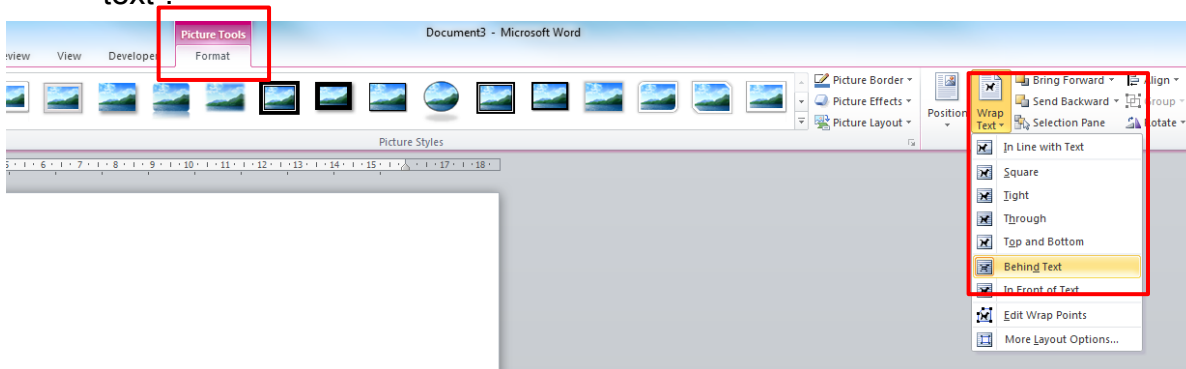
## Letterhead / logo

1. **Copy and paste** the relevant letterhead/logo from [Appendix 1](#) to **each** of the following pages in the PICF
  - **First page** of the PICF document
  - **Consent form** (first page only)
  - Consent **withdrawal form** (if there is one, first page only)

**Here's a tip!**  
Paste option = "Keep source formatting"  
Wrap text = 'behind text'

## Barcode for digital medical record (FSH only)

1. **Copy and paste** the barcode from [Appendix 1](#) to the **first page only** of the PICF document
2. **Adjust position** until it's a couple of centimetres down from the top of the page and close to the left hand edge of the form
3. If the barcode doesn't seem to be cooperating, format the picture so that it sits "behind text":



**WARNING! Do not adjust the size of the barcode or the letterheads/ logo.**

# APPENDIX 1

## South Metropolitan Health Service

- ATTENTION!**
- Ensure the page size is A4
  - No co-badging please
  - Do not adjust size of the logo or letterhead
  - Letterheads should be centred
  - Logos should be aligned with left margin

### Option 1:

One logo for all WA public health organisations (ref [WA Health PICF template](#) available from [web](#))



Government of **Western Australia**  
Department of **Health**

OR use site-specific letterhead/logo (current templates available on [SMHS intranet](#))



FS000380

[Fiona Stanley Hospital](#)  
PICF barcode for digital medical record

FSH



Government of **Western Australia**  
**South Metropolitan Health Service**



Government of **Western Australia**  
**South Metropolitan Health Service**  
**Fremantle Hospital and Health Service**

All sites within [FHHS](#)  
Align to left margin



Government of **Western Australia**  
**South Metropolitan Health Service**  
**Rockingham Peel Group**

All sites within [RPG](#)  
Align with left margin



This document can be made available in alternative formats on request.

**South Metropolitan Health Service**

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