**WH Site Specific PIS/PICF Requirements Template**

To find the recommended Participant Information and Consent Form (PICF) templates to be used, please see the Victorian State Government’s Clinical Trials and Research website to download PICF templates:

<https://www.clinicaltrialsandresearch.vic.gov.au/training/steve/downloads>

**As a Western Health site requirement, please ensure the following are included in the PICF templates at Western Health:**

1. For interventional studies only; please ensure that the Barcode (Booklet) and Patient Label section is inserted in the header of the first page. This is required to scan the PICF into the participant’s electronic medical record. Click the header of this document to copy and paste into your PICF.
2. Non interventional studies; do not need a barcode on Patient Label section on the first page.
3. Ensure the first page clearly lists:
	1. Project title
	2. Site Principal Investigator Name
	3. Site location (e.g. Western Health – Sunshine Hospital & Footscray Hospital)
4. Please ensure the WH logo is inserted in the header of the following pages:
	1. First Cover Page
	2. Consent Form page
	3. Form for Withdrawal of Participation
5. For the footer (See Example 1), please ensure the version numbers and dates for the following have been included:
	1. Master Approved Participant Information and Consent Form version and date; and
	2. Local Governance Site Specific Participant Information and Consent Form version date.
6. Please ensure page numbers are correct and visible on every page.

Example 1. Sample wording for footer details:

Master Participant Information Sheet/Consent Form version [number] dated [Date] Page 1 of 1

**Local governance version [Date]**

1. For contacts section please ensure the following Complaints contact person and/or local governance contact has been inserted:

For matters relating to research at the site at which you are participating, and if you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Mr Bill Karanatsios |
| Position | Research Program Director, Western Health Office for Research  |
| Telephone | (03) 8395 8073 |
| Email | ComplaintandFeedback@wh.org.au |

1. For consent form section an interpreter signature panel has been inserted when this document is read to the participant in a language other than English.

**Declaration by Interpreter#**

|  |
| --- |
|    |
|    | Name of Interpreter# (please print)   |    |    |
|    |
|    |   Signature   |    |   Date   |    |    |
|    |

#Required when this document is read to the participant in a language other than English