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

Participant Information and Consent Forms

Guidelines for developing Participant Information and Consent Forms (PICF) related to research projects utilising single or linked data

If you intend to obtain consent from participants to obtain their personal information from health information systems or by linking data, the following suggested wording may assist participants in understanding how you will collect, use and manage their information securely and ethically.

You are encouraged to use the PICF templates approved by the National Health and Medical Research Council (NHMRC) and recommended under the National Mutual Acceptance process. Refer to the Research Governance and Single Ethical Review Standard Operating Procedures (SOPs) for further guidance.

The information provided below can be added to the NHMRC templates, which are available at: https://www.nhmrc.gov.au/health-ethics/national-approach-single-ethical-review/standardised-participant-information-and

Participant Information and Consent Form

Your PICF should include a simple explanation that will give participants a clear understanding of the following sections.

What is the purpose of this research?

In addition to the standard prompts provided in the NHMRC PICF templates, consider the following points when describing the various aspects of your project in simple terms:

- aim(s) of the study
- the type of information that will be collected and the source
- the period of time the information will cover
- why it may be necessary to obtain information from various databases
- where appropriate, data obtained from data collections will be linked to information collected by the researchers.

The following examples may be included or adapted for this section.

Example 1 – Single data collection project: *We would like to collect information from [insert site] about your hospital admissions related to your heart condition [and related complications] for the next five years. This will help us understand how…….*

Example 2 – Linked data collections project: *We would like your permission to link the survey information about your heart condition to information about you held by [insert site] [and insert name/s of other organisation/s]. The information we collect from you will be combined with the information extracted from [name of data collection/s].*

What will happen to information about participants?

In addition to the standard prompts provided in the NHMRC PICF templates, consider providing explanation to participants about the following points:

- how privacy will be protected for each participating site
- how information will be stored for each participating site
- how information will be made available by Data Custodians
- how information will be transported between participating sites and your organisation or research institution
- the period of time that data are retained for and the destruction process.

The following examples may be included or adapted for this section.

Example 1 – De-identified data: *Your name and other identifying information will be removed by [insert site/organisation] before the information is provided to the research team and no one in the research team will be able to identify you.*

Example 2 – Coded (re-identifiable) data: *Your name and other identifying information from your records will be stored separately in case we need to contact you or you wish to withdraw your participation. The researchers analysing the information will not be able to identify you.*

Example 3 – Data retention and destruction: *We will store the information for [insert number of years] after we finish the research in case we have to answer any questions about our research. At the end of [insert number of years] all your personal information related to this research project will be completely destroyed.*

Consent Form

If you intend to obtain information about participants with their consent from a single data collection, then the following paragraphs should be included in your participant consent document.

I authorise [insert name of site/organisation] to provide information about <insert general description e.g. my hospital admissions related to my heart condition> for the period <insert inclusion dates> to <insert name of research institution>

I agree that this information can be used for <insert the name of the project.>

If you intend to link information from more than one data collection etc. then include this paragraph.

I agree that <insert description e.g. my survey information, or e.g. health information about me obtained from my GP> collected by < insert name of organisation or research institution, or e.g. my GP> for <name of project, or e.g. for my health care > can be linked to my health related records held by [insert name of site/organisation] for the purposes of <insert the name of the project.>.

For further information

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