**HUNTER NEW ENGLAND HUMAN RESEARCH COMMITTEE**

**GUIDANCE FOR PARTICIANT INFORMATION STATEMENTS AND CONSENT FORMS**

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| * **The bolded text are possible subheadings for your Participant information Statement and the dot-points provide guidance as to the content for each section. You may not need to include all the sections from this template or the suggested content within each section.** * **The document must be non-technical and easily understood by all potential participants:** * **Keep the wording simple and sentences short** * **The language should be understandable by 10 -12 year old.** * **The document should be written in the second person e.g. “You are invited”.** * **Headings that refer to a participant should be written in first person e.g. “What happens to my data”?** * **Avoid using the term ‘participant’ unless the document is for a parent/guardian where it should be clear that it is the person’s child or relative/friend who cannot consent for themselves who is participating in the research** * **Consider using lists (dot points) and tables to present information. In particular, if your research involves multiple study visits with multiple study assessments/tests at each visit consider presenting as a time and events table.** * **Consider using icons and simple pictures/diagrams to enhance meaning.** * **Before you submit**  1. **Run the document through a computer reader and listen to it without reading at the same time. This will show you sentences that are difficult to understand.** 2. **Run the text of the document through a reading age checker.**   **The reading age should be grade 8 for an adult participant information sheet.**  **Hemingway**  [Hemingway Editor (hemingwayapp.com)](https://hemingwayapp.com/)  **SMOG and Flesch-Kincaid**  [AUTOMATIC READABILITY CHECKER, a Free Readability Formula Consensus Calculator (readabilityformulas.com)](https://readabilityformulas.com/free-readability-formula-tests.php) |

**<LETTERHEAD OF SENIOR RESEARCHER’S INSTITUTION>**

**[TITLE OF PROTOCOL in Lay language “Public Title” or “Plain Language Title”]**

**PARTICIPANT INFORMATION STATEMENT**

**Introduction**

* Begin with an invitation to participate in the project and reason why

For example: *You are being invited to participate in in this research because you have X (medical condition] or are going to have X (a medical procedure).*

* Purpose of the research in one /two sentence in simple language.

For example:

* *This project will investigate the effect of x on y.*
* *This project will test a new treatment for x.*
* If the project is being conducted as a requirement of a degree, the student, supervisor, the course and institution should be identified.
* The potential participant should be advised to:
  + Read the document and think about their involvement before they decide to participate.
  + Ask questions about and discuss their involvement in the research with the researchers and someone independent of the researchers (family members, their GP or another health professional).
  + Take as much time as they like to decide whether to participate.

**Do I have to participate?**

* There should be statements covering:
  + That participation is voluntary and a potential participant can decide not to participate or having enrolled in the research withdraw at any time without giving a reason.
  + If a person decides to withdraw from the study, that all the information they have provided or has been collected about them will be destroyed or if it can’t be, then a reason provided.
  + Any implications for a participant should they decide to withdraw from the research.
  + A decision not to participate or to later withdraw from the study will not affect ongoing medical care or any pre-existing relationships (e.g. with medical professionals, educators, employers).

**What is the purpose of this research?**

* Short paragraph stating the main goal of the research in non technical language, or if technical language or medical terminology cannot be avoided, then the relevant explanations should be given.
* Short description about how the main goal will be achieved.

**Note.** This should **not** include the specific details about the study procedures and what the participants will be required to do. This information should be included in the following section.

**What would I be required to do?**

* Detailed information about what will be required by participants including:
  + The time commitment required (how many study visits and how long each visits takes, and how long a participant will be involved in the study - a one of visit or a number of weeks, months or years).
  + Where the research visits take place including any study requirements the participants will complete at home.
  + List and explain everything the participants are required to do at each study visit.
  + What, if anything, will be required between study visits.
  + Note any specific requirements for example:
    - Need internet and internet accessible devices.
    - any preparation prior to study visits (fasting for blood tests, completion of questionnaires).
* Include a table of major events at each time point of the project (ensure all study procedures are explained in plain English - these could be listed below the table.)

**What are the risks and benefits of participating in this research?**

* State the known risks of participation, both of the intervention (drug/device/procedure) or any testing. The potential risks can be physical, psychological or social.
* If there are no anticipated benefits for the participants, then this should be stated. Any possible benefits for the participants or for society as a whole should be stated circumspectly.

**Randomisation and blinding** (if applicable)

* State that randomisation and blinding will occur:
  + Provide short definitions of “randomisation” and “blinding” and explain why these are necessary for this project.
* For randomisation:
  + State number of groups (study arms).
  + Explain how group allocation will occur and that participants have an equal chance of being assigned to any group.
* For Blinding:
  + Note who (researchers, clinician, participant) will be blinded and who will not.
  + State how blinding will be broken in case of medical emergency.

**If I take part, what happens to my information and samples?**

* Detailed information regarding:
  + What will be collected (specific bio specimens and specific data).
  + Where the data and/or samples be stored and for how long.
  + Where the samples will be sent for analysis (including overseas).
  + What format the data will be stored in (identifiable, re-identifiable, anonymous).and whether and under what circumstance the format will change from re-identifiable to identifiable.
  + Who will have access to it.
  + How it will be used.
  + If genomic information will be used or generated:
    - Address how this may impact family members.
* There should be a statement about the intention to present or publish the results and that individual participants will not be identifiable.
* Advice should be given that a summary of results is available to all participants and they should indicate on the consent form if they wish to have the results sent to them.

**Who is conducting this research?**

* Information about who is conduction this research project.

**Note** - this should include all members of the research team who have contact with the participants or will be accessing their personal information or research data they provide.

* Statement of who is funding this research and any conflict of investigators.

**How to proceed**

* State what the person needs to do if they wish to join this research project (e.g. sign a consent form, click “I agree” once they have competed the survey).
* If proposing an opt-out consent process, include the following statement “By doing nothing, you are agreeing to …”.

**More information is available at**

* Give details for where to get further information.
* Include contact details for project staff and site staff.

**Complaints Information**

* As per the Guidance document on the HNE Research Office website

[HNE Complaint Statements for Participant Information Statements](https://www.hnehealth.nsw.gov.au/__data/assets/pdf_file/0016/423502/Research_HNE_Complaint_Statements_for_Patient_Information_Statements_v2.pdf)

**Document Identification**

* **In the footer of the document there should be the type of document identified, version number and date**.

**For example:**

* MASTER Participant Information Statement and Consent Form, Version #, dd/mm/yyyy
* SITE SPECIFIC Participant Consent Form, Version #, dd/mm/yyyy (**only required for multisite studies)**
* **If there is more than one participant cohort, then the footer should be adjusted accordingly.**

**For example:**

* MASTER Parent/Guardian Information Statement and Consent Form, Version #, dd/mm/yyyy
* MASTER Child Information Statement and Consent Form, Version #, dd/mm/yyyy

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**CONSENT FORM TEMPLATE**

I have been given an Information Statement about this research project. I am aware of the activities involved in the study, including any inconvenience, risk, discomfort, or potential side effects that are currently known by the researchers.

* [If appropriate] I understand that the interview / focus group discussion will be audiotaped, and I agree to this.
* [If appropriate] I understand that my participation in this study will allow the researchers to access my medical record, and I agree to this.
* I understand that my personal information will remain confidential to the researchers.
* I would like a summary of the study results sent to me.

**YES/NO** (Circle one)

Email/Mailing address:

* I have had the opportunity to have questions answered to my satisfaction.
* I understand that I can withdraw at any time without providing a reason, and all the information about me and that I have provided will be destroyed.

I hereby agree to participate in this research study.

**NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Declaration by person conducting the consent process**

I have fully explained this research to the patient named above.

**NAME: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**