**LETTERHEAD OF SENIOR RESEARCHER’S INSTITUTION**

[**TITLE OF PROTOCOL in Laylanguage]**

**INFORMATION FOR PARTICIPANTS**

**Introduction**

You are invited to take part in a research study into [description of the study]. The objective is to investigate whether … **OR**… You are invited to take part in a research study which will investigate whether …

[Where appropriate, also include up to three sentences of background information in plain English].

The first paragraph should state if it is a student project with the relevant details.

**What is the research about?**

Include a brief description in laylanguage about the purpose of the study, and use the following to explain the relevant aspects of the research design:

* Explanation of randomisation should refer to a common example such as “like tossing a coin”
* Explanation of blinding should include a statement such as “This is necessary so that the results of the study are accurate”
* Explanation of placebo should “a medication (or equivalent) that looks like the trial medication but contains no active ingredients” and not “a dummy (sugar) tablet”

If useful, the project could be put in context such as “We already know that X, so we are trying to find out Y”

**Where is the research being done?**

The study is being conducted within this institution by … [names, positions, departments and, if outside the HNEHD, institution. If there are several investigators, listing the names and details one below the other may be clearer.]. [If appropriate:] … as part of the requirements for a … degree under the supervision of …

[If appropriate:] The study is part of a national/international collaborative study coordinated by [Australian, European, US researchers …]

[If appropriate:] The study is being sponsored by … [name of commercial or other entity. Include a statement about any conflict of interest which one or more of the investigators have.] **OR** The study is being supported by a research grant from …

If data, tissue, blood is being sent overseas this should be stated, and to where

**Who can participate in the research?**

State who is being invited to participate ie the category or group, and how they have been identified to receive the invitation eg. We are seeking people aged 18-60 years to participate in this research. Your name was selected at random from the White Pages telephone directory.

Include information on who should not, or cannot, participate ie identify the exclusion criteria: Example 1. If you are currently on medication for a heart complaint, then unfortunately this study is not suitable for you;

Example 2. People who are claustrophobic should not participate in this study because ….

The language should be in terms of suitability rather than eligibility, that is: “You are eligible to participate in this research” should be changed to “Participating in this research is suitable for you” and equivalent phrases should be rewritten accordingly. The meaning to be conveyed, should always be that “the study is suitable for you” NOT that “you are suitable to the study”.

Add another example---Your name has been selected from ? hospital records by a person with legitimate access to these records.

**What Choice do you have?**

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. [Where applicable you can ask that any data collected concerning you also be withdrawn from the study]. Whatever your decision, please be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you. [If appropriate:] Of the people treating you, only [those named above or others, eg all nursing staff] will be aware of your participation or non-participation.

[If appropriate:] Sometimes during the course of a study, new information becomes available about the treatment that is being studied. While you are participating in this study, you will be kept informed of any significant new findings which may affect your willingness to continue in the study.

**What would you be asked to do if you agree to participate?**

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. You will then be asked to … [for one study procedure]**OR** You will then be asked to undergo the following procedures: [list multiple procedures as numbers or bullet points, and list them in the order that they will happen] **Alternatively**… [Insert a table of the study visits and procedures, ensuring all procedures are in laylanguage and include the list of procedures with explanations of what is involved below the table]

Ensure all terminology is Australian for example do not use “Vital Signs” and “blood draws”

[See the following page for suggested wordings for some common research procedures]

[If appropriate:] In addition, the researchers would like to have access to your medical record to obtain information relevant to this study.

For Clinical Trails, information should be included as to what happens once the study ends, including whether the trial medication or device will still be available and under what conditions.

Make sure medication is listed, length of visits. In case of Parent info make it clear if it is just the child or is both the parent and child participating. If there are any interviews the Tape Rule re editing should be included. Pictures can often make things clearer.

**What are the risks and benefits of participating?**

**Risks**

All medical procedures - whether for diagnosis or treatment, routine or experimental – involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. In spite of all precautions, you might develop medical complications from participating in this study.

The risks of participating in this study are:

[Provide information on inconvenience, risks, discomforts or side effects that may occur and an estimate of their severity and duration.] These should be categorised as Common (>10-%) Uncommon 1-10%) and Rare (<1) and presented in an easily accessible format]

[If appropriate:] It is important that women participating in this study are not pregnant and do not become pregnant during the course of the study. If you are a woman of child-bearing potential and there is any possibility that you are pregnant, the researchers will perform a pregnancy (urine) test before you start in the study. If necessary, you should use reliable contraception (such as oral or implanted contraception, an IUD or have had a tubal ligation) during the course of the study. If at any time you think you may have become pregnant, it is important to let the researchers know immediately.

**For Catholic Institutions**

The following statement was developed through the deliberations of the Catholic Health Australia working group representing Catholic Hospital Ethicists and Clinicians. This is recommended for use by any Human Research Ethics Committee seeking to provide clear communication to potential research participants of child-bearing age and is consistent with Catholic teaching.

The effects of [Name of investigational product]on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least [number]months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of [number] months after completion of the research project. You should discuss effective methods of avoiding pregnancy with your study doctor.

[For female participants]If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention, should this be necessary. You must not continue in the research if you become pregnant.

[For male participants]You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary.

**Benefits**

[If appropriate:] While we intend that this research study furthers medical knowledge and may improve treatment of [name of disease being studied, or as appropriate] in the future, it may/will [delete whichever is not applicable] not be of direct benefit to you.

[If appropriate:] **Compensation for injuries or complications**

[This section should only be included if the study involves procedures more invasive than venous blood sampling. It can be deleted if the study procedures are confined to questionnaire, interview, focus group participation or venous blood sampling.]

If you suffer any injuries or complications as a result of this study, you should contact the study doctor as soon as possible, who will assist you in arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

In addition, you may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is sufficiently serious and is caused by unsafe drugs or equipment, or by the negligence of one of the parties involved in the study (for example, the researcher, the hospital, or the treating doctor). You do not give up any legal rights to compensation by participating in this study.

[For Clinical Trials of new drugs or devices:] In the event of loss or injury, the parties involved in this study agree to be bound by the Medicines Australia Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial. A copy of these guidelines is available from the Research Staff or online at <http://medicinesaustralia.com.au/files/2010/09/Clnical-Trials-Compensation-Guidelines.pdf>

**Will the study cost you anything?**

Participation in this study will not cost you anything, nor will you be paid. [If appropriate:]However, you will be reimbursed for your travel expenses for study visits, and meals will be provided during the study visits. [If there is a maximum amount for this reimbursement, then it should be stated.]

Parking should be mentioned.

**How will your privacy be protected?**

All the information collected from you for the study will be treated confidentially, and only the researchers named above [or others, as appropriate] will have access to it. [If appropriate:] The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

It should be stated that the participant’s personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

There should be a statement as to what will happen to a participant’s data if he/she decides to withdraw from the study including:

* Whether the data already collected can be withdrawn, and if not, why not; and
* Whether there is a request to collect follow up data, how this will be done, and that it is

 optional

Note. The preferred position is that once a person decides to withdraw from the study all the information collected from and about them is withdrawn from the study data and is destroyed. It is understood, that in some cases the data would have already been included in the study database or included in the analysis, and so it is not possible to withdraw the data but this needs to be explained.

**Further Information**

When you have read this information, [name of researcher] will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact him/her on [telephone number. If the person to be contacted for further information is different from the person named in line 1 of this paragraph, then give name and phone number].

Retaining data, disposal of data, possibility of being contacted for future research.

This information statement is for you to keep.

Do not presume agreement to participate. ‘Thank you for agreeing to participate’ is

inappropriate. It would be acceptable to add something like, ‘Thank you for considering this

invitation’.

**Summary:**  Complaint Statements for Participant Information Statements for HNE Research

Please refer to the below approved statements from HNELHD for use in all Patient Information Statements in the following scenarios:

**- 1. # HNE Ethics and Governance statements** for mandatory use for all research approved by the Hunter New England Human Research Ethics Committee (HNEHREC) and authorised by the Hunter New England Local Health District (HNELHD) to be conducted at a HNE site.

**- 2. # HNE Governance (only) statement** for mandatory use for all research approved by another Human Research Ethics Committee (ie not HNEHREC) and authorised by the Hunter New England Local Health District (HNELHD) to be conducted at a HNE site.

- **3. # HNE Ethics (only) statement** for mandatory use for all research approved by the HNEHREC, but not being conducted at a site within HNELHD:

**1. # HNE Ethics and Governance statements**

**Ethics:**
This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference *[insert REGIS ETH reference*).

**Governance:**

The conduct of this research has been **authorised** by the Hunter New England Local Health District to be conducted at the [*Name of site*] site.

**Complaints about this research:**
Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact the **HNE Research Office,** Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number (insert REGIS ETH Reference Number).

**2. # HNE Governance (only) statement:**

**Ethics:** *Add in mandatory ethics statement from the approving HREC*

**Governance:**

The conduct of this research has been **authorised** by the Hunter New England Local Health District to be conducted at the [*Name of site]* site.

**Complaints about conduct of this research within HNELHD:**

Should you have concerns or a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact the HNE Research Office, Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number (insert STE reference number).

**3. # Ethics (only) statement:**

**Ethics:**
This research has been **approved** by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference *[insert REGIS ETH reference*).

**Complaints about this research:**
Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact the **HNE Research Office,** Hunter New England Local Health District, Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305. Telephone: 02 4921 4140. Email: HNELHD-ResearchOffice@health.nsw.gov.au and quote the reference number: [insert REGIS ETH reference).

**Some suggested wording for common research procedures:**

Blood sampling

You will then be asked to provide a ? mL blood sample. This would be taken from a vein in your arm. **OR** This would be collected at the same time as your routine blood sample, so no extra procedure would be required.

Describe the amount of blood in teaspoons as well.

Tissue sample

A portion of the tissue removed during your operation and not required for diagnostic purposes will be used in the study. This tissue would otherwise be discarded. Participation in this study will have no effect on your clinical care.

Questionnaire(s)

You will then be asked to complete *n* questionnaires. These will seek information on [describe the nature of the information to be collected] and will take about ? minutes to do.

**Risks**

Blood sampling

Blood collection involves some discomfort at the site from which the blood is taken. There is also a risk of some minor bruising at the site, which may last one to two days. In rare cases, a person may feel faint or dizzy.

Exposure to radiation

This research study involves exposure to a very small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 to 3 millisieverts (mSv) each year. The effective dose from this study is about ... mSv. At this dose level, no harmful effects of radiation have been demonstrated, and the risk is negligible [if dose≤0.0 mSv] / minimal; [if 0.02mSv≤ dose ≤0.2 mSv] / very low [if 0.2mSv≤dose≤2mSv] / low [if 2mSv≤ dose≤20mSv]. The dose from this study is comparable to that received from routine diagnostic x-ray and nuclear medicine procedures [if 2mSv≤ dose≤20mSv].

Please inform us if you have participated in any other research studies using radiation in the last five years. Please keep this form in a safe place for the next five years in case you volunteer for any more studies using radiation, when you should show it to the Investigator.

MRI

There are no health risks associated with MRI scanning, provided you do not have any metallic objects in your body with a strong magnetic charge (e.g. pacemaker, hearing implants) and/or you are pregnant. The space inside the scanner is quite small, so patients suffering from claustrophobia (severe discomfort in enclosed places) are advised not to participate in this study. The MRI dye (gadolinium), that is given intravenously, extremely rarely causes a serious allergic reaction (about 1 in 5 million injections). Less serious allergies, especially rash, occur in about 1 in 1000 injections. One of the Study Doctors and an MRI radiographer will help you to fill out a screening questionnaire to ensure it is safe for you to have the scan.