**LETTERHEAD OF SENIOR RESEARCHER’S INSTITUTION**

[**TITLE OF PROTOCOL in Laylanguage]**

**INFORMATION FOR PARENTS / GUARDIANS**

**Introduction**

You are invited to allow your child to take part in a research study into [description of the study]. The objective is to investigate whether … **OR** … You and your child 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]. We encourage you to discuss this research with your child if he/she is old enough, and for he/she to read this information statement as well as the age appropriate one that has been provided. If your child is old enough to understand what the study involves, then it should be a joint decision with him/her whether he/she participates in the research.

**What is the research about?**

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

* 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 …

**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 children aged 6-17 to participate in this research with X condition/disease

Include information on who should not, or cannot, participate, ie identify the exclusion criteria, eg If your child currently on medication for \*\*\* , then unfortunately this study is not suitable for him/her/ this study is not suitable for children who have an allergy to …. People who are claustrophobic should not participate in this study because …

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

**What Choice do you and your child have?**

Participation in this study is entirely voluntary. You should discuss the study and what it involves with your child. You do not have to agree for your child to take part in this research and your child’s refusal to take part will also be respected. If you and your child do decide to take part, you can withdraw your child at any time without having to give a reason.    [Where applicable you can ask that any data collected concerning your child also be withdrawn from the study]. Whatever your decision, please be assured that it will not affect your child’s medical treatment or your relationship with the staff who are caring for your child. [If appropriate:] Of the people treating your child, 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 your child be asked to do if you and your child agree to participate?**

If you agree to allow your child to participate in this study, you will be asked to sign the Parent/Guardian Consent Form. Your child may also sign this form. Your child will then be asked to … [for one study procedure]**OR** …Your child 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 child's 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.

**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, your child 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 participants in this study are not pregnant and do not become pregnant during the course of the study. If your child is of child-bearing potential and there is any possibility that she is pregnant, the researchers will perform a pregnancy (urine) test before she starts in the study. If necessary, she should use reliable contraception during the course of the study. The researcher can discuss appropriate contraception if you or your daughter wish. If at any time you or your daughter think that she may have become pregnant, it is important to let the researchers know immediately.

**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 your child.

[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 your child suffers 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 for your child. If your child is eligible for Medicare, they 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 child's 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 and your child 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 or your child be paid. [If appropriate:]However, you will be reimbursed for your and your child's 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.]

**How will your privacy be protected?**

All the information collected from you and your child 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 the child’s data if the decision is made to withdraw the child from the study including:

* Whether the data already collected can be withdrawn, and if not, why not
* 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].

This information statement is for you to keep.

**Ending**

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’.

**Signatures**

All Information Statements must be signed.

The printed name and position of at least the Chief Investigator must appear, together with

his/her signature.

For student projects, the Information Statement must be signed by **both** the Project

Supervisor and the student.

**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

Your child will then be asked to provide a ? mL blood sample. This would be taken from a vein in their arm. **OR** This would be collected at the same time as your child's routine blood sample, so no extra needle puncture would be required. Mention pain relieving options such as ELMA cream

Tissue sample

A portion of the tissue removed during your child's 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 child's clinical care.

Questionnaire(s)

You and/or Your child will then be asked to complete 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.

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].

Please inform us if your child has 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 or until your child turns 18, whichever is the longer period, in case your child volunteers for any more studies using radiation, when you or they should show it to the Investigator.

Additional advice to researchers on the use of radiation in children from the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code:

* The condition under study must be related to the age of participants and cannot be obtained using adult participants.
* Written information must include purpose, methods, dose, risk and discomforts.
* There is a longer information sheet retention period.
* Risk must be assessed with age and risk-specific data in the Code.
* The dosimetry report from the medical physicist must include dose to bone marrow, thyroid, gonads and breast, as well as uterus, highest organ dose and effective dose as for adults.

The dose constraints for children are:

* Effective Dose <0.5mSv in any year from birth to 18 years and total <5mSv to 18 years.
* Organ dose <100mSv to age 18 years. [This sounds very high, as it is <100mSv/year for adults to avoid risk of cataract. In practice, the annual effective dose constraint will restrict most organ/tissue doses to much less.]

Examples of research procedures that may be acceptable for children:

* DXA protocols for following bone development, which are very low dose.
* Medical imaging in oncology trials which might raise the prospect of tumour evaluation at more frequent intervals than required for clinical management. In this case, the research protocol would need to be compared with the age-specific protocols for the institution.
* Sometimes an Adolescent Information sheet is needed.
* If there are a series of Info sheets, eg participant, controls, staff, make sure each is correctly labelled.
* Child Info-Some of the information is clinical, but in this case these children are probably patients and understand. For other projects, information must be simpler.