

Human Research Ethics Committees - Standardised Patient Information Sheets (PIS)

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Functional Sub group Clinical/ Patient Services - Research
Clinical/ Patient Services - Human Tissue

Summary Three standardised Patient Information Sheets (1) Clinical Trials (excluding genetic testing and collection/storage of human tissue), (2) Trials involving genetic testing and collection of human tissue, and (3) Tissue 'Banking' or storage of tissue samples) provide a 'proforma' for researchers and industry to use when developing patient information sheets to be used with potential research participants. They have been developed in clear, non-technical language in a 'question and answer' format to aid understanding by potential participants for three kinds of activities: participation in clinical trials, participation in trials involving genetic testing and tissue sampling, and where tissue 'banking' or storage is proposed for future unspecified research.

Author Branch Health Research and Ethics

Branch contact Julie Letts 9391 9465

Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Public Health System Support Division, Dental Schools and Clinics, NSW Dept of Health, Public Health Units, Public Hospitals

Audience Clinical and research staff involved in development of research trial protocols

Distributed to Public Health System, Dental Schools and Clinics, Divisions of General Practice, Government Medical Officers, Health Professional Associations and Related Organisations, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

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STANDARDISED PATIENT INFORMATION SHEETS (PIS) FOR POTENTIAL RESEARCH PARTICIPANTS

Human research protocols contain a 'patient information sheet' or PIS as an adjunct to the informed consent process. Such forms are provided to potential research participants to aid understanding and describe, in lay language, the trial, what participation by a research subject will entail, the risks, costs, potential benefits and any other information that is likely to be material to a participant's consent. Use of these forms is in addition to use of requisite consent forms. Any questions and concerns the participant has should be addressed before they sign the consent form.

NSW Health has developed standardised or 'proforma' PIS for use by researchers that they can modify, according to the specifics of the proposed research, in developing trial-specific PIS. These NSW Health PIS relate to three types of research activity: clinical trials, clinical trials involving genetic testing and/or tissue sampling, and tissue 'banking' or storage.

Use of these forms by researchers is recommended but optional.

This Policy Guideline should be read in conjunction with GL2006_021 Human Tissue – Requirements of the Human Tissue Act 1983 in relation to research and use of tissue.

Professor Debora Picone AM
Director-General

PARTICIPANT INFORMATION SHEET (PROFORMA)

**CLINICAL TRIAL
(EXCLUDING GENETIC TESTING AND COLLECTION/STORAGE OF
HUMAN TISSUE)**

[STUDY TITLE]

[Use plain English equivalent if a technical title]

Invitation

You are invited to participate in a research study into [*lay description of study*].

The study is being conducted by... [*names, positions, departments – if several, list them one under the other for clarity*].

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

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose is to investigate whether [*insert*].

2. 'Why have I been invited to participate in this study?'

You are eligible to participate in this study because [*insert*].

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to continue in the study.

If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason.

Researcher's institutional letterhead

[If appropriate: *insert any potential consequences that might arise from withdrawing from the trial, for example...*] However, it may not be possible to return your samples to you or withdraw your data from the study results if these have already had your identifying details removed.

4. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

This study will be conducted over *XX days/weeks/months/years*.

[If appropriate] The treatment being investigated in this study differs from the standard treatment offered in this institution because of ...its' use of drug *NEWDRUG* which is in early stage of development. OR ...its' use of *OLDDRUG*, an agent that has been recently found to have new properties that may be useful in treating [*insert disease/condition*]. OR ...its' use of the technique *NEWTECH*.

[If appropriate, include the following definitions:

'Randomised trial': Sometimes doctors don't know the best way of treating patients with a particular condition so comparisons need to be made between different treatments. To do this, study participants are put into groups and given different treatments, and the results are compared to see whether one treatment is better. To ensure the groups are similar to start with, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the doctor nor the study participant can decide which treatment the participant receives.

'Blind trial': In a "blind trial" the study participants do not know which treatment group they are in. If the trial is "double blind", neither the doctor nor the study participant knows which treatment the participant is receiving (although, if the doctor needs to find out, he/she can do so).

'Placebo': A placebo is a dummy treatment that looks like the genuine medicine but contains no active ingredient.]

If you agree to participate in this trial, you will then be asked to ...[*for one study procedure*] OR...

If you agree to participate in this trial, you will then be asked to undergo the following procedures: [*list multiple procedures as numbered or bullet points and give them in the order they will happen*].

[If appropriate: *definition of blood sampling*] Samples of blood taken from a vein will be required. The amount of blood taken will be equivalent to [*insert number*] of millilitres (or [*insert number*] of teaspoons) taken on [*insert number*] occasions.

Researcher's institutional letterhead

[If appropriate] Participating in the trial will require some restrictions on your lifestyle during the study. These include...*[insert]*.

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

5. 'How is this study being paid for?'

The study is being sponsored by *[name of commercial or other entity - include a statement about any duality or conflict of interest that any investigators may have]*.

[If appropriate] All of the money being paid by the sponsor to run the trial will be deposited into an account managed by *[insert hospital/Area Health Service]*. No money is paid directly to individual researchers.

6. 'Are there risks to me in taking part in this study?'

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study. The known risks of this study are:

[Provide information on inconvenience, reasonably foreseeable risks, discomforts or side effects that may occur, their likelihood, potential severity and duration (where possible)]

There may also be risks associated with this trial that are presently unknown or unforeseeable.

[Complete this section carefully. In certain circumstances e.g. terminal illness, elderly population its use would be inappropriate.] It is important that women participating in this study are not pregnant and do not become pregnant during the study as the study *[drugs, procedures]* may damage an unborn baby.

The effect of the study *[drugs/procedures]* on an unborn baby is unknown. If you are a woman of childbearing age and there is any possibility that you are pregnant, the researchers will need to perform a urine pregnancy 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 if you are female, or condoms if you are male) during the course of the study. If at any time you think you, or your sexual partner may be pregnant, it is important to let the researchers know immediately.

OR

Researcher's institutional letterhead

[*Applicable for Catholic institutions:* You should speak to the study doctor about the need to avoid pregnancy during this study.]

7. 'What happens if I suffer injury or complications as a result of the study?'

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.

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). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

[*If applicable*] The parties to this study agree to follow the Medicines Australia *Guidelines for Compensation for Injury Resulting from Participation in an Industry-Sponsored Clinical Trial*. These Guidelines allow for some claims for compensation to be settled without the need for legal action to be taken. You can obtain a copy of these Guidelines from the Secretary of the Human Research Ethics Committee.

8. 'Will I benefit from the study?'

This study aims to further medical knowledge and may improve future treatment of [*name of disease or condition, as appropriate*], however it [*may not / will not*] directly benefit you.

9. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything. You will be reimbursed for your time and reasonable travel expenses to the amount of [*state maximum amount of reimbursement, if applicable*] [*If applicable*] Meals will be provided during the study visits.

10. [*If appropriate*] 'What will happen to my tissue sample after it has been used?'

The blood or tissue sample/s you provide during the study will be [*stored/destroyed*] at the completion of the study. If the researchers wish to store (or 'bank') the samples, you will be asked whether you agree to this and, if so, will be asked to sign a specific consent form.

Researcher's institutional letterhead

If you do agree to your tissue samples being stored, they will not be used for other research projects, except with your written consent or, under some circumstances, with the approval of a Human Research Ethics Committee at that time.

[See NSW Health Standard Patient Information Sheet for 'tissue banking']

11. 'How will my confidentiality be protected?'

Of the people treating you, only [*those named above or necessary others eg all nursing staff involved in your care*] will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above [*or others - as appropriate*] will have access to your details and results that will be held securely at [*institution*].

12. 'What happens with the results?'

If you give us your permission by signing the consent document, we plan to discuss/publish the results (state the persons/agencies to whom the information will be disclosed, the nature of the information disclosed and the purpose of the disclosure e.g. the sponsor for monitoring purposes, the HREC for monitoring purposes, peer-reviewed journals, presentation at conferences or other professional forums).

In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish.

13. 'What happens to my treatment when the study is finished?'

[*As appropriate*] The [*drug/procedure*] will not be available after the study finishes. The treatment available will be.... OR....

You may be able to continue [*drug/procedure*] following completion of this study if it found to be of benefit to you.

This decision will be made in consultation between you and your treating doctor about the most appropriate treatment for you at that time.

14. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher [*name*] will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on [*number – or other if different*].

Researcher's institutional letterhead

15. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by [*relevant HREC*]. Any person with concerns or complaints about the conduct of this study should contact [*name*] who is the person nominated to receive complaints from research participants. You should contact them on [*number*] and quote [*HREC project number*].

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**

PARTICIPANT INFORMATION SHEET (PROFORMA)

TRIALS INVOLVING GENETIC TESTING AND COLLECTION OF HUMAN TISSUE

[STUDY TITLE]

[Use plain English equivalent if a technical title]

Invitation

You are invited to participate in a research study into [*lay description of study*].

The study is being conducted by...[*names, positions, departments – if several, list them one under the other for clarity*].

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

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose is to investigate whether ... [*insert*].

2. 'Why have I been invited to participate in this study?'

You have been invited to participate in this study because ... [*insert*].

3. 'What does this study involve?'

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

The study procedure involves removal of a new sample of [*X amount of blood, tissue - specify*]. OR removal of [*X amount of blood, tissue - specify*] taken during the clinical procedure where [*specify*]. OR accessing your previously stored sample.

These samples will be *examined/tested* by [*describe the process*] to determine [*insert purpose of test*].

4. 'What are the risks associated with this procedure?'

[As appropriate]: You may experience some mild discomfort and minor bruising or swelling at the site where blood sampling is collected. OR

There are no additional risks involved in participating in this study. The tissue sample used for the study is taken from the tissue that is being removed during your [state procedure]. No additional tissue will be taken. OR

There are no additional risks involved in participating in this study. Your sample was collected on a previous occasion.

5. 'Will I benefit from this study?'

[If appropriate]: The testing will not provide you with any direct benefit because the link between you and your sample will be removed before your sample is analysed. However, it may provide valuable information to improve the management of people with [specify condition/disease] in the future. OR

You will be contacted if the testing shows important information for you, and you will be asked if you wish to know the results. The results may be important to you where they provide information about:

- A risk of an inherited condition AND/OR
- Information that may reveal non-paternity, non-maternity, or non-relationship to siblings; AND/OR
- Information that might influence a decision to have children AND/OR
- Information that might affect your ability to obtain insurance or employment.

Should you wish to know these results, expert counselling will be provided by [state where] to explain what the results mean for you and to support you as necessary.

[If appropriate]: It may also be necessary to refer you for re-testing by genetic services outside this study.

6. 'What happens if I don't want to take part in the study?'

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

7. 'How will my confidentiality be protected?'

Your sample will not be linked to your name or any personal details. The link between this information and your sample will be removed before your sample is analysed. Your test results will not be linked to you.

OR

Although your sample will be linked to information identifying you, all aspects of this study will be kept confidential and only those conducting and monitoring the study will have access to your results.

We plan to discuss/publish the findings. (state the persons/agencies to whom the information will be disclosed, the nature of the information disclosed and the purpose of the disclosure e.g. the sponsor for monitoring purposes, the HREC for monitoring purposes, peer-reviewed journals, presentation at conferences or other professional forums). In any publication, information will be provided in such a way that you cannot be identified.

[If appropriate]: This study's findings will be provided to you, if you wish.

8. 'What will happen to my sample after it has been tested?'

[If appropriate]: Your sample will only be used for the purpose of this research study. The blood or tissue sample/s you provide during the study will be destroyed at the completion of the study, although some samples may be kept if required under the laboratory's accreditation standards.

[If appropriate] We would like to store this tissue for future use. This is explained further in the attached information sheet on storing or 'banking' tissue.

9. 'Will I be able to get my sample back if I want?'

It may not be appropriate in all circumstances to return your sample, for example where this may pose an infectious risk. However, where this can be done,

[If appropriate]: You may contact your study doctor at any time and request that your sample be *destroyed/returned*.

[If appropriate]: You may contact your study doctor at any time up until [insert date] and request that your sample be *destroyed/returned*. However, after that time it will not be possible to destroy/return your sample because [insert reason].

10. 'How is this study being paid for?'

The study is being sponsored by ... [*name of commercial or other entity - include a statement about any duality or conflict of interest that any investigators may have*].

11. 'Will drug or biotechnology companies be able to use my sample for profit in the future?'

[If appropriate]: There is the possibility of this research resulting in commercially viable technology or treatments. However, you will not be able to claim financial benefit from any discoveries arising from the use of your blood or tissue sample.

12. 'What should I do if I want to discuss this study further before I decide?'

When you have read this information, the researcher [*name*] will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on [*number – or other if different*].

13. 'Who should I contact if I have concerns about the conduct of this study?'

This study has been approved by [*relevant HREC*]. Any person with concerns or complaints about the conduct of this study should contact [*name*] who is the person nominated to receive complaints from research participants. You should contact them on [*number*] and quote [*HREC project number*].

14. [If appropriate]: 'What if I don't want to know the results?'

It is entirely your decision as to whether or not you decide to be told the results. This will not affect the treatment you receive now or in the future.

15. [If appropriate]: 'What if the results are relevant to members of my family or other relatives?'

Your results may be relevant to the health or well-being of family members or other relatives, for example because:

the results indicate an inherited disease or other condition which might affect them,

AND/OR

the results have the potential to detect that either you or a family member are not the parent of a child, as presumed.

If this is the case, your results will only be disclosed to those family members or relatives with your consent.

Depending on your results, it might be appropriate to approach your relative/s to join the study. However, this will not occur without your consent.

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**

PARTICIPANT INFORMATION SHEET (PROFORMA)

TISSUE 'BANKING' OR STORAGE OF TISSUE SAMPLES

Request

We ask that you consider giving your permission for storage of a sample of your tissue at [*specify name of tissue banking facility*] for possible use in future research. You will have previously needed to give consent to removal of this tissue and for it to be used for research purposes.

This form provides you with information to help you decide whether you will allow this.

Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What kind of tissue will be taken, and how?'

[*Specify the type and amount of tissue to be taken, as well as the bodily location that the tissue is to be taken from*]

The tissue will be removed by [*specify in what manner it will be removed and invasiveness of acquisition*].

2. 'Will the tissue sample be identifiable as mine after it is stored?'

The stored tissue sample [*will / will not*] be identifiable as yours.

[*If appropriate*]: As the sample will be identifiable as yours, we will still maintain your confidentiality by [*include applicable privacy measures*].

3. 'What will happen to my tissue sample?'

Your sample will be stored [*for how long, and where?*].

[*If appropriate*]: Your sample will be transferred and stored overseas.

[*If appropriate*]: We wish to store (or 'bank') the sample for potential, and as yet unspecified, research in the future. Not all potentially beneficial future research can be known at any one time, as the need for future research is determined by ongoing developments in the field. If you agree to your sample being stored, you will be asked to sign a specific consent form to store your sample in this way.

4. 'How will I know if my samples are being used in the future?'

If you agree to your tissue sample/s being stored for future research, they may be used for research projects in the future with the approval of a Human Research Ethics Committee. The Human Research Ethics Committee will

determine whether, or not, your consent should be obtained at that time for a particular research project. However, notifying you and obtaining your consent for specific research may not be possible if the stored sample is not linked to your identifying information.

It [*will / will not*] be possible to provide you with feedback about the findings of potential future research.

5. 'Who will have access to my tissue sample once it has been stored?'

The custodians charged with ensuring appropriate standards are met in storing and managing the tissue bank will have access to your sample. Researchers involved in research approved by a Human Research Ethics Committee may also have access to your sample.

6. 'Will drug or biotechnology companies be able to use my sample for profit in the future?'

There is the possibility that research involving your blood or tissue sample may result in commercially viable technology or treatments. You will not however be able to claim financial benefit from any discoveries arising from the use of your tissue sample.

7. 'How long will my tissue sample be stored?'

Your tissue sample will be stored for [*xx weeks/months/years*]. The sample [*will/ will not*] be destroyed at the end of this period.

8. 'Will I be able to get my sample back if I change my mind once it has been stored in the 'tissue bank'?''

[*If appropriate*]: It may, or may not be possible to return your sample because [*insert reason*].

**Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.**