Participant information and consent form — Trial details

Insert the short name of the trial

An invitation from [Name, Title of Principal Researcher]

1 Would you like to take part in this clinical trial?

We would like to invite you to take part in our clinical trial. This is because you have [enter condition].

This document tells you about the trial and describes what will happen if you decide to take part. If there is anything you don't understand or want to know more about, please ask us. We will be happy to provide more information.

If you don't know what to ask, there are some questions to consider in the *Clinical trial participant information and consent form: Part A – General information*.

You might also want to talk to a relative, a friend or your GP before you make up your mind. If you decide to go ahead, we will ask you to sign the consent form (the last page of this document). We will give you a copy of the complete signed document to keep.

2 Why are we doing this research?

Include a one-sentence description of the study objective in lay terms. For example: '*In this trial, we are trying to find out if older people live longer when they take a small daily dose of aspirin.*'

Describe the background of the trial. For example: '*Today, the most successful approach is a combination of three drugs. They work well, but a new discovery may work even better than one of the standard three.*'

Describe the hypothesis. For example: '*We believe that using a small current to stimulate part of the spine may help people with chronic pain who have not been helped by any other procedure*.'

Make sure you:

- Name the drug/device or procedure you are testing.
- State the TGA registration status of each drug/device to be used in the study.
- State whether approval has been given for the drug/device to treat this or another condition.
- Distinguish between registration in Australia and elsewhere.

If it is a Clinical Trial Notification (CTN) application, state that the drug or device is experimental.

3 Do I have to take part?

No. It's your choice. If you don't wish to take part, you don't have to. If you decide to take part and later change your mind, you are free to withdraw at any stage. If you choose not to take part, or if you choose to take part and then later withdraw, you will still be able to access your usual medical care. Your choice will not affect your relations with those treating you, or with this institution.

If you do withdraw your consent during the clinical trial, the research team will stop collecting personal information from you. But they will keep the personal information they have collected up to that point. There is a good reason for this. Sometimes, the law requires it. It is also retained for accurate measurement, the trial results must include all the data actually collected.

Just to be clear on this point. We must keep any information about you we collect, up to the time you withdraw. The institution conducting the trial (and the sponsor, if there is one), has access to this information so they can check it is correct. If you do not agree with this then we cannot allow you to join the clinical trial.

4 What are the main steps in the study?

List only the main procedures from the protocol.

We first need to confirm that you are eligible to take part.

State the inclusion criteria. For example: '*For this trial we need the help of male and female participants aged from 18 to 70 who are in good health, have never been treated for depression, do not smoke, and are willing not to drink coffee, tea or certain soft-drinks containing caffeine for a month during the trial.*' State the number of expected recruits and the number of institutions and/or countries in a multi-site trial.

Explain the screening step, if any. For example: '*Next, we will ask you to take a blood test to check that your virus count is low. We will take the equivalent of just a teaspoon-full of blood from your arm.*'

Explain the randomisation step, if there is one. For example: '*To ensure a fair test of our assumptions we will assign you to one of (x) groups of participants on a 'chance' basis: like flipping a coin.*'

'You will have a [specify the ratio e.g. 1:1 (50%)] chance of being given one of the following treatments:

- *list each treatment arm*

If there is a control group, describe the control. For example: '*One group of participants, selected at random, will receive a sham or 'placebo' [drug/procedure].*' For drug trials: '*A placebo is a substance that does not contain an active ingredient. This looks like the real thing, but has no clinical effect. [In one sentence describe the placebo process or appearance in lay terms]. Using a placebo in one group helps us to be confident that effects we measure in the other groups really are due to the [drug/device or procedure]*'.

If the procedure is blinded or masked you should say: '*To avoid accidentally influencing the tests, neither you nor the researchers will know* [describe the blinding, for example: "*whether you got the placebo or a dose of the real drug". But don't worry. If it is necessary for your care, we can find out what procedure you have been given.'*

Explain what exactly will happen (e.g. questionnaire, interview, discussion group, measurement, sample collection, blood tests, X-rays, etc. Use plain-language descriptions, preferably as a list of sequential steps. Use simple directive instructions ('you will, you must, you must not ...'). It may help if information is displayed in a simple tables, a flowchart or diagram indicating what will happen at each visit. Include brief descriptions as well. This type of testing is done to further our knowledge about how the study medication works and it will not produce the type of results that will have any useful meaning that would affect your health or treatment. Therefore you will not be informed of the results of the tests.

For example:

'You will have a number of visits to our clinic during your time on the study. Your visits at Screening, Baseline, week 8, week 52 and week 104 will take approximately 4 hours. Visits for the xx test will take approximately 30 minutes and all others will be 2-3 hours. The tests and visit schedule are described and summarised in Table 1:'

[Insert table or grid, example in User Guide]

5 What other options do I have?

There may be other options. You do not have to take part in this clinical trial to receive treatment that may help you. If there are other options, the study doctor will discuss them with you before you decide whether to take part. You can also discuss the options with your GP.

6 Who is conducting and paying for this research?

Include if the trial is being coordinated outside of an institution, if it is commercially or grant funded, if it is investigator initiated, or if the purpose is to obtain an educational qualification. Any conflicts of interest should be declared. Explain how the research will be monitored.

Some of the tests or treatments used in this study may be part of standard care used to maintain your health even if you did not take part in the study. You will be responsible for the cost of this standard care in the usual way (health insurance, Medicare and your personal contribution depending on your circumstances). All medication and study-related tests will be provided at no cost to you. You should ask the study doctor to explain any payments for which you may be responsible.

7 What if something new comes up during the trial?

We will tell you about it. Occasionally, we find out something new about an intervention while the study is under way. If this happens, the study doctor will discuss with you what it means and whether you want to continue in the study. If you decide to withdraw, the study doctor will make arrangements for your regular health care to continue. If you decide to continue in the clinical trial we will ask you to sign an updated consent form.

8 Could the researchers stop the trial early?

Yes, it happens sometimes. If it does, the study doctor will let you know and explain the reason behind the decision.

9 What will happen to information about me?

We will keep any information confidential and securely stored. We will use and retain information that we collect about you only for this clinical trial. We will not disclose your information without your permission, except in compliance with the law.

Information about you may be obtained from your health records held at this institution and may be obtained from other health services for the purposes of research. If you sign the consent form, you agree to the study team accessing health records if they are relevant to your participation in this study.

All of the collected data will be coded. No personal information about you, such as your name and address will leave the clinic, and in all study information sent out from the clinic you will be identified with a code number only. All of your collected information will be kept for at least 15 years after the end of the study. After the 15 years your identifying information at the institution will be permanently deleted from the computer system and any hard copies will be destroyed. The re-identifiable/coded (it is possible to use the code to re-identify you) information held by the sponsor however, will not be destroyed.

Australian and [Insert the name of a state or territory] privacy law gives you the right to request access to your information that the researchers have collected and stored. The law also gives you the right to request corrections to any information about you that you disagree with. Please contact the study team (contacts on page [insert the number of the page containing the study-team contact] of this document) if you would like to access your information.

10 What are my responsibilities during the trial?

Tell the participant what other things they must do during the study. There is no need here to repeat the steps detailed in the previous section. If this is a drug/procedure trial, say:

If you agree to participate in this study you agree to be responsible for taking/using the [drug/device or procedure] according to our instructions. You also agree to comply with the other conditions in this document. If you cannot, or do not wish to accept this responsibility, then we cannot accept you as a participant in the trial.

11 What possible benefits might I get by taking part?

This section is about health benefits. Do not discuss participant reimbursement or incentives in this section. That information comes later.

Do not attempt to build up participant hopes in this section. A reference to the potential benefit to future patients may be appropriate, but should not be exaggerated.

If the participant may derive some benefits from the treatment: 'We cannot promise you any personal benefits from this research. It is possible that ...' You may offer a conservative view of other potential benefits. For example: 'You may benefit from the more frequent review of your condition during the trial.'

Or, if the participants will receive no significant benefits from the clinical trial this should be made explicit: For example: 'This research will not provide you with any personal benefit.'

In either case you could add: *'By taking part you may be helping other people in future [*describe any likely benefits to participants or others in the future].'

12 What risks do I run by taking part?

Explain, first, about side effects and list those that are known or expected.

Medical procedures often have side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

Also, there may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after the intervention ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your procedure. Your study doctor will discuss the best way of managing any side effects with you.

List, for each medication/device/procedure, the possible side effects including the type of symptoms, frequency, severity and duration. Use short and well-spaced paragraphs with short uncomplicated sentences. Risks may be grouped according to frequency, severity, duration and/or significance (eg what implications the risks may have for participants).

13 How will you use any tissues or samples you take from me?

We will not collect any tissues or samples from you in this trial.

Or, If you agree to participate in this trial, we will collect [name the samples] as part of your routine diagnosis or care in this clinical trial.

Or, If you agree to participate in this trial, we will take some [name the samples] that we will store for testing in this trial.

Separate out the various categories of samples (eg Routine medical care, pharmacokinetic, biomarker etc.) and explain for each: whether they are mandatory or optional.

This should include:

- the secure procedures for collecting, using, storing and/or destruction of each sample
- how long the samples will be stored
- who will have access
- where the samples will be processed/stored (Australia or Internationally)
- the level of identifiability (for this study and for storage for future studies)
- any possible intended use in the future for research that cannot yet be specified. A separated or two part consent form is recommended if future use is intended, and it should be clear if further HREC approval will be sought for future research activities – especially in the case of a biobank.

If applicable: Neither you nor we will obtain the results of these tests. This type of testing is done to further our knowledge about how the study drug works and it will not produce the type of results that will have any useful meaning that would affect your health or treatment. Therefore you will not be informed of the results of the tests.

If there is an option for blood or tissue samples to be taken and stored for this or further research, it is suggested that consent to the use and storage of tissue be separate from the general consent to participate in the study.

Will you be doing any genetic tests?

If not: There are no genetic tests in this trial.

Or, if there is a required genetic testing component, make it clear what you will be testing (i.e. will this be a broad genomic test or will the test be confined to a narrow genome target). You will need to cover the information required in NHMRC National Statement sections 3.5.8, 3.5.2b, 3.5.2c, 3.5.3.

Potential participants should be given sufficient information about whether or not research using their biospecimens is likely to provide information that may be important to their health or to the health of their blood relatives or their community.

If applicable: The type of testing being done in this study is not testing that would result in information about a participant's future health or risk of having children with a genetic disorder, or information that may be relevant to the health of family members who are not a part of the trial.

If information is likely to be revealed, disclose whether or not the participant or blood relatives or their community will have the choice to receive this information, and how this will be managed.

Or, *if there is an optional sub-trial with a genetic testing component, say something like:*

As a separate part of our research we will be undertaking some genetic tests. We will give you information about that sub-study on a separate document for you to consent to the genetic tests. You do not have to participate in the tests if you do not wish to do so.

Please select, if appropriate:

If you withdraw from the study you can request that your samples be destroyed.

Or, Since there will be no way to link your samples to you, it will not be possible to withdraw your samples if you decide to leave the study and make a request for the samples to be destroyed.

14 What happens if I am injured as a result of my participation in this trial?

If you suffer any injuries or complications as a result of this trial, please contact us as soon as possible. We will help you to get medical treatment.

[Insert compensation clause from User Guide which is appropriate for funding and type of trial]

15 Will you pay me to participate in this trial?

State the terms of any monetary reimbursement for participation (e.g. a limit or if receipts will need to be provided).

Or, There is no reimbursement or payment for this trial.

16 Can I have other procedures during this clinical trial?

First, answer this question directly. Then add the following sentences.

You must tell us about any procedures or medicines you may be taking. This is in your interest as well as important for the trial. You must tell us about any over-the-counter medications, vitamins or herbal remedies you are taking and about acupuncture or other alternative procedures because they may interact or interfere with the product. You must also tell us about any changes to these while you are participating in the clinical trial.

17 What happens when the trial ends?

Provide details of follow-up arrangements.

18 Will the results of the trial be published?

To protect your privacy, no information will be published that could identify you as a participant in this trial.

Provide information on how the participant will find out about the outcomes of the trial.

19 What if I have a question or need to make a complaint or seek compensation for injury?

We have included several contacts for you below. Who you contact depends on what information you need.

For all study enquiries or if you want to talk to the study team at any time:

- A business-hours contact for the study team. [Add name, position, telephone number, email]

If you experience any side-effects or complications as a result of this clinical trial, you should contact the study team as soon as possible. They will arrange appropriate medical help:

- 24-hour medical emergency contact for the study team. [Add name, position, telephone number, email]

If you wish to discuss the study or with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact:

- Reviewing HREC, [Add name, position, telephone number, email].

If you are injured or experience severe side effects, you can take your complaints or requests for compensation to:

- A contact at the research site to whom patients may take complaints or requests for compensation. [Add name, position, telephone number, email]

20 The consent form

Sign the consent form only after you have made up your mind to take part in this clinical trial. If you wish, we will arrange for someone to read the form to you in a language you understand. All study participants must be provided with a signed and dated copy of the participant information and consent Form for their personal record.

Consent form

Title	[Study title]	
Short title	[Short project title]	
Protocol number	[Protocol number]	
Project sponsor	[Project sponsor in Australia]	
Principal investigator	[Principal Investigator]	
Clinical contact person	[Name ,Location]	[Business number]
24-hour medical contact	[24-hr phone number]	[Email address]

Note: All parties signing the consent section must date their own signature.

Declaration by participant

I have read, or have had read to me, and I understand the participant information and consent form.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this clinical trial as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand the purposes, procedures and risks of the research described in the trial.

I give permission for my doctors, other health professionals, hospitals, laboratories or ambulances outside this hospital to release information to [name of institution] concerning my disease and treatment for the purposes of this trial. I understand that such information will remain confidential.

I consent to my treating doctor/s being notified of my participation in this study and any clinically relevant information noted by the trial doctor in the conduct of the trial.

I understand that I will be given a signed copy of this document to keep.

Signature _____ Date_____

Name of participant (please print) _____

Declaration by trial doctor/senior researcher†

I have given a verbal explanation of the clinical trial, its procedures and risks and I believe that the participant has understood that explanation.

Signature _____ Date_____

Name of trial doctor/ researcher† (please print) _____

† A senior member of the research team must provide the explanation of, and information concerning, the clinical trial.