Handout

Workshop 3 – Experiences with national differences in information package constitution

PARTICIPANT INFORMATION and consent form (PICF)

TEMPLATE FOR CLINICAL DRUG / DEVICE RESEARCH PROJECTS

Using this template

In this template, you will notice that there are the following:

- *Prompts for the content of your PICF (**in standard blue text**);*
- *Instructions regarding the format of your PICF (**in blue italics**); and*
- *'Preferred language' recommendations for use in your PICF (**in black text**).*

Headed with Institution's name or on Institution's Letterhead

Participant Information and Consent Form
[Insert site name]

Full Project Title:

Principal Researcher:

1. Introduction Group 1

The purpose of this section is to state the reason the participant is being invited to take part in the research project and to explain the purpose of the form and the nature of informed consent.

PREFERRED LANGUAGE

You are invited to take part in this research project. This is because you have *[insert name of condition]*. The research project is testing a new treatment for *[condition]*. The new treatment is/is called *[name]*.

This Participant Information and Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to have the tests and treatments that are described;
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research? Group 1

Briefly describe the following aspects of your project, in simple terms and in only in a couple of sentences for each point:

- The aims of the project (how your project intends to fill the gap in knowledge) and why it is important (how it may contribute to care or education or research in the future);
- The background to the research (what is already known);
- The justification and significance of your project (what earlier studies haven't been able to cover, what aspect of a condition/behaviour/program your project will focus

on);

- The current registration status of each drug/device to be used in the research. Indicate whether the drug/device is approved for this indication or another.

PREFERRED LANGUAGE

Medications/drugs/devices have to be approved for this use by the Government. *[Name of drug/product]* is approved in XXX to treat *[condition]*
OR
[Name of drug/product] is an experimental treatment. This means that it is not an approved treatment for *[condition]* in XXX or other parts of the world.
OR
[Name of drug] is approved in XXX to treat *[other condition]*. However, it is not approved to treat *[condition]*. Therefore, it is an experimental treatment for *[condition]*. This means that it must be tested to see if it is an effective treatment for *[condition]*.

- How many people will be taking part in the project overall and at this site;
- Whether there are different arms to the project or case/control groups;
- The size or scope of the project e.g. number of schools or hospitals or countries involved;
- Whether this is a follow-on study/sub-study/extension study. If so, state the relationship to the previous research;

PREFERRED LANGUAGE

Where the research project is investigator-initiated, insert:

This research has been initiated by the investigator, Dr/Professor *[name]*.

Where commercial sponsorship is available, insert:

This research is being conducted by *[name of international pharmaceutical company]* and sponsored in XXX by *[name of local sponsor]*.

3. What does participation in this research involve? Group 1

Include information and clear explanation of the following:

- Initial steps
  - Screening for eligibility
  - Randomisation and blinding, use of a control group (including use of placebo)
- Procedures
  - All procedures;
  - Nature, number, timing and time commitment of tests, procedures, visits, questionnaires (include scientific and lay measurements of samples to be taken);
  - Nature of follow-up;
  - Duration of patient's participation (including follow-up);
  - Device monitoring (if applicable). In the case of medical device trials, information should be provided about the mechanisms in place to track participants for the lifetime of the device, to detect any relevant adverse events and to enable remedial action if a significant defect is detected.
- Reimbursement and costs (if applicable)

PREFERRED LANGUAGE

You will not be paid for your participation in this research, but you will be reimbursed for any of the following costs that you incur as a result of participating in this research project *[give specific amount for specific items e.g. $30 for taxi fares each visit]*.

[If applicable, also add] You will have to pay for some medicines according to hospital policy. For example, *[give an example]*.

4. What are the possible benefits?

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

PREFERRED LANGUAGE

We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits may include *[describe any likely benefits to participants or other people in the future.]*
[If the significant benefits from the trial are to accrue to members of society in the future and NOT the individuals taking part in the trial, this should be made clear.] There will be no clear benefit to you from your participation in this research.

5. What are the possible risks? Group 2

The layout of this section will depend on the nature of the research and the number, severity and significance of the risks.

PREFERRED LANGUAGE

Medical treatments often cause 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 doctor. Your doctor will also be looking out for side effects.

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

Risks may be grouped according to frequency, severity, duration and significance (i.e. what implications the risks may have for participants).

If relevant, a paragraph regarding risks associated with injections is required.

PREFERRED LANGUAGE

Having a drug injected or blood (or tissue sample) taken may cause some discomfort or bruising. Sometimes, the blood vessel may swell, or blood may clot in the blood vessel, or the spot from which tissue is taken could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

If relevant, a section regarding risks related to conception, pregnancy and breast-feeding is required. If sterility is a possible risk of participation in the research project, then this should be stated in a separate paragraph in this section. This section should <u>not</u> be entitled 'Risks Related to Pregnancy,' as there are other risks being described.

PREFERRED LANGUAGE

Please remember to adapt this clause if the project is specifically for female or male participants only and check for any site-specific requirements in relation to this statement.

The effects of *[insert name of trial drug]* on the unborn child and on the newborn baby are not known. Because of this, it is important that study 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 male, you should not father a child. 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.

Both male and female participants are strongly advised to use effective contraception during the course of the research and for a period of [*insert number*] months after completion of the study. You should discuss methods of effective contraception with your doctor. *[For female participants]*If you do become pregnant whilst participating in the study, you should advise your treating doctor immediately. Your doctor will withdraw you from the study 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 treating doctor if you father a child while participating in the research project. Your doctor will advise on medical attention for your partner should this be necessary.

Include the following as a final statement:

PREFERRED LANGUAGE

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

6. What if new information arises during this research project?

PREFERRED LANGUAGE

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and your doctor will discuss whether this new information affects you.

7. Can I have other treatments during this research project?

PREFERRED LANGUAGE

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your doctor about any changes to these during your participation in the research.

8. Are there alternatives to participation? Group 2

PREFERRED LANGUAGE

Participation in this research is not your only option. Your other options may include: *[give examples]*. Discuss these options with your doctor before deciding whether or not to take part in this research project.

If applicable, indicate how the research treatment differs from standard treatment.

9. Do I have to take part in this research project?

PREFERRED LANGUAGE

Participation in any research project is voluntary. If you do not 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 from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[the Institution]*.

10. What if I withdraw from this research project?

PREFERRED LANGUAGE

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing.

[If applicable] If you decide to leave the project, the researchers would like to keep *[the personal and health information about you/your tissue samples]* that have been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you join the research project.

11. Could this research project be stopped unexpectedly?

The participant should be advised of the potential for the project to be terminated before completion and the reasons that might make termination necessary.

PREFERRED LANGUAGE

This research project may be stopped for a variety of reasons. These may include reasons such as:

- Unacceptable side effects;
- The drug/treatment being shown not to be effective;
- The drug/treatment being shown to work and not need further testing; and
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities. *[Note - the reference to the sponsor's interests should be omitted where the trial is initiated by the investigator(s)]*

12. What else do I need to know?

- **What will happen to information about me? Group 3**

Information should be provided regarding the following:

- The storage and disposal of data;
- Whether the data is individually identifiable, re-identifiable (coded) or non-identifiable;
- Where the data will be kept and who will have access to it;
- How long it will be stored and what will happen to the data at the end of the storage period.
- Whether the person is being asked to consent to the specific (this project only), extended (related research) or unspecified (any future research) use of their data;
- Whether the research project involves the establishment of a databank.

PREFERRED LANGUAGE

Any information obtained in connection with this research project that can identify you will remain confidential and will only be used for the purpose of this research project. *[If additional use of the information is contemplated, this should be explained and specific*

consent should be sought from the participants for that additional use.] It will only be disclosed with your permission, except as required by law.

If relevant, provide information regarding the review of health records by researchers and by representatives of regulatory authorities and the sponsor for the purpose of verifying the procedures and the data. For example:

PREFERRED LANGUAGE

Your health records and any information obtained during the study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, *[sponsor's name],* this organisation *[organisation's name]* or as required by law. *[If the study involves both an international and an Australian sponsor, insert the names of both in this section.]* By signing the consent section, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

PREFERRED LANGUAGE

In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. *[Describe how confidentiality will be maintained.]*

- **What happens if I am injured as a result of participating in this research project? Group 3**

PREFERRED LANGUAGE

If you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

For commercially sponsored clinical trials insert the following information about compensation:

The sponsor *[full name of sponsor]* has agreed to provide compensation to you for any injury suffered as a result of your participation in the research project, in accordance with the XXX Guidelines for compensation for injury resulting from participating in a company-sponsored research project.

13. Consent Group 3

PREFERRED LANGUAGE

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to [*name of Institution*] concerning my disease and treatment that is needed for this project. I understand that such information will remain confidential.

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 research project as described.

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

Participant's name (printed) ……

Signature Date

Name of witness to participant's signature (printed) ……

Signature Date

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed) ……

Signature Date

** A senior member of the research team must provide the explanation and provision of information concerning the research project.*

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

14. Who can I contact?

PREFERRED LANGUAGE

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal researcher on [*provide contact phone number*] or any of the following people: *[list the names and contact phone numbers of other appropriate persons involved in the project including research nurses and research project coordinators. The name and contact phone number of a person who can act as a 24-hour medical contact must be provided and clearly denoted]*.

Name:

Role:

Telephone:

For complaints:

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Name:

Position:

Telephone: