MRC CTU at UCL Patient information sheet template

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1 Background and rationale

This template is to be used when a patient information sheet (PIS) is given to an adult. For trials involving children, seek advice from a group that specialises in paediatric trials such as the MRC CTU at UCL's Paediatric HIV Programme or the Children's HIV Association (CHIVA) – and see the guidance published by the Health Research Authority (HRA) at:

<http://www.hra-decisiontools.org.uk/consent/docs/MRCN%20YPAG%20-%20Guidance%20for%20Researchers%20designing%20Patient%20Information%20Leaflets.pdf>

We updated this template in 2015 with the aim of making all MRC CTU at UCL patient information sheets as easy as possible for patients to understand. As with previous versions of the template, it follows HRA guidance. The structure for the template has been taken from work byPeter Knapp and colleagues. They have developed and extensively user tested a number of patient information sheets. See for example:

**P Knapp, DK Raynor, J Silcock, B Parkinson.** Performance-based readability testing of participant materials for a Phase I trial: TGN1412. Journal of Medical Ethics 2009; 35: 573-578. <http://jme.bmj.com/content/35/9/573.abstract>

This work is now used as an example by the HRA.

2 How to use the template

This template can be adapted as required for each trial or study, and can be implemented at any stage of a trial.

Remove these introductory pages before using the template. Adjust all template text as required for your study. Red text is to be changed by the study team during development of a trial-specific document. Text highlighted in yellow is to be changed by sites during creation of the site-specific copy.

The template document has been set up with suitable Styles, and, for consistency, you should try to use these rather than amending formatting yourself. Most body text you need to add uses the ‘Normal’ Style.

The blue numbers in the headings are in text boxes for cosmetic reasons. They should stay with their headings without any problems, but if you do have any problems, consider deleting the text boxes and adding in numbers in the text instead.

Use the accompanying guidance document for advice on updating all sections of the template. The guidance document also provides example text from two trials that have used the template.

3 The template and guidance for sites

The template itself follows on the next page. Please remove all other pages before using, but leave in the ‘Guidance for sites’ below, if you feel it will be useful. This could alternatively be sent to sites as a separate document.

**Guidance for sites**

On the following pages you will find the template Patient Information Sheet for the [trial]. Some changes need to be made to this before you use it for your site. The items requiring change are all highlighted in yellow, so should be easy to identify.

1. Add your local header to the top of the first page; please ensure this is only the relevant logo(s) and not any addresses. Addresses can be entered elsewhere, and if you try to add them to the top of the document they might push information onto the second page
2. Add relevant contact details, including the hospital address, into the section ‘How to contact us’ on the front page. It is best to name an individual here who is likely to have time to receive contact from trial participants. Please ensure that the address does not go over onto the second page.
3. On the final page, ‘Research and Development Office’ is highlighted in case your relevant local department has a different name to this. Whether you change it or not, make sure the highlighting is removed before using the document.
4. At the end of the final page, add the relevant contact details again for reference.
5. Before finalising the document, remove this guidance page and make sure no text is highlighted in yellow.
6. When the document is finalised, please remember to do the following:
	1. File a copy of the local headed paper version in the Investigator Site File
	2. Send a copy of the local headed paper version back to MRC CTU at UCL

To be presented on local headed paper To be presented on local headed paper

[Remove text box and insert relevant logos here]

**[Trial name] Clinical Trial**

**We are inviting you to take part in a research study called [Trial name]**

* Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
* You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
* You can stop taking part in the study at any time, without giving a reason.
* Ask us if there is anything that is not clear or if you would like more information.
* Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and asked to sign a consent form. You’ll get a copy of that as well.

**Important things that you need to know**

* We want to find out…[add brief details of research question]
* We are testing…[add brief details of the treatment, procedure or other intervention]
* This study has [add number] different groups or treatment options.
* Like all medicines used to treat [name of condition], the medicines used in this study can have unwanted side‑effects. The most common side‑effect of [add name of treatment, procedure or other intervention] is [add details]
* The study fits into your normal treatment, so there are no extra hospital visits. [OR] This study will require you to visit the hospital [insert number] more times than if you were being treated in the usual way for [add condition].

**Contents**

1. Why are we doing this study?
2. Why am I being asked to take part?
3. What do I need to know about [the medicines or procedures or other interventions] used in this study?
4. What will I need to do if I take part?
5. What are the possible side‑effects?
6. What are the possible benefits of taking part?
7. What are the possible disadvantages and risks of taking part?
8. More information about taking part
9. Contacts for further information

**How to contact us**

If you have any questions about this study, please talk to your doctor or nurse:

Name of doctor or nurse

Hospital Department

Hospital

Address

Address

Tel: 01234 XXX XXX

|  |  |
| --- | --- |
| 1 | **Why are we doing this study?** |

This study is for [insert name of condition].

## What is [name of condition]?

[Insert two or three sentences about the condition].

If you want to know more about [add name of condition], talk to the doctor or nurse who is treating you.

## How is [name of condition] usually treated?

## What are we trying to find out?

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| 2 | **Why am I being asked to take part?** |

You are being asked to take part in the [trial name] study because [explain what it is about the person that makes them eligible for the study].

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| --- | --- |
| 3 | What do I need to know about the [medicines/ procedures/ other] in this study? |

[Refer to guidance document for possible contents of this section.]

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| 4 | What will I need to do if I take part? |

## Can I definitely take part?

Not everyone may be able to take part in this study. We need to do some tests first to see whether you are able to take part.

## What if the tests show I can take part?

If these tests show you can take part and you agree to join the [name] study, we will ask you to sign a consent form.

There will be [add number] different [treatment/procedure/other] groups in this study. These are: [add list]

Everyone who takes part will be in one of these groups.

## Which group will I be in?

It is important that the groups receiving each [treatment/procedure/other] are as similar as possible at the start of the study. To ensure that this happens, a process called randomisation is used to allocate people to each group.

## What will happen to me during the study?

[Refer to guidance document for possible contents of this section.]

## What checks and tests will be done?

[Refer to guidance document for possible contents of this section.]

## Will I get back any travel costs?

 [There are two alternative suggestions about the best place for this section, which is why it appears twice. Refer to guidance document for more details, and ensure only one entry remains.]

|  |  |
| --- | --- |
| 5 | What are the possible side‑effects? |

## What are the most common side‑effects?

All [treatments/procedures/other] can have unwanted side‑effects. The most common side‑effects of this [treatment/procedure/ other] are:

If you become concerned about any side‑effects, please tell the study staff as soon as possible.

## Are there other side‑effects?

[Refer to guidance document for possible contents of this section.]

|  |  |
| --- | --- |
| 6 | **What are the possible benefits of taking part in this study?** |

We hope that you will be helped by having any of the [treatments/procedures/other] in this study, but this cannot be guaranteed.

The information we get from this study will help us to improve treatment for future patients with [name of condition].

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| 7 | What are the possible disadvantages and risks of taking part? |

[Refer to guidance document for possible contents of this section.]

|  |  |
| --- | --- |
| 8 | More information about taking part |

## Do I have to take part in the [insert name] study?

No, it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form.

If you decide not to take part in this study, you are likely to receive the standard treatment, which is [insert sentence about standard treatment]. A decision to not take part at any time will not affect the standard of care you receive.

## Will I get back any travel costs?

[There are two alternative suggestions about the best place for this section, which is why it appears twice. Refer to guidance document for more details, and ensure only one entry remains.]

## Can I stop taking part after I’ve joined the study?

You can stop taking part in all of this study, or in any part of it, at any time and without giving a reason. But you must talk to your study doctor or nurse first. They can advise you about any concerns you may have.

If you decide to stop taking your study treatment, we will need to continue collecting information about you. This is important, because it helps us to ensure that the results of the study are reliable.

If you stop taking part in this study, you are likely to receive the standard treatment. A decision to stop taking part at any time will not affect the standard of care you receive.

## **How will my personal information be used?** THIS SECTION IS MANDATORY FOR GDPR PURPOSES DO NOT REMOVE

USE THIS PARAGRAPH IF THE STUDY SPONSOR IS THE SOLE DATA CONTROLLER - *[Insert Sponsor name e.g. University College London (UCL)]* is the sponsor for this study, based in *[Insert location e.g. the United Kingdom.]* *[Insert Sponsor name e.g. University College London (UCL)]* will be using information from you and your medical records in order to undertake this study and will act as data controller for this study. *[Insert Sponsor name e.g. University College London (UCL)]* will be responsible for looking after your information and using it properly and will keep identifiable information about you for 25 years after the study has finished.

USE THIS PARAGRAPH IF UCL IS NOT THE STUDY SPONSOR BUT IS JOINT DATA CONTROLLER - *[Insert Sponsor name e.g. PENTA Foundation]* is the sponsor for this study, based in *[Insert location e.g. France.]* MRC Clinical Trials Unit at UCLwill be using information from you and your medical records in order to undertake this study and will act as join data controller for this study. *[Insert Sponsor name e.g. PENTA Foundation]* andMRC Clinical Trials Unit at UCLwill both be responsible for looking after your information and using it properly and will keep identifiable information about you for 25 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information at [**www.ctu.mrc.ac.uk/general/privacy-policy**](http://www.ctu.mrc.ac.uk/general/privacy-policy)

## How will your data be stored and collected? THIS SECTION IS MANDATORY FOR GDPR PURPOSES DO NOT REMOVE

Your hospital will collect information from you and your medical records for this research study in accordance with our instructions.

Your hospital will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. UCL will collect information about you for this research study from your hospital. This information will include health information, which is regarded as a special category of information. We will use this information to conduct our research. Individuals from *[Insert Sponsor name e.g. University College London (UCL)]* and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

USE THIS PARAGRAPH IF YOU PLAN TO COLLECT PERSONAL IDENTIFIERS - Your hospital will pass your *[Insert details of all personal identifiers which will be collected e.g. name, NHS number and Date of Birth]* to MRC Clinical Trials Unit at UCL along with the information collected from you and your medical records.

USE THIS PARAGRAPH IF YOU DO NOT PLAN TO COLLECT PERSONAL IDENTIFIERS - Your hospital will keep your name, NHS Number and contact details confidential and will not pass this information to MRC Clinical Trials Unit at UCL.

Where information could identify you, the information will be held securely with strict arrangements about who can access the information. The people who analyse the information will not identify you.

Your hospital will keep identifiable information about you from this study for at least 25 years after the study has finished.

REMOVE THIS PARAGRAPH IF YOU ARE NOT PLANNING ON USING ELECTRONIC HEALTH RECORDS TO FOLLOW UP PARTICIPANTS

*[Insert Sponsor name e.g. University College London (UCL)]* will collect information about you, for research, from your hospital site, *[Insert names of registries through which you plan to follow patients up e.g. NHS Digital, Public Health England (PHE,) and the National Cancer Registration and Analysis Service (NCRAS).* This information will include *[Insert details of the personal identifiers which will be collected to facilitate follow up through the registries e.g. name and NHS number]* and health information. We will use this information to track your long term health status.

## Future Research THIS SECTION IS MANDATORY FOR GDPR PURPOSES DO NOT REMOVE

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with relevant legislation, ethics and NHS research policy requirements.

We won't share information with others that can identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance. If there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

## What will happen to the results of the [insert name] study?

When the study is completed, we will publish a summary of the results on the website of the MRC CTU at UCL: <http://www.ctu.mrc.ac.uk/>.

We will also publish the results in a medical journal, so that other doctors can see them. You can ask your doctor for a copy of any publication. Your identity and any personal details will be kept confidential. No named information about you will be published in any report of this study.

## Who is organising and funding the study?

This study is organised by the [insert name of organisations] and the MRC CTU at UCL, which has run trials for many years. The study coordination, data collection and analysis and administration will be provided by the MRC CTU at UCL. You can find out more about us at [www.ctu.mrc.ac.uk/](http://www.ctu.mrc.ac.uk/).

Your doctor is not receiving any money or other payment for asking you to be part of the study.

[Name of sponsor] has overall responsibility for the conduct of the study. [We/they] are responsible for ensuring the study is carried out ethically and in the best interests of the study participants.

## Who has reviewed the [insert name] study?

The study has been reviewed by international scientists. It has been approved by [add organisations that have approved the study, e.g. NCRI].

It has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA), as well as by [insert name of NHS research ethics committee] and the hospital’s Research and Development Office.

## What if new information becomes available during the course of the study?

Sometimes during a study, new information becomes available about the [medicines/ treatments/procedures] that are being studied. If this happens, your doctor will tell you about it and discuss with you whether you want to continue the study. If you decide to stop taking part in the study, your doctor will arrange for your care to continue outside of the study.

Your doctor might also suggest that it is in your best interests to stop taking part in the study. Your doctor will explain the reasons and arrange for your care to continue outside the study.

## What happens if the [insert name] study stops early?

Very occasionally a study is stopped early. If it happens, the reasons will be explained to you and your doctor will arrange for your care to continue outside of the study.

## What if something goes wrong for me?

If you have any concerns about the way you have been approached or treated during the study, please talk to your study doctor or nurse. If you are still unhappy, or if you wish to complain, please use the normal NHS complaints process.

If you are harmed by taking part in the study, or if you are harmed because of someone’s negligence, then you may be able to take legal action.

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| 9 | **Contacts for further information** |

If you want further information about the [name] study, contact your study doctor or nurse (see below).

[Insert address and telephone number of study doctor and/or nurse]

More information is also available on our website [insert study website or address for study page on MRC CTU at UCL website].

Thank you for taking the time to consider taking part in this study.

**[Study name] protocol version [version number]**