PREPARATION AND CONTENT OF PARTICIPANT INFORMATION SHEETS AND CONSENT FORMS FOR ADULT RESEARCH PARTICIPANTS

POLICY STATEMENT/KEY OBJECTIVES:
This Standard Operating Procedure aims to provide guidance to researchers on the preparation and content of Patient Information Sheets and Consent Forms

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BACKGROUND

There are numerous ethical guidelines in use for consenting patients. These include numerous versions of the Declaration of Helsinki (1996), International Conference of Harmonisation (ICH) Good Clinical Practice (GCP) guidelines, General Medical Council recommendations (GMC 1998), Nursing and Midwifery Council guidance (NMC2002) and consumers for ethics in research reports (CERES 1994). However the general principles in all of these remain the same; that in order to gain consent a subject should: -

- Be given full Information (standard of disclosure)
- Have the ability to understand the information and make a decision (capacity)
- Not be acting under duress (voluntary)
- Be able to withdraw at any time (living document)

It is essential that research subjects have complete understanding of a study before providing their consent to take part. This operating procedure will outline the format that information sheets and consents should take to fulfil ethical and statutory guidelines (Data protection act 1998 and 2001/20/EU) on informed consent.

PURPOSE

This Standard Operating Procedure (SOP) aims to provide guidance to researchers on the preparation and content of Patient Information Sheets and Consent Forms. Information sheets are to be used to ensure potential subjects are provided with sufficient information on a research study to allow them to make an informed decision on whether to participate, or not in the proposed research.
PROCEDURE

WHO?

It is the responsibility of the Researcher to ensure that an adequate Patient information sheet (PIS) is provided to potential participants. It is important that the person seeking consent spends time going through written information and should not simply give it to the participant to read on his or her own and then return to ask questions. The Research Ethics Committee is responsible for providing independent review of patient information sheets and consent forms (CF). A research project must not commence without an approved PIS and CF. Researchers are expected to abide by the standards set out on the IRAS website:

http://www.nres.nhs.uk/applications/guidance/consent-guidance-and-forms/

HOW?

Potential participants to your research study must be given sufficient information to allow them to take an informed decision about potential risks of the study and what is involved for them. An Information Sheet should contain information under the headings given below. It should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs. A guide is available for download at the Integrated Research Application System (IRAS) website:

http://www.nres.nhs.uk/applications/guidance/consent-guidance-and-forms/

Consumers for Ethics in Research (CEREC) publish a leaflet entitled ‘Medical Research and You’. This leaflet gives more information about medical research and looks at some questions potential recruits may want to ask. This leaflet is available at http://www.whri.qmul.ac.uk.cardiology.research.patients/docs/ceres_medicalresearch.pdf

Headed paper

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Use headed paper of the hospital/institution where the research is being carried out. Un-headed paper is unacceptable. If you are a local researcher for an MREC approved study, the PIS should be printed on Trust paper with local contact names and telephone numbers before it is submitted as a site Specific application on the IRAS form.

See appendix one for an example of an information sheet and consent adapted from the IRAS guidance. In most studies all sections will be necessary in this format.

OTHER RELATED PROCEDURES, POLICIES, LEGISLATION OR GUIDANCE

SOP 03 Preparation and Content of Participant Information Sheets and Consent Forms for Child Research Participants

SOP 02 Preparation and Content of Participant Information Sheets and Consent Forms for Vulnerable Adult Research Participants

SOP 06 Informed Consent Procedures for Researchers

GLOSSARY

International Conference of Harmonisation (ICH)

Good Clinical Practice (GCP)

Consumers for Ethics in Research (CEREC)

Integrated Research Application System (IRAS)

APPENDICES

Appendix A: Sample Patient Information Sheet

Appendix B: Sample Consent Form
Appendix A: Sample Patient Information Sheet

Header: Patient Information Sheet

**HEADED PAPER**

Version:

Date:

Project ID:

**Study title**- Is the title self-explanatory to a lay person? If not, a simplified title should be included. The title of the project should be clearly stated at the beginning of the sheet.

**Invitation paragraph**- This paragraph is an invitation to ask the potential participant to consider the study and then decide whether to take part. The following is a suitable example:

‘You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you may have. We suggest this would take approximately XX minutes. Please discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. This is your copy of this information sheet to keep for future reference.

Thank you for reading this.”

**What is the purpose of the study?**- Why are you conducting this study? This should include background information and the duration of follow-up. This should be presented clearly and succinctly.
Why have I been invited? - You should explain why and how the patient was chosen or recruited and how many other patients will be in the study.

Do I have to take part? - You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:

'It is up to you to decide whether or not to take part. If you do decide to take part you we will describe the study and go through this information sheet with you. If you agree to take part we will ask you to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.'

What will happen to me if I take part? - Type of information required, if appropriate:

- How long the participant will be involved in the research
- How long the research will last (if this is different)
- If and how often they will need to meet a researcher, visit a clinic or see their GP
- How long these visits will be
- What exactly will happen, e.g. access to personal information/samples, questionnaire, interview, discussion group, measurement, sample collection, blood tests, x-rays, (over and above those involved in standard diagnosis and treatment), etc.

Use the most appropriate format (tables, diagrams, photos etc.) The detail required will depend on the complexity of the study. It may help if the information is displayed in a simple flowchart or grid indicating what will happen at each visit rather than lengthy lists in the text. Long-term monitoring/follow-up should be mentioned. You should inform the participant if your study will involve video/audio-taping or photography. Specific consent will be needed if published material identifies the subject.
Expenses and payments? - Are there any expenses and payments available? (i.e. travel, meals, child-care, compensation for loss of earnings etc.), You should consider whether any vouchers or gifts which you are intending to give as a thank you for participation should be detailed in the information sheet.

What will I have to do? - Briefly describe what you will expect from the research subject.

For medical studies you should include a short description of the drug, device or procedure and give the stage of development. Explain (if appropriate) that the participants should take the study medication regularly as directed and whether they can continue to take their regular medication or other prescribed or over-the-counter drugs. It should also be explained that they will need to consider whether they should participate if they are in other drug studies, or have been in the recent past (specify how long). Explain other essential study requirements, e.g. attendance at all scheduled visits, keeping diaries, filling questionnaires, etc. Any lifestyle, medical health product or dietary restrictions should be stated.

What are the possible disadvantages and risks of taking part? Risk of the disease/condition/illness and the risk of research should be carefully separated. Any risks, discomfort or inconvenience should be outlined. However, explanation of risk is difficult and researchers should consider carefully how to explain any risk in their study. The published literature should be consulted and material presented to likely participant groups to assess its value.

In designing the information sheet you should consider insurance issues and whether patients should be informed that their participation may affect insurance cover. If it is a possibility, the potential participant should be told what would happen if other conditions were discovered of which he or she was unaware.

What are the side effects of any treatment received when taking part? For any drug or procedure you should explain the possible side effects. For any new
drug it should be explained that there might be unknown side effects. International Conference on Harmonisation Good Clinical Practice (ICH GCP) requires participants to be told about “reasonably foreseeable risks”.

Side effects should be listed in terms the participant will clearly understand (e.g. “damage to the heart” rather than “cardiotoxicity”; “abnormalities of liver tests” rather than “raised liver enzymes”).

The information should be prioritised in terms of seriousness, severity and frequency, with a simple example of frequency, which a participant would understand. It should reflect what a reasonable person would expect to be mentioned (i.e. rare side effects are relevant if they may be serious or permanent). The level of detail should also be influenced by the expected benefit from the treatment and the underlying prognosis of the condition.

For a very new or very potent investigational drug, a fuller list of suspected side-effects may be appropriate. Adverse events that have been noted with an equal rate in active and control groups and that are most likely due to the underlying condition should not usually be listed as likely side effects.

If participants suffer these or any other symptoms they should be given clear guidance on when, how and to whom to report them. Contact numbers should be given clearly and boldly.

**Harm to an unborn child**

For Women

A clear warning must be given in studies where there could be harm to an unborn child or there was risk in breast-feeding. The information should include the need for pregnancy testing, contraceptive requirements, and reporting of a pregnancy during the trial. If any pregnancy were to be monitored, this needs to be made clear, particularly if the mother’s notes or child’s notes are going to be accessed. If the baby will be followed up or examined post-natally, this should also be explained.
For Men

There should also be an appropriate warning and advice for men if the treatment could damage sperm and consequently the foetus. Information concerning the importance of careful contraception and what to do if their partner becomes pregnant is essential. Specific advice for pregnant partners may be needed, including information on any compensation arrangements.

*What are the possible benefits of taking part?* Explain these, but where there is no intended clinical benefit, this should be stated clearly. It is important not to exaggerate the possible benefits

*Studies on tissue*

Research subjects should be told that the samples are being donated as a gift and that the samples may be retained for future research. Any new research will be reviewed by a research ethics committee but consent for future studies may only be required if the committee considers that the study is likely to substantially effect the subjects interests.

*Gene Studies*

The groups of genes to be studied need to be specified. A description of how these genes relate to the project is also required.

Insurance and mortgage issues. The participants must be given a properly phrased covering letter such as:

*“Some insurance companies ask whether you have had gene studies to see if you suffer from hereditary disease. In your case the reply should be: ‘I am part of a (normal) population studied by ............department of ........ in which gene studies form part of research on normal people. No abnormality or risk has been reported to me as a result of these studies.’”*

Consent must be given to store samples or you must state that samples will be destroyed at the end of the project.

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State whether there is any link between DNA and the subject’s name/notes.

Consent must be requested before any other genes are studied.

**What happens when the research study stops?**- The arrangements after a therapeutic trial must be given, particularly if this differs from that normally expected for their medical condition. It must be clear whether the participant will have continued access to any benefits or intervention they may have obtained during the research. If the treatment will not be available after the research finishes, this should be explained to the participant with information on what treatment will be available instead.

You should consider whether and when it may be possible to tell participants which arm of the study they were in.

**What if there is a problem?**- You should inform patients how complaints will be handled and what redress may be available. This must be applicable, as appropriate, to NHS and private settings for the research.

Complaints - A contact number should be given. This may be the researcher, who can try to solve the problem in the first instance. However, a participant may not wish to complain to the researcher if he/she is the object of the complaint, and may wish to make a more formal complaint.

**Will my taking part in this study be kept confidential?**- You should tell the participant how their confidentiality will be safeguarded during and after the study. You may wish to tell the participants how your procedures for handling, processing, storage and destruction of their data match the Caldecott principles and/or appropriate legislation.

The participant should be told: how their data will be collected; that it will be stored securely, giving the custodian and level of identifiably (e.g. coded, anonymous, etc.); what it will be used for. It must be clear if the data is to be retained for use in future studies and whether further REC approval will be sought; who will have access to view identifiable data (authorised persons such as researchers, sponsors, regulatory authorities & R&D audit (for monitoring of the quality of the
research) etc (not normally RECs in the UK); how long it will be retained and that it will be disposed of securely.

Involvement of the General Practitioner/Family doctor (GP)
You should explain if the participant’s GP (or other health care practitioner) needs to be notified of their participation, and seek consent for this. You should explain what information will be exchanged. There may be circumstances in which informing the GP may not be necessary, acceptable or possible

What will happen to any samples I give? It should be clear to the participant, in the description of study procedures whether:

- new samples will be taken (e.g. blood, tissue, specifically for this study)
- samples excess to a clinical procedure will be asked for
- access to existing stored samples will be asked for.

The same type of information, as for data, is needed. This should include:

- the secure procedures for collecting
- using and storing samples
- 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 REC approval will be sought
- who will have access
- the level of identifiability (for this study and for storage for future studies); provision for destruction
- procedures for possible feedback of individually significant information from their use
- whether samples will be transferred outside the UK.
If there is any possibility that samples may be used in future research, we strongly advise prospective consent is obtained.

Will any genetic tests be done (Annex 21)? A separate consent form for genetic studies should be used to allow participants to take part in the main study alone without joining a genetic sub-study, unless this is a necessary condition of trial entry.

What will happen to the results of the research study? - You should be able to tell the patients what will happen to the results of the research. When are the results likely to be published? Where can they obtain a copy of the published results? Will they be told which arm of the study they were in? You might add that they will not be identified in any report/publication.

Who is organising and funding the research? - The answer should include the organisation or company sponsoring or funding the research (e.g. Medical Research Council, Pharmaceutical company, charity, academic institution). The patient should be told whether the doctor conducting the research is being paid for including and looking after the patient in the study. This means payment other than that to cover necessary expenses such as laboratory tests arranged locally by the researcher, or the costs of a research nurse. You could say:

‘The sponsors of this study will pay (name of hospital department or research fund) for including you in this study’

or

‘Your doctor will be paid for including you in this study.’

Who has reviewed the study? - You should give the name of the Research Ethics Committee(s) which reviewed the study (you do not, however, have to list the members of the Committee).
**Contact for further information** - You should give the patient a contact point for further information. This can be your name or that of another doctor/nurse involved in the study.

The patient information sheet should be dated and given version number.

The Patient Information Sheet should state *that the patient will be given a copy of the information sheet and a signed consent form to keep.*
Appendix B: Sample Consent Form

The Consent Form

The example of the consent form given below will be suitable for many studies but may need alterations to be commensurate with your study; sections 3 and 4 may not be relevant to some. The participant is consenting to everything described in the text of the information sheet.

For some studies a fuller, itemised or hierarchical consent form may be needed to cover important issues, especially if additional elements are optional for the participant. These may include: additional invasive tests or samples required for study purposes only; consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs; transfer of data/samples to countries with less data protection; agreement to receive individual feedback from testing.

The signatories to the consent should be those who are involved in the consent process, e.g. the participant, the researcher or a representative of the researcher delegated to take consent.

An independent witness is not routinely required except in the case of consent by a participant who may be blind, illiterate etc.
CONSENT FORM

Title of Project: [PROJECT TITLE]

Name of Researcher: [NAME OF CHIEF INVESTIGATOR]

1. I confirm that I have read and understand the information sheet dated [DATE] (version [VERSION NUMBER]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [COMPANY NAME], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my GP being informed of my participation in the study.

5. I agree to take part in the above study.

Name of Participant   Date    Signature
Name of Person   Date    Signature

Taking consent.

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.

Consent form date of issue: [DATE]
Consent form version number: [VERSION]