

GUIDELINES FOR RESEARCHERS

INFORMATION SHEETS & CONSENT FORMS

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Background and Preface

COREC established and funded two working parties to provide such guidelines for applicants to Research Ethics Committees. One, in 2002, chaired by Dr Carol Barton, former Chair of Thames Valley MREC, was asked to draw up recommendations for applicants when considering how to provide information for children entering research projects. The other, in 2003, co-chaired by Dr Sandra Evans, Chair of Eastern MREC, and Dr Gordon Taylor, Vice-Chair of MREC for Wales, was asked to update the general guidance for patient information sheets.

It would be illogical to present these two reports separately and this work is a synthesis of the two working parties reports. As such I have had to make some changes to their final reports to achieve my goals of consistency, logic and brevity (so applicants will not be daunted by length). I have also made changes to bring these reports up to date.

COREC is grateful for the time and effort the chairs and members put into their report, and where I have changed the text, I have made every effort to retain what I have understood to be the spirit of the reports.

Dr Hugh Davies
Ethics and Training Adviser
COREC, NPSA

This guidance will be posted on the COREC website and subject to a period for comment and revision. Please send comments to infosheets@corec.org.uk. We propose holding 3 meetings to allow comment from REC members and researchers. The date and venues of these will be announced later. Once the comments are collected, these documents will be revised and updated for the COREC website.

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General comments applicable to information sheets for adults

This revised guidance is based on the requirements of the ICH Good Clinical Practice guidelines, the European Clinical Trials Directive 2001/20/EC and the UK Medicines for Human Use (Clinical Trials) Regulation 2004. This should also be read in conjunction with COREC guidance on informed consent in clinical trials.

These guidelines give guidance for all research, but the content may not, of course, be relevant to some studies and should be omitted. **The level of detail should be appropriate to the nature of the study and the population to be studied.**

There is concern that Information Sheets (IS) are becoming increasingly lengthy and complex for recruitment purposes. It is therefore recommended that, where appropriate, the IS is divided into Part 1 and Part 2.

- Part 1 should provide the potential participant with brief and clear information on the essential elements of the specific study: what the research is about, the condition or treatment under study, the voluntary nature of involvement, what will happen to the participant during and after the trial, what usual treatment may be withheld, the participant's responsibilities, the potential risks, inconvenience or restrictions balanced against the potential benefits (if any), and the alternative(s). This should allow the participant to make an initial choice of whether the study is of interest to them and they wish to read and discuss further.
- Part 2 should contain additional information on factors such as confidentiality and data protection, communication with the GP, indemnity and compensation, publication, etc., which should, of course, be read and understood before the participant can decide whether they want to take part and give informed consent.

Information Sheets should be written in simple, non-technical terms and be easily understood by a lay person. Use short words, sentences and paragraphs with clear subheadings to make the text manageable, and a font size for easy reading. As a guide, the language level used should be no more difficult than that used in the information leaflets of medicines for the general public or in tabloid newspapers. Large sections of unbroken text should be avoided, and bullet pointed lists used where appropriate.

The tone should be invitational and not coercive or overly persuasive. It is good practice to try out the information sheet on representatives of the group likely to be recruited and where possible to involve representatives in the writing of the information sheet.

For the first page, use headed paper of the (hospital/institution) where the research is being carried out. Information Sheets submitted to a REC may be headed simply 'Hospital/Institution/GP Practice headed paper'. If you are a local researcher for a REC approved study, the Information Sheet should be printed on local hospital/surgery paper (trial site) and must include the relevant local contact names and telephone numbers before it is used.

All consent forms and IS should be version dated in the header/footer to ensure the most recent is used, and pages numbered e.g. p2 of 5.

There may be some issues where local requirements need to be included, e.g. radiation doses, alternative treatments, and the Chief Investigator should make this clear in the submission to the main Research Ethics Committee (REC) giving the single opinion.

If there are any general information or advice documents from other sources, e.g. CERES, patient groups, etc, that you feel are relevant to your study, you may wish to recommend or provide these for potential participants for additional background reading.

General comments on information for children (minors) and young people

This section outlines the important differences to be considered when designing information for children.

It is recommended that information sheets are produced for the following age ranges, which broadly reflect cognitive stages of development.

- Children 5 years and under
- Children 6-12 years
- Children 13-15 years

and parents / guardians

When designing information sheets for children, researchers need to consider their

- likely attention span
- potential fear of hospitals/procedures
- mental capacity if affected by disease
- disease severity
- previous experience of illness (some children have greater knowledge as the result of long term illness e.g cystic fibrosis).

Ideally therefore such material should be shorter than that designed for adults.

It is good practice and will help to show your information sheets to a group of similar aged children to the study, for comment before you submit the formal version to the REC.

As with adults, information sheets should accompany verbal explanations.

It is important to give guidelines in your information about how the study will affect the child at home, school and his/her social activities.

Consent

Arrangements will vary according to the type of study proposed, according to ethical considerations and applicable law.

(i) Studies governed by the European Union Clinical Trials Directive 2001/20/EC

- Written consent must be given by parents or those with legal responsibility for the child, but children should **also** give their assent (the voluntary permission given by one who is old enough to understand and know if they want to take part or not).
- Where the parent is competent to decide for their child but unable to read or write, an impartial witness could sign the consent form to say that the information sheet has been read to the parent and verbal consent has been given.

(ii) Studies **NOT** governed by the European Union Clinical Trials Directive 2001/20/EC

- UK law is untested with regard to the legal age of consent to take part *in research* (as opposed to treatment) and it is therefore possible to apply the principle of "Fraser" (formerly known as "Gillick") competence for research in the UK. This can be summarised: Children who are felt to be competent to understand the research proposal and thus make decisions can give consent on their own behalf.

Guidance for design of information sheets for competent adults

Part 1.

1. Study title

It is recommended that the document be headed 'Patient Information Sheet', or 'Participant Information Sheet' where the participants are not patients.

One consistent title for the study should appear on all the documents and should be self-explanatory to a layperson. The simplified title, given on the REC application form after the full title, is usually the most suitable. An appropriate protocol reference should appear on the IS and Consent Form, with the version number, and date to permit cross-reference. If acronyms are used in the title they must be spelled out in full the first time they appear. The title should not consist of an acronym alone.

2. Invitation paragraph

This should explain that the participant is being asked to take part in a research study. The following is an 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. Please take time to read the following information carefully. Talk to others about the study if you wish.'

- *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
- *Part 2 gives you more detailed information about the conduct of the study.*

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.

3. What is the purpose of the study?

The background and aim of the study should be given here. The purpose should be brief but informative and should not mislead.

It should be made clear if the study is a student research project.

4. Why have I been chosen?

You should explain briefly why and how (particularly if the approach is not directly by the care clinician) the participant was chosen and how many other participants will be studied.

5. Do I have to take part?

You should explain that taking part in the research is entirely voluntary. The following is an example:

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

If further explanation is needed of other possible implications of withdrawal, this should be given in Part 2.

6. What will happen to me if I take part?

The potential participants should know exactly what will happen to them during the research study. The detail required will depend on the complexity of the study

This should include:

- how long the participant will be involved in the research,
- how long the research will last (if this is different),
- how often they will need to visit a clinic or their GP surgery (if this is appropriate)
- how long these visits will be.
- what exactly will happen e.g. blood tests, x-rays, interviews etc.

It should be clear which procedures are experimental. It should also be stated which procedures are over and above those involved in standard diagnosis and treatment.

It is very helpful to collect the information into a simple flowchart or grid indicating what will happen at each visit rather than lengthy lists in the text.

All invasive procedures must be explained; in some cases a standard hospital leaflet on the procedure could be included. It is also essential to explain whether any normal treatment will be withheld for all or part of the study.

Long-term monitoring/follow-up should be mentioned.

You should set out simply the research methods you intend to use - the following simple definitions may help:

Randomised Trial:

Sometimes we don't know which way of treating patients is best. To find out, we need to make comparisons between the different treatments. We put people into groups and give each group a different treatment; the results are compared to see if one is better. To try to make sure the groups are the same to start with, each patient is put into a group by chance (randomly). The results are then compared.

You should tell the patients what chance they have of getting the study drug/treatment e.g. a one in four chance.

Blind trial:

In a "blind trial" you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor your doctor will know in which treatment group you are (although, if your doctor needs to find out he/she can do so).

Cross-over trial:

In a cross-over trial the groups each have the different treatments in turn. There may be a break between treatments so that the first drugs are cleared from your body before you start the new treatment.

Placebo:

A placebo is a "dummy treatment", which looks like the genuine medicine but contains no active ingredient.

If the study will involve video-/ audio-taping or photography, you should explain what is intended, including the confidentiality issues. Specific consent will be needed for this and for any use of verbatim quotation in publications if they identify the subject.

Expenses and payments:

You should explain if the participant will need to make study visits more often than for his/her usual treatment and specify if expenses (e.g. travel, meals, child-care, compensation for loss of earnings, etc.) are available.

You should consider whether any vouchers, gifts, etc, which you are intending to give as a 'thank-you' for participation, should be detailed in the information sheet.

The arrangements for any other payment, e.g. for Phase I volunteers, should be given, including, if necessary, an explanation of how payments may be influenced by the duration of involvement in a study or factors such as the completeness of diaries.

7. What do I have to do?

(a) What are the participants' responsibilities? Set down briefly and clearly what you expect of them.

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 should not normally be involved in any other drug studies currently 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.

(b) Any lifestyle, medical health product or dietary restrictions should be stated.

8. What is the drug, device or procedure that is being tested?

You should include a short description of the drug, device or procedure and give the stage of development. You should, when appropriate, state the dosage of the drug and method of administration.

Details are needed of any contraindicated drugs, including over the counter drugs. Appropriate arrangements to inform clinics or doctors supervising their treatment must be explained.

9. What are the alternatives for diagnosis or treatment?

For therapeutic research the participant should be told what other managements are available, with the important comparative risks and benefits. It should not just be stated that 'your doctor will tell you what alternatives are available'. Standard hospital/GP leaflets on alternative treatments may be useful to the participant.

For a multi-site study, the Chief Investigator should check on local variations in alternative treatments, which may need to be reflected in the information given to the main REC for approval. Relevant information can then be drawn to the attention of participants at each trial site.

10. What are the side effects of any treatment received when taking part?

For any new drug or procedure you should explain the possible side effects. For any relatively new drug it should be explained that there might be unknown side effects.

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').

Good Clinical Practice (GCP) requires participants to be told about 'reasonably foreseeable risks'

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 extent of 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 – the rarer side effects could be listed in an Appendix to Part 2 of the main information sheet.

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 under section 16.

11. What are the other possible disadvantages and risks of taking part?

Any other risks, discomfort or inconvenience should be briefly outlined.

If future life insurance status could be affected by taking part, this should be stated. Similarly, if the participants have private medical insurance you should ask them to check with the company, before agreeing to take part in the trial, whether participation is considered a 'material fact' that should be reported. They will need to do this to ensure that their participation will not affect their medical insurance.

If it were likely, the potential participant should be told what would happen if other conditions were discovered of which the participant was unaware.

A separate section on possible implications of genetic research is given in Appendix 2.

Ionising Radiation (Medical Exposure) Regulations - IRMER:

If the use of additional ionising radiation is required as part of the research study, then information must be given to the participant on the additional amount of radiation involved, in everyday terms that they can understand. Since treatments may differ at individual sites in a multi-site study, expert local advice must be sought for each site. The Chief Investigator should check on local variations so that the range can be reflected in the information given to the main REC for approval. Relevant information can then be drawn to the attention of participants at each trial site.

Harm to the unborn child

For women:

A clear warning must be given in studies where there could be harm to an unborn child if the female participant were pregnant or became pregnant during the study, or there was risk in breast-feeding a baby. The information should include the need for pregnancy testing, contraceptive requirements, and reporting of a pregnancy during the trial. If any pregnancy will be followed, 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 consented to.

Complete this section carefully. In certain circumstances (e.g. terminal illness, elderly population) its use would be inappropriate.

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.

Examples of possible wording are given in Appendix 1.

12. What are the possible benefits of taking part?

Where there is no intended clinical benefit to the participant from taking part in the trial, this should be stated clearly.

It is important not to exaggerate the possible benefits. This could be seen as misleading. It would be reasonable to say something similar to:

'We cannot promise the study will help you but the information we get might help improve the treatment of people with (name of condition).'

Note on Sections 10,11 and 12:

Separation of risks, benefits and purpose of the study may sometimes lead to a loss of clarity about the balance of risk and benefit. In such cases, the risk and benefit information should be sensibly linked.

13. What happens when the research study stops?

The arrangements after the 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.

14 What if there is a problem?

A short statement could be given here, e.g.

'Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed'. The detailed information on this is given in Part 2.'

A contact number for complaints should be given.

15. Will my taking part in the study be kept confidential?

A short general statement can be given here, e.g.

'Yes. All the information about your participation in this study will be kept confidential. The details are included in Part 2.'

16. Contact Details:

You should give the participant a contact point for further information about the study. This can be your name or that of another doctor/nurse involved in the study.

You should also give the contact number for any concerns during the study, if this is different.

For some studies an emergency contact number (which will be manned out-of-hours), if different, should be given and clearly displayed.

In a multi-site trial, the numbers must be appropriate for each site.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

17 What if relevant new information becomes available?

If such information becomes available during the course of the research you will need to tell the participant about this. The following is an example:-

'Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss whether you want to or should continue in the study. If you decide not to carry on, your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form.'

Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, you will be told why and your continuing care will be arranged.'

18. What will happen if I don't want to carry on with the study?

If the participant can withdraw from the study at any time and their data/samples can be destroyed immediately this can be stated in Part 1

In a clinical trial, the participant may wish to withdraw entirely or may wish to withdraw from treatment but be willing to continue to be followed up. If there are any restrictions on withdrawal, e.g. a single intervention will take place but they may withdraw from any further data collection, this should be made clear. If continuing follow-up is genuinely in the participant's own interests, or an 'exit' check up will be needed, then this should be stated. The participant, however, retains the right to decide if data from this visit can be used.

The position on retention/destruction of data/samples on withdrawal must be made clear. In a clinical trial it is usually important to retain data already collected, and may be important to collect further outcome data on the 'intention to treat' basis.

It is important to make your intentions clear to the participant, and ask for the relevant consent e.g.

'If you withdraw from the study, we will destroy all your identifiable samples, but we will need to use the data collected up to your withdrawal.'

Or

'You can withdraw from treatment but keep in contact with us to let us know your progress. Information collected may still be used. Any stored blood or tissue samples that can still be identified as yours will be destroyed if you wish.'

If the participant's data is going to be tracked through the NHS Central Register (NHSCR), this also needs to be stated, and consent obtained.

19. 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.

You will need to distinguish between complaints from patients about their treatment by members of staff (doctors, nurses etc.) and something serious happening during or following their participation in the trial i.e. a reportable serious adverse event. There should be a procedure for both.

Complaints:

A suitable contact number should be given which can genuinely assist the participant. 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.

'If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (Contact number). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure (or Private Institution). Details can be obtained from the hospital.'

Harm:

Appropriate redress and/or compensation should be available and details of insurance/indemnity schemes should be given.

NHS bodies are liable for clinical negligence and other negligent harm to individuals covered by their duty of care. NHS Institutions employing researchers are liable for negligent harm caused by the design of studies they initiate. The provision of such indemnity for negligent harm should be stated to the participant.

e.g. 'In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against (name of Sponsor Organisation, NHS Trust, Private Clinic) but you may have to pay your legal costs.. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).'

This will apply to most studies where there are no Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements. Even if the study appears to carry no significant risk of physical or psychological harm, any research where participant data is involved carries the risk of negligent harm by breach of confidence.

NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They are able to consider an ex-gratia payment in the case of a claim. The REC, however, is required to consider in each trial whether it is acceptable to seek consent without no-fault compensation, given the risks. If a study (as considered by the approving REC) carries a significant risk of non-negligent harm from study procedures required by the protocol, then the Chief/Principal investigators should obtain agreement from their employers for statements on how this might be handled and a suitable wording to be included in the IS.

For a Pharmaceutical-sponsored trial, where there are ABPI or other no-fault compensation arrangements, the following (or similar) should be included:

“We will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).

We will pay compensation where the injury probably resulted from:-

- *A drug being tested or administered as part of the trial protocol*
- *Any test or procedure you received as part of the trial*

Any payment would be without legal commitment. (please ask if you wish more information on this)

We would not be bound by these guidelines to pay compensation where

- *The injury resulted from a drug or procedure outside the trial protocol*
- *The protocol was not followed*

It is expected that ABPI guidelines require cover for all study procedures carried out in accordance with the protocol, e.g. to include placebo arms, wash-out periods , etc.

Universities and other public bodies employing researchers have vicarious liability for their actions, and are expected to insure against risk of claims against the University and its staff relating to clinical trials they design and undertake in their University employment. They may have clinical trials insurance that covers both negligence and no-fault compensation; this would normally exclude clinical negligence for which NHS bodies are liable. Appropriate statements should be included in the IS as required by the approving REC.

20. Will my taking part in this study be kept confidential?

The participant must be told in simple terms how their confidentiality is being safeguarded during and after the study. You will need to obtain the patient's permission to allow access to their medical records and to the information collected about them in the course of the study.

You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting, handling, storing, using or destroying data, you are not contravening the legal or regulatory requirements in any part of the UK. This is not the responsibility of the REC.

You may wish to tell the participants that your procedures for handling, processing, storage and destruction of their data are compliant with the Data Protection Act 1998.

The participant should be told in simple terms

- how their data will be collected
- that it will be stored securely, giving the custodian and level of identifiability (e.g. coded, anonymous, etc – (the definitions given in the MRC guidelines are suitable)
- 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.

A suggested form of words that you may wish to include for drug company sponsored research is:

‘If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the company sponsoring and/or the company organising the research. They may also be looked at by people from the company, by representatives of regulatory authorities and by authorised people from (the Trust, other NHS bodies) to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.’

or for other research:-

'All information which is collected about you during the course of the research will be kept strictly confidential. If applicable: Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.'

Researchers need to ensure that confidentiality promises such as these do not prevent them from disclosing identifiable data to external organisations who need this information to help you keep track of individuals or their health outcomes. For example, researchers intending to trace or flag individuals on the National Health Service Care Register (NHSCR) in order to be informed of cancer registrations or the cause of death (for those who die) must send named identifiable information to the register. In such cases the participant information sheet should explain that names / identifiable information will be sent to the NHSCR for the purposes of follow up. Patient consent forms should include a phone number and email address. Researchers wishing to obtain data from the NHSCR should also discuss their requirements with the Office of National Statistics (ONS) before finalising research protocols, participant information sheets and consent forms (email medres.lon@ons.gsi.gov.uk).

Participants have the right to check the accuracy of data held about them and correct any errors.

Participants should be informed, and consent to, any transfer of their data to countries having a lower standard of Data Protection than the UK.

The following or similar words could be used:

'Data collected during the study may be transferred for the purpose of (processing, analysis, etc) to associated researchers within/outside the European Economic Area. Some countries outside Europe may not have laws which protect your privacy to the same extent as the Data Protection Act in the UK or European Law. The company will take all reasonable steps to protect your privacy.'

Involvement of the General Practitioner/Family doctor (GP)

You should explain that for studies not being conducted by a GP, the participant's own GP may be notified of their participation in the trial, with the participants consent. This should include other medical practitioners not involved in the research who may be treating the patient. There may be special circumstances in which informing the GP may not be acceptable, possible or may inhibit recruitment.

The participant should be told if significant information is to be exchanged with the GP, e.g. if the GP is asked for additional medical details or given feedback on study findings, and should consent to this.

It is important where the researcher is neither the participant's own GP nor care clinician, that he/she is referred to in the IS as the 'research doctor' to avoid confusion with own GP/ care clinician.

21. What will happen to any samples I give?

It should be clear to the participant, in the description of study procedures (Section 6), whether

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

A commonly accepted concept, the “sample as a ‘Gift’” has been proposed by the MRC. If this is how researchers wish to see collection of samples, it will need to be explained to the subject. Any commercial significance or development should be included.

22. Will any genetic tests be done?

Guidance is given in Appendix 2.

The MRC recommends a separate study sheet and consent form for genetic studies with information on possible individual implications, feedback, counselling etc.

23. 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, whether it is intended to publish the results and how the results will be made available to participants. You should add that they will not be identified in any report/publication unless they have consented to release such information.

24. Who is organising and funding the research?

The answer should include the organisation or company sponsoring the research and that funding the research if these are different (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. The following is an example:

‘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.’

25. Who has reviewed the study?

You should give the name of the Research Ethics Committee which reviewed the study (you do not however have to list the members of the Committee, or contact number).
e.g. This study was given a favourable ethical opinion for conduct in the NHS (or private sector) by the xxxx REC.

The Information sheet should be dated and given a version number (referring to a protocol number if necessary).

The Information Sheet should state that the patient will be given a copy of the information sheet and a signed consent form to keep.

You may wish to thank your participant for considering taking part or taking time to read this sheet.

The Consent Form

The example of the Consent Form given below is the minimum requirement, which will be suitable for many studies but may need alterations to be commensurate with the study. The participant is consenting to everything described in the text of the IS.

For some studies a fuller itemised consent form may be needed to cover other important issues, especially if additional elements are optional for the participant. These may include:

- i) additional invasive tests or samples required for study purposes only
 - ii) consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs
 - iii) transfer of data/samples to countries outside the EEA (the EU Guidance notes include consent to archive coded information and its transmission outside the Community if applicable)
 - iv) agreement to receive individual feedback from testing
- etc.

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.

If the consent form is to be signed at home and returned by mail to the researcher, 2 copies must be provided, both to be returned and countersigned by the researcher, and one copy posted back to the participant.

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

(Form to be on headed paper)

Centre Number::
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated
(version) 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 any of my medical notes and data collected during the study, may be looked at by responsible 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 Patient

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Information sheets for children aged 13 to 15

This should be read alongside the “General comments on information sheets for minors (children)”

Part 1 – to give you first thoughts about the project

Study title

Is the title self explanatory to a young person? If not, give a short title that is easily understood.

Invitation paragraph

This should explain briefly what research is and that the young person is being asked to take part in a research study. The following is a suitable example:

- *We are asking if you would agree to take part in a research project to find the answer to the question....(insert your research question).*
- *Before you decide if you want to join in it's important to understand why the research is being done and what it will involve for you. So please read this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to.*

Thank you for reading this.'

Why are we doing this research?

The background and aim of the study should be given briefly here.

What is the medicine, device or procedure that is being tested?

You should include a short description of the medicine or device. You should also state the dosage of the medicine and method of administration.

Why have I been asked to take part?

You should explain

- If the research is on a specific disease this should be explained so they understand why they have been chosen.
- how the young person was chosen
- how many other children will be studied in this project.
- how many children have previously been studied for this medicine/device

e.g. “You have been chosen because you have asthma,... 3000 young people have already helped test this medicine and this project will involve a further 5000 from seven countries.”

Do I have to take part?

You should explain that taking part in the research is entirely voluntary. You could use the following paragraph:-

'No! It is up to you. If you do,

- *your doctor will ask you to sign a form giving your consent or assent.*
- *will be given a copy of this information sheet and your signed form to keep*
- ***you are free to stop taking part at any time during the research without giving a reason. If you decide to stop, this will not affect the care you receive.***

What will happen to me if I take part?

You should say how long the young person will be involved in the research, how long the research will last (if this is different), how often they will need to visit a clinic (if this is appropriate) and how long these visits will be. You should explain if they will need to visit the GP (or clinic) more often than for his/her usual treatment and if travel expenses are available. Explain exactly what will happen e.g. blood tests, x-rays, (over and above those involved in standard diagnosis and treatment), interviews etc. Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the parent's and child's responsibilities? Set down clearly what you expect of them.

You should set out simply the research methods you intend to use - some simple definitions in the glossary may help.

What will I be asked to do?

- Explain clearly all study related procedures and schedules.
- It should be made clear what their responsibilities are during the trial, especially if they have to do anything at home e.g. diary cards,
- Explain (if appropriate) that medicine must be taken regularly, if there are there any lifestyle or dietary restrictions and if they can take their usual medicines.
- Explain also any consequences that might affect schooling.

What other medicines could I have instead?

For therapeutic research the young person should be told in easy language what other treatments are available.

What are the side effects of the medicines and might I have some if I take part in the research?

For any new drug or procedure you should explain the possible side effects and what would be the appropriate action to take. You should give them a contact name and number if they or their parents become concerned and a name and number to contact in the event of an emergency (if that is different). Contact details should be updated if they change.

The known side effects should be listed in terms that are understandable (eg 'damage to the heart' rather than 'cardiotoxicity', 'changes in tests showing how the liver works' rather than 'raised liver enzymes'). For any new drug it should be explained that there may be unknown side effects.

Is there anything else to be worried about if I take part?

- Issues such as pregnancy testing are covered in **APPENDIX 1**
- If the use of additional ionising radiation is required as part of the research study, then information must be given to the young person on the additional amount of radiation involved, in everyday terms that they can understand.
- Will the child be having a general anaesthetic as part of the research?
- Will there be any invasive procedures and how are you going to manage these?

What are the possible benefits of taking part?

Where there is no intended clinical benefit, this should be stated clearly. If there are benefits these can be stated but should not be coercive.

'We cannot promise the study will help you but the information we get might help treat young people with (name of condition) with better medicines in the future'.

Contact Details:

You should give the young person and parents or responsible adult a contact point for further information. This can be your name or that of another doctor/nurse involved in the study. It is important that contact numbers are kept up to date.

Thank you for reading so far – if you are still interested, please go to Part 2:

Part 2 - more detail – information you need to know if you still want to take part.

What happens when the research project stops?

If the treatment will not be available after the research finishes this should be explained carefully. You should also explain what treatment will be available instead. Occasionally the company sponsoring the research may stop it. If this is the case the potential reasons should be briefly explained.e.g.

What happens if new information about the research medicine comes along?

If additional information becomes available during the course of the research you will need to tell the patient about this. You could use something like the following:-

‘Sometimes during research, new things are found out about the research medicine. Your doctor will tell you all about it if this happens. What is best for you might be:

- *To carry on as before*
- *To stop taking part and go back to your usual treatment’*

What if there is a problem or something goes wrong?

You will need to explain what will happen in such an eventuality, but complicated lengthy wording should be avoided as this is in the parent information sheet.

Will anyone else know I'm doing this?

Yes –

- *Some people from the research company or research inspectors will see your medical notes to make sure the research is being done properly.*
- *Your family doctor will be told you are taking part*

If applicable, you should explain that all information collected will be kept strictly confidential. A suggested form of words is

‘If you agree to take part in the research, any of your medical records may be looked at to check that the study is being carried out correctly. Your name, however, will not be disclosed outside the hospital/GP surgery.’

or for other research:-

‘All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery, will have your name and address removed so that you cannot be recognised from it.’

If records will not be confidential this must be clearly explained.

You should explain, if applicable, that for studies not being conducted by a GP, the young person's own GP will be notified of their participation in the trial. This should include other medical practitioners, not involved in the research, who may be treating them.

What will happen to any samples I give?

It should be clear in the description of study procedures whether

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

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

- the security 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 confidentiality (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.

A commonly accepted concept, the "sample as a 'Gift'" has been proposed by the MRC. If this is how researchers wish to see collection of samples, it will need to be explained to the subject. Any commercial significance or development should be included.

What are genetic tests and will any be done? (only include heading if relevant)

Guidance is given in Appendix 2.

Who is organising and funding the research?

The answer should include the organisation or company sponsoring or funding the research. The young person should be told whether the doctor conducting the research is being paid for including and looking after the patient in the study. You could say:-

'The organisers of this project will pay (name of hospital department or research fund) for including you in this study' or

'Your research doctor will be paid for including you in this study.'

25. Who has reviewed the study?

You may wish to say something like:

'Before any research goes ahead it has to be checked by an Ethics Committee. They make sure that the research is OK to do..Your project has been checked by the Ethics Committee'
Thank you for reading this – please ask any questions if you need to..

Information sheets for children aged 6 to 12 years

This section should be read alongside the general guidance on page 4

It is unlikely that the children in this age group will be asked to consent. The information form can therefore be much shorter, with an explanation that their parents will be asked for consent.

If the child is to provide consent the information sheet will need to be considered so it provides all the necessary detail.

Study title

This should be in very simple, clear terms.

What is research? Why is this project being done?

Give a brief definition of research and state clearly and simply why your research is being done.

e.g. Research is a careful experiment to find out the answer to an important question. This project is to test to see if Medicine X treats (asthma) better than Medicine Y.

Invitation to take part. Why have I been asked to take part?

Did anyone else check the study is OK to do?

'Before any research is allowed to happen, it has to be checked by a group of people called an Ethics Committee. They make sure that the research is OK to do. Your project has been checked by the Ethics Committee'

Do I have to take part?

You should explain very simply that taking part in the research is entirely voluntary.

What will happen to me if I take part in the research?

A simple flow diagram or timetable may help -

How many visits will there be and will the child need to miss any be off school?

- procedures needs simple, non-frightening explanations –
- Will he or she miss sports as a result of study participation?

Is there another e.g. sort of medicine I can have instead?

Briefly explain what the alternatives are for diagnosis/treatment/procedure so that the research is not given as their only option.

Will the medicine upset me?

Explain briefly what side effects are

- Any side effects need to be explained in simple, accessible language. You need to give clear instructions and a contact name and phone number if the child or parents are concerned during the trial.

Might anything else about the research upset me?

Simple, sensitive explanations are needed to prepare child so that there are no nasty surprises. You should also say how they can be alleviated. : e.g.

Will joining in help me?

'We cannot promise the study will help you but the information we get might help treat young people with (name of condition) with better medicines in the future'.

What happens when the research stops?

State briefly but clearly what will happen afterwards:

- Will the study medicine still be available?
- Will the child go back to previous treatment?

What if something goes wrong during the project?

You will need to explain what will happen in such an eventuality, but complicated lengthy wording is unnecessary as this is in the parent information sheet.

Will my medical details be kept private if I take part? Will anyone else know I'm doing this?

In simple terms you will need to explain that others will not know of the child's participation unless its necessary.

What happens if a better medicine comes along?

There should be a simple statement that if better, proven treatment is developed, taking part in this study will not stop him/her getting it.

What if I don't want to do the research anymore?

State that a child or parent can opt out at any time, and give reassurance that the doctor will discuss other treatments with child and parents.

e.g. "If at any time you don't want to do the research anymore, just tell your parents, doctor or nurse. They will not be cross with you. Your doctor will help you decide which medicine is best to use afterwards."

What if something goes wrong?

You will need to explain what will happen in such an eventuality, but complicated lengthy wording should be avoided as this is in the parent information sheet.

Information for children five years and under

This should be predominantly pictorial, with simple sentences to be shown/read to the child. It should say at the top that it is intended to be shown/read to the child by their parent/guardian.

Protocols could be supported by videos, or audio-tapes.

(Form to be on headed paper)

Centre Number:
Study Number:
Patient Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet dated
(version) 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 any of my medical notes and data collected during the study, may be looked at by responsible 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 Patient

Date

Signature

Name of Person taking consent
(if different from researcher)

Date

Signature

Researcher

Date

Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

ASSENT FORM FOR CHILDREN
(to be completed by the child and their parent/guardian)

Project title

Child (or if unable, parent on their behalf) /young person to circle all they agree with please:

Have you read (or had read to you) about this project? Yes/No

Has somebody else explained this project to you? Yes/No

Do you understand what this project is about? Yes/No

Have you asked all the questions you want? Yes/No

Have you had your questions answered in a way you understand? Yes/No

Do you understand it's OK to stop taking part at any time? Yes/No

Are you happy to take part? Yes/No

If any answers are 'no' or you **don't** want to take part, **don't** sign your name!

If you do want to take part, please write your name and today's date

Your name _____

Date _____

Your parent or guardian must write their name here too if they are happy for you to do the project

Print Name _____

Sign _____

Date _____

The doctor who explained this project to you needs to sign too:

Print Name _____

Sign _____

Date _____

Thank you for your help.

Information sheets for parents/guardians

These should be designed using the guidance for patient information sheets for competent adults but modified appropriately as suggested in this document.

For the sake of brevity only differences have been recorded here

Where the word “parent” is used, please read parent/guardian i.e. those who have parental responsibility, which may include a legal representative e.g. grandparent.

Part 1.

1. Study title

It is recommended that the document be headed ‘Parent/Guardian Information Sheet’

2. Invitation paragraph

This must explain that the parents and children are being asked to take part in a research project.

3. What is the purpose of the research project?

4. Why has my child been chosen?

You should explain briefly why and how (particularly if the approach is not directly by the care clinician) the potential participant was chosen and how many other participants will be studied.

5. Does my child have to take part?

You should explain that taking part in the research is **entirely voluntary**. e.g

‘No. It is up to you and your child (wherever possible) to decide whether or not to take part. You are both free to withdraw from the research at any time and without giving a reason. Your decisions about this will not affect the standard of care your child will receive.’

6. What will happen to my child if we agree to take part?

The consent/assent process

This may depend on the nature of the research.

Studies governed by the European Union Clinical Trials Directive 2001/20/EC

Consent must be obtained from the parent/guardian along with assent of the child

“If you are happy to take part, and are satisfied with the explanations from your research team, you will be asked to sign a consent form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an “assent” form with you, if they want to. You will be given a copy of the signed information sheet and consent/assent forms to keep for your records.”

Studies NOT governed by the European Union Clinical Trials Directive 2001/20/EC

The researcher has a choice. If “Fraser” competent, he or she can consent. If not parental consent is required

What does my child have to do if we agree to take part?

Explain:

- (if appropriate) that the child should take the study medication regularly as directed. This may require extra supervision by the parent.
- Some studies require greater input from parents, especially re supervision of children taking medication, completing diary cards, attending extra hospital visits etc . How much extra time this involves should be made clear at the outset, to minimise the drop-out rate.

What is the drug, device or procedure that is being tested?

What are the alternatives for diagnosis or treatment?

What are the side effects of any treatment received when taking part?

What are the other possible disadvantages and risks of taking part?

Any other risks, discomfort or inconvenience should be briefly outlined. You may wish to say something like

“Every effort will be made to reduce the anxiety felt by some children e.g.during a blood test. Local anaesthetic cream will be used to help numb any pain and your child will appreciate having you there for support. If at any time you or your child feel that the actual or perceived distress is too great, please don’t hesitate to tell your research doctor/nurse.

What are the possible benefits of taking part?

What happens when the research stops?

What if there is a problem?

A short statement could be given here, e.g.

‘Any complaint about the way you or your child have been dealt with during the study or any possible harm you might suffer will be addressed’. The detailed information on this is given in Part 2 Section 19.’

A contact number for complaints should be given.

Will my child’s taking part in the research project be kept confidential?

Contact Details:

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available?

What will happen if my child or I don't want to carry on with the research?

What if there is a problem?

****This is an important part as it probably won't be fully covered in the child's information sheet.****

Will my child's taking part in this study be kept confidential?

The parent must be told in simple terms how their child's confidentiality is being safeguarded during and after the study. You will need to obtain the parent's (and young person's if applicable) permission to allow access to their medical records and to the information collected about them in the course of the study.

Involvement of the General Practitioner/Family doctor (GP)

What will happen to any samples my child gives?

Will any genetic tests be done?

Guidance is given in Appendix 2.

What will happen to the results of the research study?

Who is organising and funding the research?

Who has reviewed the study?

Appendix 1 Examples of wording to explain the risk of harm to the unborn child

For women:

The following are examples

'The treatment might harm the unborn child; therefore you should not take part in this study if you are pregnant, breast-feeding or you intend to become pregnant during the study. If you are a woman who might become pregnant, you will be asked to have a pregnancy test (urine or blood) before taking part. You must agree to use a reliable form of contraception during the trial, e.g.

- Oral contraceptive +condom
- Intra-uterine device (IUD)+ condom
- Diaphragm with spermicide + condom

This should be continued for at leastmonths after the treatment has finished.'

*'If you do become pregnant during the course of the study, you must tell your study doctor **immediately** so appropriate action can be discussed. You will be referred for specialist counselling on the possible risks to your unborn baby and arrangements will be offered to monitor the health of both yourself and your unborn baby. The pharmaceutical company may also request your consent to collect confidential information about your health and that of the baby.'*

For men:

The following are examples

'Please share this information with your partner if it's appropriate

It is (or is not) known if the study medicine will affect sperm or semen and therefore you must not father a child during this study or for a safety period ofmonths after treatment. If your partner might become pregnant you must use reliable forms of contraception during the trial and formonths afterwards, e.g.

- Oral contraceptive +condom
- Intra-uterine device (IUD)+ condom
- Diaphragm with spermicide + condom

If your partner becomes pregnant during the study or within ...months of stopping treatment, you should inform your study doctor immediately. As the risk to your partner and baby is unknown, it is desirable for your partner to agree to medical supervision during her pregnancy and for the baby after it is born. Your study doctor will work with the sponsoring company to organise this. Your partner will be invited to sign a consent form to allow medical supervision. The pharmaceutical company may also request you and your partner's consent to collect confidential information about her health and that of the baby.'

Appendix 2 Genetic Testing

For a genetic sub-study to a main study, it is recommended that separate information and consent documents are used and, if appropriate, the participant should be able to refuse participation in this but still take part in the main study.

Documents should explain clearly

- the background and purpose of the genetic study.
- what samples are required and what analyses are planned.
- whether there could be any results of individual significance to the participant and whether it is planned/possible to make feedback available to the participant. Any implications, e.g. inherited risk, reproductive decisions, insurance status, etc, should be explained, together with what counselling support would be given. It may be necessary to refer the participant for re-testing by genetic services outside the study. The participant must retain the right to choose whether to access this information. If there will be no reliable information of individual significance, this should be explained, e.g. the samples are fully anonymised, results for individuals are not meaningful at this stage but the research may inform future testing programmes which would then be available later through the NHS.
- whether samples are to be kept for future analyses in conjunction with the planned project and whether later feedback could be available (consented).
- that if samples and information are to be retained, the same information as for other biological samples should be given.
- that if there may be later genetic studies then either additional consent will be sought from the participants or the study will be presented to an ethics committee for consideration. Feedback possibilities must again be considered.
- that if there is any likelihood of commercial significance, the participants would not benefit financially.
- the arrangements, if any, for transfer of samples outside of the UK.

Further material for reference

The MRC guidance 'Human Tissue and Biological Samples for Use in Research'

The Human Tissue Act

The CERES leaflets "*Genetic Research and YOU*" and "*Genetic Research: Taking part in large studies*"

Appendix 3 Questionnaires

If the study involves questionnaires, interviews or focus groups, the following points should be addressed where relevant:

Questionnaires

- If the questionnaire is forwarded with an introductory letter/information sheet, does it make clear how the participant was chosen for approach? E.g. forwarded via known health worker so that confidentiality has not been breached?
- If consent is by return of the completed questionnaire, is it made clear that return of an uncompleted form implies a wish not to participate and for no further reminders?
- Is there a description at the front outlining the area(s) the questionnaire will cover and a realistic estimate of the time it will take to complete the questionnaire?
- Does the questionnaire enable the responder to bypass irrelevant or upsetting questions?
- If the questions may potentially cause distress is any support available?

Focus groups and interviews

- Is it clear why the participant is being approached?
- Is the subject to be discussed clearly defined?
- Is the time commitment clearly stated. Is it made clear where the interview is to take place? Is a confidential venue guaranteed?
- If at a site away from the participant's home, are travel expenses offered?
- Is there a guarantee of confidentiality of the discussion?
- Is it clear whether the interviews/ focus group will be audio- or video- taped? If so, is this specified in the consent form?
- What will happen to the tapes/transcripts? Where will they be stored, how will they be labelled, when will they be destroyed?
- Will the tapes or transcripts of the tapes be reviewed by the participant as a check of accuracy? And will they be free of data from any other participant? Will participants have the right to reconsider any taped material?
- If verbatim quotation are to be used in publication is consent taken for this?
- Are the participants of focus groups requested to maintain confidentiality of the views of other participants?
- What happens if distress is caused? Is there any support offered?

Appendix 4 Research in groups with special communication needs (eg ethnic minorities, visually impaired or illiterate).

Translations and sometimes audio information needs to be available for those for whom English is not their mother tongue. The help of an experienced translator, with back translation of the material e.g. PIS is important. An interpreter should be available for consent. A family member is not generally a suitable translator.

Where there are difficulties due to visual impairment or illiteracy it is suggested that the PIS is read to the participant (by e.g. research nurse) and audio-recorded at the same time to provide a copy for the participant to keep. Questions and discussion with the researcher could be recorded on the same tape and, after consideration, the consent could also be recorded to give a complete record. Two copies of the tape (for researcher and participant) would be required.