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

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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 full fill ethical and statutory guidelines (Data protection act 1998 and 2001/20/EU) on informed consent.

Be clear whether you are you seeking consent or assent and, if in doubt, seek guidance. Consent requires a full explanation of the study. Assent (seeking the child’s agreement) requires a clear explanation (comprehensible rather than comprehensive) as consent will be sought from the parent.

An information sheet should be designed for the appropriate age range to reflect their comprehension and development, for example: Children or young people 11-15 years; Children 6-10 years; (Children 5 years and under) – the value of this is uncertain and written information may be pointless. Parents will obviously need to provide consent.

Ideally such material should be shorter than that designed for adults.
Consider the child’s world. It is important to indicate how the study will affect the child at home, school and his/her social activities.

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

- Studies governed by the Medicines for Human Use (Clinical Trials) Regulations 2004 -. Written consent must be given by parents or those with legal responsibility for the child (under 16), but children should also be asked for their assent, if appropriate.
- Studies not governed by the Medicines for Human Use (Clinical Trials) Regulations 2004 - UK law is untested with regard to the legal age of consent to take part in research (as opposed to treatment). It is possible to apply the principle of Gillick competence for research in the UK. This can be summarised that children who are felt to be competent to understand the research proposal and thus make decisions can give consent on their own behalf. It is unwise to use this for children younger than ten years of age.
- In long-term studies where the child may reach the age of majority, you will need to consider if it would be appropriate or feasible to obtain their consent to continue in the study or use samples already obtained.

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
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 04 Preparation and Content of Participant Information Sheets and Consent Forms for Adult Research Participants

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

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 for Children/Young People Aged 11-15 Years

Appendix B: Sample Patient Information Sheet for Children Aged 6-10 Years

Appendix C: Information for Children Five Years and Under

Appendix D: Sample Assent Form

Appendix E: Information Sheets for Parents/Guardians
Appendix A: Sample Patient Information Sheet for Children/Young People
Aged 11-15 Years

Header: Patient Information Sheet

HEADED PAPER

Version:

Date:

Project ID:

Study title- Can the title be understood by a child? If not, give a short title that is easily understood.

Invitation paragraph- This paragraph 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 join 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 consider this leaflet carefully. Talk to your family, friends, doctor or nurse if you want to”.

What is the purpose of the study?- Why are you conducting this study? The background and aim of the study should be given briefly here.

Why have I been invited?- You should explain

• 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.

If the research is on a specific disease this should be explained so they understand why they have been chosen, for example: “You have been invited to
join our study because you have [condition]. 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. We will ask you for your consent / assent [use the appropriate word] and then ask if you would sign a form (if applicable). We will give you 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?- This section should include:

- 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 attend, meet a researcher, visit a clinic or their GP surgery (if this is appropriate)
- 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, 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.

You should make clear which procedures are experimental and which procedures are over and above those involved in standard care. 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.

...
What will I have 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? - Explain what other treatments are available, and their relative risks and benefits.

What are the possible side effects of the medicines? - 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). The known side effects should be listed in terms that are understandable. 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? - The issues of pregnancy and pregnancy testing must be handled sensitively. If the use of ionising radiation is required as part of the research study, then information must be given to the young person on the amount of any radiation involved (whether part of standard care or the research protocol), in terms that they can understand.

What are the possible benefits of taking part? - If there are benefits these can be stated but should not place undue influence. Where there is no intended clinical benefit, this should be stated clearly.

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

Will anyone else know I'm doing this?- You should explain that all information collected will be kept confidential and what this means. A suggested form of words is:

“We will keep your information in confidence. This means we will only tell those who have a need or right to know. Wherever possible, we will only send out information that has your name and address removed”

What will happen to any samples I give?- It should be clear 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 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.
**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”

**Who has reviewed the study?**- You may wish to say something like:

“Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the ___________________ Research Ethics Committee.

Thank you for reading this – please ask any questions if you need to”

**Contact for further information** - You should give the young person and parents 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.
Appendix B: Sample Patient Information Sheet for Children Aged 6-10 Years

Header: Patient Information Sheet

**HEADED PAPER**

Version:

Date:

Project ID:

*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. “Research is a way we try to find out the answers to questions. We want to see if Medicine X treats [condition] better than Medicine Y”

*Why have I been asked to take part?*- Explain this in clear simple terms

*Did anyone else check the study is OK to do?*- You could say “Before any research is allowed to happen, it has to be checked by a group of people called a Research Ethics Committee. They make sure that the research is fair. Your project has been checked by the ___________________ Research 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?*- A simple flow diagram or timetable may help. How many visits will there be and will the child need to miss any school?
Procedures need simple, non-frightening explanations

*Is there another 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?* Any side effects need to be explained in simple language

*Might anything else about the research upset me?* Simple, sensitive explanations are needed to prepare the child and you should also say how they can be alleviated.

*Will joining in help me?* You could say “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 it is 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

**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.
Appendix C: Information for Children Five Years and Under

This should be predominantly pictorial, with very 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.
Appendix D: Sample Assent Form

(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:

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, you can write your name below

Your name  ________________________________________
Date   ________________________________________

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

Print Name  ________________________________________
Sign  ________________________________________
Date   ________________________________________

Thank you for your help
Appendix E: Information Sheets and Consent Forms for Parents/Guardians

These should be designed using the guidance for information sheets for competent adults given earlier but modified appropriately (see SOP XX Preparation and Content of Participant Information Sheets and Consent Forms for Adult Research Participants)

If the child is not deemed competent to consent or the study is a clinical trial of an investigational medicinal product (CTIMP), a person with parental responsibility should sign a consent form after reading this information sheet, once they are happy with the explanation given. This should be separate from the child’s consent or assent form.

Rarely, where a person with parental responsibility is not available or willing to act as legal representative in a CTIMP, another person may be nominated as the legal representative and invited to give consent for the child to participate in the trial. This legal representative may be the child’s usual doctor or another person nominated by the health care provider. The information sheet for such legal representatives will be similar to that for parents but modified appropriately.

Informed consent in CTIMPs is governed by Schedule 1 to the Medicines for Human Use (Clinical Trials) Regulations 2004. For further guidance, see the NRES information paper available at http://www.nres.npsa.nhs.uk/rec-community/guidance/#CTD