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Informed Consent for Research

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1. PURPOSE

This Standard Operating Procedure (SOP) describes the process for obtaining informed consent from a study subject. It outlines the informed consent procedures for adult subjects with capacity who are able to give informed consent, and informed consent procedures for more vulnerable subjects (minors and incapacitated adults) and emergency research.

2. INTRODUCTION

Informed Consent is the process by which a subject voluntarily confirms his/her willingness to participate in a study, having been informed of the full details of the project. Informed consent is documented by means of a written, signed and dated informed consent form.

Informed consent is a three step process which involves:

1. The giving of information
2. The discussion and clarification of the information and finally
3. Taking the subject's verbal and written consent

All participants entering into a clinical study/research project must have given informed consent before any aspect of the project starts (interventional or non-interventional) and a copy filed in their medical records.

3. INFORMED CONSENT OF ADULTS WITH CAPACITY

3.1. Responsible Personnel

The Declaration of Helsinki states that the person seeking informed consent should be a qualified physician: '*The **physician** should then obtain the subject's freely given informed consent, preferably in writing*' (1996 version).

However ICH GCP guidelines state that '*The **investigator, or, a person designated by the Investigator** should fully inform the subject*' (ICH GCP 4.8.5) and the written informed consent form should be signed and dated by the '***person who conducted the informed consent discussion***'.

The delegation of Informed Consent to an appropriate, suitably qualified member of the research team should be considered on a study-by-study basis. If staff other than the Chief Investigator (CI) or Principal Investigator (PI) are to accept responsibility for the informed consent process, it is important the following criteria are met:

- i. S/He is prepared to take on this additional responsibility AND feels confident to seek informed consent in line with their professional organisational guidelines.

- ii. S/He has a full understanding of the study, potential risks/benefits and the associated disease area. They should be qualified by experience and/or should have received appropriate training for this study. All training must be documented.
- iii. This delegation of responsibility should be documented on the Study Delegation Log/Site Responsibility Log (title can vary from centre to centre, but is essentially a log that captures each member of the study team and their individual responsibilities in the management and conduct of the study and is signed and dated by the CI/PI).
- iv. The process has been approved by the relevant Research Ethics Committee (REC).
- v. An effective line of communication is maintained back to the CI/PI who is the person ultimately responsible for the subject's care.

It is ultimately the responsibility of the CI/PI to ensure that subjects have fully understood what they are consenting to, and it is usual practice for the CI or Co-Investigator to sign/countersign the consent form.

It is best practice for any other research personnel involved in giving information during the informed consent procedure to sign and date the informed consent form. All those responsible for obtaining written informed consent must have a copy of their signed and dated CVs in the Trial Master File (TMF), and must have completed the study delegation log/site responsibility log, which is also signed and dated by the CI. The consent form should also be signed off by the CI/PI in any instance where they do not take consent themselves.

3.2. Contents of Consent Form

3.2.1 The person(s) responsible for seeking Informed Consent must ensure they are completely familiar with all aspects of the clinical study as described in the latest version of the protocol and approved by the REC.

3.2.2 Copies of the Participant Information Sheet and Informed Consent Form must be approved by the REC and should be used, together with any documents the subject may need to use e.g. subject diaries. The Informed Consent Form must be checked for the following:

- i. It should be on departmental headed paper
- ii. The correct title and version number for the study is clearly visible and relates to the written information sheet given to the participant.
- iii. A statement to say the participant has had the study explained to them and by whom. The risks, benefits and alternative treatments have been discussed and all the subject's questions have been satisfactorily answered.

- iv. A statement that their participation is voluntary and they are free to withdraw at any time, without the loss of any treatment to which they would otherwise have been entitled or the loss of any legal rights.
- v. A statement that their medical records may be reviewed by authorised personnel and that confidentiality will be maintained at all times.
- vi. That compensation arrangements have been discussed.

3.3 Procedure

3.3.1 All potential participants should be given information about the study prior to inclusion in the study. The dignity of the potential participant should be taken into consideration, and a private area used for the consent process if required.

3.3.2 Subjects who potentially fulfil the inclusion/exclusion criteria will be identified and approached. A verbal explanation of the study must be given to the potential participant (and friends and family if appropriate). If necessary, diagrams should be used to explain the study. Time for questions throughout the discussion must be given and questions adequately addressed.

3.3.3 When describing the study the person seeking consent should explain:

- I. What the purpose of the study is and any background information that may be relevant.
- II. Why the subject has been approached and that confidentiality will be maintained throughout the study, should they decide to participate.
- III. Details of the study design and details of any drugs used (including any known safety profiles). If there is a placebo arm or randomisation involved then these procedures should be explained.
- IV. The number of people taking part in the study and how many have been recruited to date.
- V. The duration of the study and the number of study visits involved. It should be explained where the subject will be seen and by whom.
- VI. All procedures, such as blood tests, electrocardiograms (ECGs) etc that are required as part of the study should be included and explained in lay language e.g. 10mls (2 teaspoons) of blood.
- VII. The potential benefits and risks of participation in the study, and any alternative treatments available to the subject should be discussed.
- VIII. The availability of compensation should something go wrong
- IX. That the subject enters the study voluntarily and can withdraw at any time without any prejudice to them or their future care. Similarly if the Investigator feels that the study medication is not suiting the

subject that they have the right to withdraw them from the study in the interests of their safety.

- X. That a detailed discussion of the subject's medical history (including disclosure of all medication they are taking) will be required should they agree to participate.
- XI. If there are any payments made for participation in the study or for out of pocket expenses.
- XII. The responsibilities of the subject if they choose to take part, particularly if the study duration is lengthy.
- XIII. That giving informed consent does not necessarily mean the subject will be enrolled into the study if it is discovered they do not meet the inclusion/exclusion criteria e.g. a study specific diagnostic test.

3.3.4 Once the above information has been verbally discussed with the subject, the subject should be provided with a written participant information sheet about the study (on departmental headed paper). An example of a Participant Information Sheet is attached at Appendix 1.

3.3.5 The subject should be given adequate time to read the participant information sheet and to discuss with any family and friends (if applicable), prior to agreeing to participate. This should normally be a time period of more than 24 hours. The subject should not be coerced to participate, and should be reassured that refusing to enter the study will not affect their care.

3.3.6 Once the subject has had time to read the information sheet and has had any questions regarding their participation answered satisfactorily, then they should be asked to sign the written informed consent form relating to the study.

3.3.7 The informed consent form must be personally signed and dated in ink easily visible on photocopies by the person seeking consent, the CI/PI or Co-Investigator (if different) and the participant. Each should also clearly print their name by their signature.

3.3.8 Once all parties have signed the written informed consent form, the participant should receive a signed and dated copy, together with a participant information sheet and any other written information provided to the participants. A copy of the above must be placed in the participant's medical notes and a copy kept by the study team.

3.3.9 All subjects must be provided with 24 hour contact details where they may obtain further information about the study. This will either be the CI's number or a contact number of a member of the study team.

3.4 Ongoing Procedure throughout the study

3.4.1 The informed consent process should not end once the informed consent form has been signed. The practice of giving information about the study to participants should be an ongoing process performed by all

members of the research team and any associated healthcare professionals. This is particularly important if protocol amendments are introduced, or if important new information that may be relevant to the participant's willingness to continue taking part in the study is discovered. In these circumstances it may be necessary to re-consent the participant using an amended consent form, to continue their involvement in the study.

3.4.2 The timing of the signing of the consent form, relative to study registration and the initiation of study procedures, is subject to audit by regulatory/approval bodies. It is therefore essential to record dates correctly on both the Informed Consent form and in the subject's medical notes. The consent form must be signed by the study participant before any aspect of their involvement in the study begins.

4. INFORMED CONSENT OF MINORS

In addition to the above, there are a number of factors that must also be considered when seeking consent from minors:

- i. It is essential that the clinical study either relates directly to a clinical condition from which the minor suffers, or that the study can *only* be carried out on minors.
- ii. It should be shown that there will be some direct benefit for the research participants, and that the clinical study is necessary to validate data obtained in other clinical studies involving those able to give informed consent (or by other research methods).

The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and the minor's stage of development. Continuous monitoring throughout the study of such risks and/or distress must take place.

- iii. A full explanation of the study (including the objectives, risks/inconveniences) must be given to the parent/legal guardian of the minor. That person may then provide consent for the minor to participate in the study. If the study involves emergency treatment and the parent/guardian cannot be contacted in time to provide consent, then consent from a legal representative can be obtained. The legal representative must receive the same full explanation of the study so that they can provide consent to the minor taking part. A contact number for the research team must be given so that they can obtain further information about the study should they wish to do so.
- iv. The minor should be given information about the study according to his/her level of understanding (from staff that have experience in dealing with minors) and the person seeking consent must respect their wishes. Parental consent should reflect the wishes of the child and this may over-rule the parent's wishes.

- v. The minor, parent/legal guardian of the minor (or the legal representative of the minor) must be made aware that they can withdraw from the study at any time without any detriment to future care.
- vi. No incentives or financial inducements must be given except for compensation in the event of injury or loss.
- vii. If aged 16 or over, it is acceptable for minors to sign their own consent form.
- viii. The Participant Information Sheet should be written in a language that the minor can understand i.e. there should be different versions for e.g. under 5s, 6-12 year olds, 13-15 year olds and over 16. There should also be a version produced for the parent/guardian/legal representative.
- ix. It is best practice to obtain the assent of the child in addition to the consent of the parent/guardian, if the child is deemed competent to understand the research being explained to them. In such circumstances a signature should be obtained from both the minor and the parent/guardian on the consent form.

5. INFORMED CONSENT OF INCAPACITATED ADULTS

When seeking consent from an adult that is unable to provide informed consent for him/her it is important that the Investigator ensures that:

- i. The study relates directly to a life threatening or debilitating clinical condition from which the participant suffers, and it is expected that the study will produce a benefit to the participant. This benefit should outweigh the risks or produce no risks at all.
- ii. The clinical study must be essential to validate data obtained in other clinical studies involving persons able to give informed consent, or by other research methods.
- iii. The clinical study needs to be designed to minimise pain, discomfort, fear and any other foreseeable risks to the subject. Continuous monitoring throughout the study of risks and/or distress must take place. The interests of the subject must always prevail over the interest of science.
- iv. The participant's legal representative must have the objectives, risks, inconveniences/discomforts and associated conditions for the study explained to them. A contact number for the study team should be provided in case they wish to ask further questions about the study. The legal representative must be informed of their right to withdraw the participant at any time resulting in no detriment to care or treatment for the subject. They must then give informed consent on behalf of the subject.
- v. The subject must also be given information about the study according to their level of understanding. For those subjects able to form an opinion based on the information provided, their wish to participate (or not) must be respected by the person seeking consent.

- vi. No incentives or financial rewards must be used to influence a subject to participate (or the subject's legal representative to consent on their behalf), other than provision for compensation in the event of loss or injury.

5.1 Informed Consent in Emergency Research

Where research involves adults that temporarily or permanently lack capacity to consent, and there is a need to initiate recruitment within a short timescale due to the nature of the investigation e.g. stroke studies, the situation differs depending on whether the research falls under the UK Medicines for Human Use (Clinical Trials) Regulations 2004 or not.

5.1.1 Clinical Trials subject to UK Clinical Trials Regulations 2004

These relate to trials of medicinal products for human use. Currently an adult is anybody over the age of 16 years for the purposes of these regulations. Consent is required (before recruitment) from the personal representative of the participant, or if there is no such person, from a professional representative.

In December 2006 the regulations were amended to give provisions for emergency research. This amendment addresses the problem that in trials involving emergency treatment there may not be enough time to contact a representative before entering the patient onto the trial. This amendment allows the recruitment of patients in an emergency situation into clinical trials before consent is obtained from personal/legal representatives. Such recruitment would be subject to approval from a research ethics committee.

5.1.2 Research not included under UK Clinical Trials Regulations 2004

Following the introduction of the Mental Capacity Act (2005), researchers are required to consult a carer, or someone interested in the adult's welfare, or an independent nominee for their advice and opinion on whether the patient should be recruited. It would broadly be expected that this advice is followed (this excludes research that falls under the Clinical Trials Regulations however).

The Act also allows an adult to be enrolled in a research study in an urgent situation without such consultation, providing there is an agreement from an independent clinician. Alternatively if this is not practical, then the protocol must be approved by the appropriate research ethics committee. These arrangements only apply for the duration of the emergency. Consent and consultee input must be sought as soon as practically possible. Arrangements for this procedure should be clearly set out in the IRAS application.

6. CONSENT TO SUPPLY HUMAN TISSUE AND RELEVANT MATERIAL TO EXTERNAL ORGANISATIONS

Most external organisations require assurances that informed consent has been appropriately and legally obtained.

If you plan to store samples for future use and/or external collaboration there are key points that should be included in the participant information sheet and consent documentation:

- i. Consent should be in writing from the donor, legal representative or next-of-kin as appropriate

- ii. Ethics approval or a statement that approval is not required should be obtained
- iii. The participant information sheet and consent form explains the actual or potential use of tissue samples
- iv. Statements regarding withdrawal, data protection and duration of storage (if any) are clearly stated in the participant information sheet
- v. A statement explaining that donated samples supplied to external non-commercial and commercial organisations do not infer the right of the donor to financial gain from any commercially viable outcomes to the use of their tissue in commercial research and development.

7. REFERENCES

ICH (1996) Guidelines for Good Clinical Practice – ICH Harmonised Tripartite Agreement

Declaration of Helsinki (1996 Version)

Department of Health (2004) - Research Governance Framework for Health and Social Care Version 2.2 Draft

The Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument 2004/1031

MRC Research in emergency settings involving adults who lack capacity

http://www.mrc.ac.uk/pdf-emergency_research.pdf#xml=http://www.mrc.ac.uk/scripts/texis.exe/webinator/search/xml.txt?query=consent+for+emergency+research&pr=mrccall&order=r&cq=&id=447549572

The Mental Capacity Act 2005
<http://www.opsi.gov.uk/acts/acts2005/20050009.htm>

UK Medicines for Human Use (Clinical Trials) Regulations 2004
<http://www.opsi.gov.uk/si/si2004/20041031.htm>

The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006
<http://www.opsi.gov.uk/SI/si2006/20062984.htm>

Based on the University College London Clinical Research Network SOP for Informed Consent (CRN/04/S03/00)

NRES Information Sheets and Consent Forms – Guidance for Researchers and Reviewers. Version 3.5 May 2009
<http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId=338>

NIHR (2012) Mental Capacity Act e-learning module
<http://learning.nihr.ac.uk/learning/student/>

8. APPENDICES

8.1 Appendix 1: Guide to Writing a Participant Information Sheet

The principles of this guidance should be used as a guide for writing participant information sheets for research, which involves patients, patient volunteers and/or healthy volunteers.

A INTRODUCTION

i. Potential recruits to research studies must be given sufficient information to allow them to decide whether or not they want to take part. A Participant Information Sheet should contain information under the headings given below, where appropriate, and in the order specified. It should be written in simple, non-technical terms and be easily understood by a lay person. Short words, sentences and paragraphs should be used. 'The readability' of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages. The language used 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.

ii. If you are the Principal Investigator, the Participant Information Sheet should be printed on local hospital/surgery paper with local contact names and telephone numbers before it is submitted to the host organization for any locality assessment or for R&D local NHS approval. If after reading this guide anything is unclear, or you would like to discuss writing a Participant Information Sheet further, please contact a member of the Joint Research Compliance Office (JRCO) who will be able to clarify any queries (see contact details in SOP for Informed Consent).

B. PROCEDURES

i. Each Participant Information Sheet must have a version number and date in the footer.

- **Study title**

The document should be headed 'Patient Information Sheet' or 'Participant Information Sheet' where the participants are not patients.

Is the title self explanatory to a lay person? If not, a simplified title should be included (usually the simplified title given on the Research Ethics Committee (REC) application). One consistent title for the study should appear on all the documents. It must have the version number to track any changes made.

- **Invitation paragraph**

This should explain that the subject is being asked to take part in a research study. 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. Please take time to read the following information carefully and discuss it with others 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.

Thank you for reading this.'

- **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.

If the study is being conducted for a student research project, this should be stated here.

- **Why have I been chosen?**

You should explain how the subject was chosen and how many other participants will be studied. This is particularly important if the participant has been approached by someone other than the clinician responsible for their care.

- **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 will be given this information sheet to keep and be asked 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?**

You 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 (if this is appropriate)
- how long these visits will be.
- what exactly will happen e.g. blood tests, X-rays, (over and above those involved in standard diagnosis and treatment), interviews etc.?

If the subject will need to visit the GP (or clinic) more often than for his/her usual treatment, this should be explained here, and whether travel expenses are available. Whenever possible you should draw a simple flowchart or plan indicating what will happen at each visit. What are the subject's responsibilities? Set down clearly what you expect of them.

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

Randomised Trial:

"Sometimes because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual – i.e. by chance. Subjects in each group then have a different treatment and these are compared".

You should tell the subjects 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 such as a pill which looks like the real thing but is not. It contains no active ingredient".

Specific consent is needed if the study will involve videoing, audio-taping, or photography. The confidentiality issues should also be discussed.

Expenses and Payments: If the participant needs to make more visits because of the study than they would usually have done as part of their usual treatment, it should be specified whether expenses such as travel will be provided.

- **What do I have to do?**

Are there any lifestyle restrictions? You should tell the subject if there are any dietary restrictions. Can the subject drive? Drink? Take part in sport? Can the subjects continue to take their regular medication? Should the subject refrain from giving blood? What happens if the subject becomes pregnant?

Explain (if appropriate) that the subject should take the medication regularly as directed. It should also be explained that they should not normally be involved in any other drug studies at the time.

- **What is the drug or intervention that is being tested?**

You should include a short description of the drug, device or treatment and give the stage of development, process and what the treatment does.

You should also state the dosage of the drug and method of administration. They should be told if there are any contraindicated drugs. Subjects entered into drug trials should be given a card (similar to a credit card) with details of the trial they are in. They should be asked to carry it at all times.

- **What are the alternatives for diagnosis or treatment?**

For therapeutic research the subject should be told what other treatments are available. For multi-site studies the Chief Investigator should check on local variations in alternative treatments, and the relevant information can then be given to participants at each site.

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

For any new drug or procedure you should explain to the subjects the possible side effects. If they suffer these or any other symptoms they should report them next time you meet. You should also give them a contact name and number to phone if they become in any way concerned. The name and number of the person to contact in the event of an emergency (if that is different) should also be given.

The known 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'). For any relatively new drug it should be explained that there may be unknown side effects.

Good Clinical Practice also requires that participants should be told about 'reasonably foreseeable risks', with the information prioritised in terms of seriousness, severity and frequency. This should reflect what a reasonable person would expect to be mentioned i.e. rare side effects should be mentioned if they may be serious or permanent.

For very new or potent investigational drugs, a fuller list of suspected side-effects might be appropriate. If participants suffer these or any other symptoms, they should be given clear guidance on when, how and whom to report them to.

- **What are the possible disadvantages and risks of taking part?**

For studies where there could be harm to an unborn child if the subject were pregnant or became pregnant during the study, the following (or similar) should be said:

'It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study, neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Women who could become pregnant must use an effective contraceptive during the course of this study. Any woman who finds that she has become pregnant while taking part in the study should immediately tell her research doctor.'

The pregnancy statement should be used with sensitivity, and should include information on what happens if they do become pregnant.

There should also be an appropriate warning and advice for men if the treatment could damage sperm which might therefore lead to a risk of a damaged foetus.

If future insurance status e.g. for life insurance or private medical insurance, could be affected by taking part this should be stated (if e.g. high blood pressure is detected.) If the participants have private medical insurance you should ask them to check with the company before agreeing to take part in the trial. They will need to do this to ensure that their participation will not affect their medical insurance.

You should state what happens if you find a condition of which the participant was unaware. Is it treatable? What are you going to do with this information? What might be uncovered?

- **What are the possible benefits of taking part?**

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

It is important not to exaggerate the possible benefits to the particular patient during the course of the study, e.g. by saying they will be given extra attention, and to emphasise that there is no guarantee that they will experience a benefit. This could be seen as coercive. 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)'

What if new information becomes available?

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

'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 with you whether you want to continue in the study. If you decide to withdraw 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.'

- **What happens when the research study stops?**

The arrangements after the trial must be given, especially if this differs from that normally expected for their medical condition. If the treatment will not be available after the research finishes this should be explained to the subject. You should also explain to them what treatment will be available instead. Occasionally if an external company is sponsoring the research the Sponsor may decide to stop it. If this is the case the reasons should be explained to the subject.

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

- **What if something goes wrong?**

You should inform subjects how complaints will be handled and what redress may be available. Is there a procedure in place? You will need to distinguish between complaints from subjects as to 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.

Where there are no Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, and the study carries risk of physical or significant psychological harm, the following (or similar) should be said:

'Imperial College holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this trial. If you can demonstrate that you experienced serious and enduring harm as a result of your participation in this trial, you may be eligible to claim compensation without having to prove that Imperial College is at fault. If the injury resulted from any procedure which is not part of the trial, Imperial College will not be required to compensate you in this way. Your legal rights to claim compensation for injury where you can prove negligence are not affected. Please contact the Principal Investigator if you would like further information about the insurance arrangements which apply to the trial'

Where there are ABPI or other no-fault compensation arrangements the following (or similar) should be included:

'Compensation for any injury caused by taking part in this study will be in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). Broadly speaking the ABPI guidelines recommend that 'the sponsor', without legal

commitment, should compensate you without you having to prove that it is at fault. This applies in cases where it is likely that such injury results from giving any new drug or any other procedure carried out in accordance with the protocol for the study. 'The sponsor' will not compensate you where such injury results from any procedure carried out which is not in accordance with the protocol for the study. Your right at law to claim compensation for injury where you can prove negligence is not affected. Copies of these guidelines are available on request.'

These are available from the ABPI website.

- **Will my taking part in this study be kept confidential?**

You will need to obtain the subjects' permission to allow restricted access to their medical records and to the information collected about them in the course of the study. You should explain that all information collected about them will be kept strictly confidential. A suggested form of words for drug company sponsored research is:

'If you consent to take part in the research any of your medical records may be inspected by the company sponsoring (and/or the company organising) the research for purposes of analysing the results. They may also be looked at by people from the company and from regulatory authorities 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.'

You should always bear in mind that you, as the researcher, are responsible for ensuring that when collecting or using 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.

You should explain that for studies not being conducted by a GP that affect the participant's treatment or care, the patient'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 the patient. You should seek the participant's agreement to this. In some instances agreement from the participant that their GP can be informed is a precondition of entering the trial. Where the researcher is neither the participant's own GP nor care clinician, he/she should be referred to in the Information Sheet as the 'research doctor' to avoid confusion with their own GP/ care clinician.

For research that does not affect the care/treatment of the participant there is no requirement to inform GPs.

- **What will happen to the results of the research study?**

You should be able to tell the participants 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 subject should be told whether the doctor conducting the research is being paid for including and looking after the subject 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 may wish to give the name of the Research Ethics Committee which reviewed the study (you do not however have to list the members of the Committee). E.g. This study was given a favourable ethical opinion for conduct in the NHS (or private sector) by xxxx REC.

- **Contact for Further Information**

You should give the participant a contact point for further information. This can be your name or that of another doctor/nurse involved in the study (who must have sufficient knowledge/understanding of the study in order to deal with any questions/problems that may arise). You should also provide a 24hr contact number should the participant wish to speak to a member of the study team.

Remember to thank the participant for taking part in this study!

The Participant Information Sheet should be dated and given a version number.

The Participant Information Sheet should state that a copy of the written information and signed Informed Consent form will be given to the participant to keep.

8.2 Appendix 2: Template Informed Consent Form for Adults with Capacity

(Form to be on departmental headed paper)

Centre Number (if applicable):
Study Protocol Number:
EudraCT number (if applicable):

TEMPLATE INFORMED CONSENT FORM FOR SUBJECTS ABLE TO GIVE CONSENT

Full Title of Project:

Name of Principal Investigator:

Please initial box

1. I confirm that I have read and understand the subject information sheet dated version for the above study and have had the opportunity to ask questions which have been answered fully. ☐
2. I understand that my participation is voluntary and 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 sections of any of my medical notes may be looked at by responsible individuals from [company/institution name] or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research. ☐
4. The compensation arrangements have been discussed with me. ☐
5. I agree to take part in the above study. ☐

Name of Patient/Participant	Signature	Date

Name of Person taking consent (if different from Principal Investigator)	Signature	Date

Principal Investigator	Signature	Date

1 copy for patient/participant; 1 copy for Principal Investigator; 1 copy to be kept with hospital notes

8.3 Appendix 3: Template Informed Consent Form for Adults without Capacity (For CTIMPS)

(Form to be on departmental headed paper)

Centre Number (if applicable):
Study Protocol Number:
EudraCT number (if applicable):

TEMPLATE INFORMED CONSENT FORM FOR SUBJECTS UNABLE TO GIVE CONSENT THEMSELVES

Full Title of Project:

Name of Principal Investigator:

Please initial box

1. I confirm that I have read and understood the subject information sheet dated version for the above study and have had the opportunity to ask questions which have been answered fully.

☐

2. I understand that I am giving this consent based on what I believe would be my relative/friend/partner's wishes. In my opinion they would be willing to participate.

☐

3. I understand that participation is voluntary and I or the person I am consenting for are free to withdraw at any time, without giving any reason, without medical care or legal rights being affected

☐

4. I understand that sections of any of my relative/friend/partner's medical notes may be looked at by responsible individuals from Imperial College or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my relative/friend/partner's records that are relevant to this research.

☐

4. The compensation arrangements have been discussed with me.

☐

6. I agree to my relative/friend/partner taking part in the above study.

☐

7. I agree that my relative/friend/partner's consent will override my consent when they are able to give informed consent.

☐

Name of Patient/Participant

Signature (if able)

Date

Name of /legal
representative

Signature

Date

Name of Person taking consent
(if different from Principal Investigator)

Signature

Date

Principal Investigator

Signature

Date

1 copy for patient/participant; 1 copy for Principal Investigator; 1 copy to be kept with hospital notes

8.4 Appendix 4: Template Informed Consent Form for Parent/Legal Guardian/Representative of Minor

Centre Number (if applicable):

Study Protocol Number:
EudraCT number (if applicable)

Parent/Guardian Consent Form – Version

Study Title:

Chief Investigator:

Principal Investigator:

Child's Name:.....

This study has been explained to me by :

Prof/ Dr/ Mr/ Mrs/ Ms

- | | Please
initial box |
|--|-------------------------------|
| 1. I confirm that I have read and understood the information sheet (Version dated) for the above study. This has also been explained to me and I have had the opportunity to ask questions. | <input type="checkbox"/> |
| 2. I understand that my child's participation is voluntary and I am free to withdraw at any time, without giving any reason and without my child's medical care or legal rights being affected. | <input type="checkbox"/> |
| 3. I understand that sections of any of my child's medical notes may be looked at by staff involved in the study or from the sponsor and regulatory authorities where it is relevant to my baby taking part in this research. I give permission for these individuals to have access to those records. | <input type="checkbox"/> |
| 4. The compensation arrangements have been discussed with me. | <input type="checkbox"/> |
| 5. I agree for my child to take part in the above study. | <input type="checkbox"/> |

Name of Parent/Guardian/Legal
Representative.....

Signature.....

Date.....

Name of person taking consent

Signature

Date.....