

Consent and Participant Information Sheet Preparation Guidance

Contents

Welcome.....	5
Principles	6
Principles of consent: General principles and role of Participant Information Sheets	7
Informing potential participants: aiding understanding	7
Does consent have to be in writing?	7
The role of the Participant Information Sheet	8
Testing your Participant Information Sheet with patients / other potential participants.....	8
Who is the right person to seek consent?	8
GCP and consent	9
How do I ensure consent is given voluntarily?	10
Deception as part of the research method	10
Principles of consent: Adults who are not able to consent for themselves	12
Principles of consent: Adults not able to consent for themselves (England and Wales)	12
Clinical Trials of Investigational Medicinal Products (CTIMPs).....	13
Non-CTIMPs (other intrusive research)	13
Participants regaining capacity during your study.....	14
Losing capacity during participation in research	14
Principles of consent: Adults with incapacity (Northern Ireland).....	15
Clinical Trials of Investigational Medicinal Products (CTIMPs).....	15
Non-CTIMPs	16
Participants regaining capacity during your study.....	16
Losing capacity during participation in research	16
Principles of consent: Adults with incapacity (Scotland)	17
Clinical Trials of Investigational Medicinal Products (CTIMPs).....	17
Non-CTIMPs (other medical, surgical, nursing, dental and psychological research)	18
Participants regaining capacity during your study.....	18
Participants losing capacity during your research.....	19
Principles of consent: Children and Young People.....	20

Principles of consent: Children and Young People (England, Wales and Northern Ireland)	21
Consent for under 16s in Clinical Trials of Investigational Medicinal Products (CTIMPs)	21
Consent for over 16s in Clinical Trials of Investigational Medicinal Products (CTIMPs)	21
Consent in Non-CTIMPs	22
Children's / young people's wishes and assent	23
Consent for 16 and 17 year olds who lack capacity	24
Principles of consent: Children and Young People (Scotland)	24
Consent for under 16s in Clinical Trials of Investigational Medicinal Products (CTIMPs)	24
Consent for over 16s in Clinical Trials of Investigational Medicinal Products (CTIMPs)	25
Consent in Non-CTIMPs	25
Children's / young people's wishes and assent	26
Consent for 16 and 17 year olds who lack capacity	27
Principles of consent: Emergency research	28
Principles of consent: Emergency Research (England and Wales)	28
Adults not able to consent for themselves in emergency Clinical Trials of Investigational Medicinal Products (CTIMPs)	28
Adults not able to consent for themselves in other intrusive emergency research	29
Children / young people in emergency CTIMPs	29
Children / young people in other emergency research	29
Principles of consent: Emergency Research (Northern Ireland)	30
Adults not able to consent for themselves in emergency Clinical Trials of Investigational Medicinal Products (CTIMPs)	30
Adults not able to consent for themselves in other emergency research	30
Children / young people in emergency CTIMPs	30
Children / young people in other emergency research	31
Principles of consent: Emergency Research (Scotland)	31
Adults lacking capacity in emergency Clinical Trials of Investigational Medicinal Products (CTIMPs)	31
Adults lacking capacity in other emergency research	32
Children / young people in emergency CTIMPs	32
Children / young people in emergency non-CTIMPs	32
Principles of consent: Deceased people	34
Style: What makes a good Participant Information Sheet	35

One size does not fit all	35
Proportionality: how long should a Participant Information Sheet be?	35
Importance of your study title	36
Invitational style	36
Do not use the passive voice	36
Use plain English and avoid jargon	36
Format.....	37
Using different ways of explaining	37
Participants' perspective	38
Clarity about expected risks and benefits.....	38
Different groups - different information sheets?	38
Test with relevant people - check you have got it right	39
Adults not able to consent for themselves.....	39
Children and young people.....	39
Emergency research.....	40
Content	41
Content: Participant Information Sheet.....	42
Content: Participant Information Sheet Title	42
Content: Participant Information Sheet - Invitation and Summary	42
Invitation	42
Summary	43
Content: Participant Information Sheet - What's involved.....	44
Explanation: purpose of and background to the research and invitation.....	44
What would taking part involve?	45
What are the possible benefits of taking part?	46
What are the possible disadvantages and risks of taking part?	46
Adults not able to consent for themselves.....	48
Pregnancy and breast-feeding	48
Young people and pregnancy	49
Therapeutic research - clinical alternatives.....	50
Side effects of treatments / therapies in trials.....	50
Randomisation and blinding	51
Screening and exclusion	51
Therapeutic studies - what happens when the research study stops?	52

Tissue samples.....	52
Research databases and tissue banks.....	53
Expenses and payments.....	53
Discovering health related findings.....	54
Genetic research.....	54
Impact on insurance.....	55
Radiation: Ionising Radiation (Medical Exposure) Regulations (IRMER).....	55
Accessing ONS, NRS and other registry data.....	55
Generic consent.....	55
Content: Participant Information Sheet - Supporting Information.....	56
What if something goes wrong?.....	57
What will happen if I don't want to carry on with the study?.....	58
Will my information be kept confidential?.....	59
What will happen to the results of this study?.....	60
Who is organising and funding this study?.....	60
How have patients and the public been involved in this study?.....	60
Who has reviewed this study?.....	61
Further information and contact details.....	61
Version control.....	62
Consent process.....	62
What if relevant new information becomes available?.....	62
Involvement of General Practitioner / other healthcare practitioner.....	63
What will happen to the samples I give?.....	63
Commercial exploitation.....	64
Content: Consent Form.....	65
General content.....	65
Itemising specific elements.....	66
Signatories, witnesses and legal representatives.....	66
Adults lacking capacity (England and Wales) - consultee declaration form (non-CTIMPs only).....	67
Version control.....	67

Welcome

Welcome to the Health Research Authority's online guidance for researchers and ethics committees on consent, and how to prepare documents to support this process.

In this guidance you will find information on:

- The principles of consent (both ethical and legal)
- How the principles relate to preparation and use of a Participant Information Sheet (PIS) and consent form
- Recommended content of a PIS and consent form
- Design and style of an effective PIS and consent form

The guidance covers consent in adults, children, young people and adults not able to consent for themselves (in both emergency and non-emergency situations) and takes into account UK-wide requirements.

We have provided some examples and suggested text. The guidance should be considered as a framework, not a rigid template: we would encourage you to **think carefully about how best to inform potential participants**. One size does not fit all: you do not need to produce the same PIS and consent form to support consent for a questionnaire study as you would to recruit into a drug trial. The best way to make sure your consent documentation is fit for purpose is to test it with patient groups or other members of the public.

From this site we have provided links to other sources of information (available from our 'Links' page).

Principles

This section of the guidance focuses on the principles of consent (both ethical and legal) and how they relate to your Participant Information Sheet (PIS).

We also highlight what to consider when your research involves:

- Vulnerable groups (e.g. children / young people or adults not able to consent for themselves);
- Recruitment of participants from across the UK (i.e. explore the legal differences and requirements in England & Wales, Scotland and Northern Ireland).

- > General principles of consent and role of Participant Information Sheets
- > Adults not able to consent for themselves
- > Children and young people
- > Emergency research
- > Deceased people

We provide links to various reference texts, including the World Medical Association (WMA) Declaration of Helsinki and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guideline for Good Clinical Practice (ICH GCP), in our 'Links' page.

Principles of consent: General principles and role of Participant Information Sheets

For consent to be considered both legal and ethical it must be:

- Given by a person with capacity;
- Voluntarily given, with no undue influence;
- Given by someone who has been adequately informed;
- A fair choice.

Although most adults are able to make decisions for themselves, there are some who will be judged not competent to do so. Young children are also usually considered not able to give consent themselves, however as they grow up and mature, most will develop capacity in time.

There are further legal and ethical considerations that you need to make before anyone not able to consent for themselves is included in your research. You will find additional guidance on this site.

General principles of consent for all studies:

[Informing potential participants: aiding understanding](#)

The Participant Information Sheet (PIS) is not usually the only information provided to potential participants. The consent process usually also involves a conversation between one or more members of the research team and the potential participant. If the potential participant would like further information, they may also talk to an independent person.

It is known that you can improve understanding by providing information in a number of different formats (e.g. by providing a written PIS that supports a conversation).

Effective informing should enable potential participants to understand what is involved. Interactive questioning of potential participants within the consent process can also aid understanding and highlight areas that potential participants are misunderstanding without appearing condescending.

Consent is an iterative and on-going process. In many situations it is not necessary to obtain consent afresh at every stage of the study. However to aid understanding you might consider, in some circumstances, providing participants with information throughout their involvement in the study. This can be particularly important where new information becomes available that might impact on the risks or benefits that the study poses.

It can be helpful for the research team to encourage participants and family members to ask questions whenever they are uncertain about study procedures. Study summaries describing relevant phases of the study and ethical safeguards can be prepared to supplement information in the PIS.

You may decide that providing written information is not the best format to use at all, the use of other media may be more appropriate. For further guidance please refer to 'Style'

[Does consent have to be in writing?](#)

Consent does have to be indicated in some way: for many studies, consent can be written, oral or non-verbal. However, in Clinical Trials of Investigational Medicinal Products (CTIMPs) consent is not considered legal unless it is in writing.

The function of a consent form is to record the participant's decision, and to indicate that the process was conducted appropriately and with suitable discussion. A signature on a consent form does not in itself make consent valid. A person's agreement with each statement contained in the consent form can be indicated by initialling or ticking boxes, or by providing the answers 'yes' or 'no' after each statement. The form itself is then signed by the parties involved in the consent conversation.

The role of the Participant Information Sheet

The Participant Information Sheet (PIS) should support the consent process by helping to ensure that all those who are invited to take part in a research study have been adequately informed. In most circumstances it should be used to support conversations with potential participants, rather than being the sole source of information being made available to them.

Effective informing should enable potential participants to make an appropriate decision that is right for them.

Potential participants must be able to understand the information given to them and consider this information in light of their own circumstances.

The PIS also provides potential participants with information to share with others who may be important to them, and who they would like to involve in the decision making process.

Testing your Participant Information Sheet with patients / other potential participants

We strongly encourage testing your Participant Information Sheet (PIS) with an appropriate group of people (patients groups or other members of the public) can be very helpful in ensuring that:

- The language used is appropriate;
- The style and format of the PIS aids understanding;
- The PIS covers the risks and benefits that are relevant to your potential participants etc.

You do not need to obtain NHS Research Ethics Committee (REC) approval to test your PIS with patient groups or others.

Involving patient groups or the public in other ways can also be invaluable, for more information please refer to our 'Links' page.

Who is the right person to seek consent?

When seeking consent from potential participants it is critical that you appropriately support them in making their decision. This includes that:

- You understand the protocol and the potential implications it may have on the people to be involved;

- You understand the alternatives that may be available to potential participants, this may include treatment alternatives;
- You have an ability to communicate effectively with potential participants, including explaining complex scientific / medical concepts;
- You appreciate how to optimise the voluntary nature of decision making, avoiding undue influence.

GCP and consent

The Research Governance Framework of each UK nation identifies the principles of Good Clinical Practice (GCP) as describing best practice in all health and social / community care research. (Extract from Principles of ICH GCP).

In Clinical Trials of Investigational Medicinal Products (CTIMPs), UK law requires compliance with the principles of GCP described in legislation. (Extract from Principles in The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, No. 1928).

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, Guideline for Good Clinical Practice (ICH GCP) provides further guidance on the information you might provide to potential participants as part of the consent process but this is not mandatory. The following is an extract of this guidance, for more information visit the ICH website. Adapt your Participant Information Sheet to your specific study (remember one size doesn't fit all).

- The study title and an invitation to participate;
- That the trial involves research;
- The purpose of the study;
- Why the potential subject has been chosen;
- The voluntary nature of participation and that subjects may withdraw from the trial at any time without penalty or loss of benefits to which they were otherwise entitled;
- The trial treatment(s) and the probability for random assignment to each treatment;
- The trial procedures to be followed, including all invasive procedures;
- Those aspects of the trial that are experimental;
- The alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks;
- The approximate number of subjects involved in the trial;
- The subject's responsibilities in the study, including the expected duration of their participation in the trial;
- The reasonably foreseeable risks or inconveniences to the subject, including specific risks of ionising radiation or pregnancy during the trial;
- The reasonably expected benefits. When there is no intended clinical benefit to the subject, they should be made aware of this;
- The subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial;
- The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated;
- Care after the trial has stopped;
- The compensation and/or treatment available to the subject in the event of trial related injury;
- The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury;

- Details of anticipated prorated payments and expenses, if any, for participating in the trial and any other arrangements for payment, including an explanation of how payment may be influenced by duration of participation or completion of diaries etc;
- Assurance that records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential;
- What subjects should do if they have a problem or a complaint regarding the trial;
- Contact details are clearly stated.

How do I ensure consent is given voluntarily?

It is important that you clearly present the voluntary nature of participation to potential participants during the consent process and in your Participant Information Sheet. Potential participants must be made aware that their care will not be affected in any way if they decide not to take part. You should also make it clear that they can choose to withdraw later, if they change their mind.

Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

At the same time, there is evidence that potential participants value help in making their decision, often from their health care practitioner.

Ensuring that decisions are made freely is largely down to the training and experience of those taking consent.

Whenever possible, potential participants should be given time to consider fully the likely implications of the research before making a decision. Potential participants should not be rushed into decisions; they should have the opportunity to discuss their decision with family and friends if they wish.

There are no fixed guidelines for an appropriate amount of time to give potential participants to consider whether to take part in research. More burdensome studies may require a longer time for deliberation while consent for simple studies, such as questionnaire based studies, could be obtained more quickly. You must consider what length of time is appropriate for your study to ensure that consent is informed and voluntary.

General principles of consent for specific studies:

Deception as part of the research method

Deception is not commonly used in research in the UK, however some researchers (e.g. clinical psychologists) do use deception to explore issues in ways that would not be possible if complete disclosure of research objectives was made during the consent process.

When deception is deemed indispensable to a study the investigators must demonstrate to a Research Ethics Committee (REC) that:

- No other research method would suffice, and
- That advances could or are likely to result from the research.

In reaching a decision, the REC will carefully consider the purpose of, and justification for the deception as well as the specific details of the proposed study.

Deception is not permissible in cases in which the deception itself would disguise the possibility of greater than minimal risk to participants. Nothing should be withheld which, if divulged, would cause a reasonable person to refuse to participate.

You should consider whether and how participants will be informed of the deception once their participation has ended. Such 'debriefing', ordinarily entails explaining the reasons for the deception.

A participant who disapproves of having been deceived should be offered the opportunity to refuse to allow the investigator to use information thus obtained.

You should be aware that some participants may resent the deception. Any participant who is upset at having been deceived should be offered the opportunity to withdraw their data from the study.

There is an important distinction between deception and sham trials. In sham trials, the participant consents to be randomly allocated to an 'active' or a 'sham' procedure. In this situation, there is no deception as the participant has been informed that they may or may not get the 'active' treatment.

Principles of consent: Adults who are not able to consent for themselves

Adults who are not able to consent for themselves should be included in research, provided that you do this in line with relevant legal frameworks and ethical principles.

You should always ensure that what capacity an adult has is optimised and used as far as possible to enable that individual to make decisions for themselves.

Guidance is provided elsewhere on how to assess capacity and when research can be conducted involving adults not able to consent for themselves. For further guidance please refer to our 'Links' page.

In this circumstance, an adult is anyone aged 16 or over.

Legal frameworks and national requirements.

The consent requirements for adults who are not able to consent for themselves, depends on the type of study and where in the UK the research is taking place. Guidance in this section is organised according to UK nation. If your study involves recruitment from more than one UK nation, you can explore other jurisdictions later.

Key points to consider are:

- Is my study a Clinical Trial of an Investigational Medicinal Product (CTIMP)?
To find out, you should visit CTIMP in our Glossary and use the MHRA algorithm. For CTIMPs the law is the same across the UK; however the details of who can give consent may vary between nations.
- If your study is not a CTIMP:
The law regulating how and when adults lacking capacity can be included in your research will vary, depending on where in the UK your research takes place.

Principles of consent: Adults not able to consent for themselves (England and Wales)

The legal frameworks that govern the inclusion of adults not able to consent for themselves in research in England and Wales are:

- Mental Capacity Act, and
- Medicines for Human Use (Clinical Trials) Regulations – applicable to CTIMP research only.

These frameworks cover many aspects of research; here we provide guidance on the principles of consent when involving adults not able to consent for themselves in England and Wales, in the following circumstances.

Clinical Trials of Investigational Medicinal Products (CTIMPs)

A legal representative can be asked to give consent on behalf of an adult lacking capacity to do so themselves.

Those who are able to act as a legal representative in Clinical Trials of Investigational Medicinal Products (CTIMPs), in England and Wales are:

- Personal legal representative i.e. a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the adult, and is available and willing to do so. If one is not available:
- Professional legal representative i.e. a doctor responsible for the medical treatment of the adult if they are independent of the study, or a person nominated by the healthcare provider.
- There is further provision for emergency situations, visit 'Emergency research'.

The legal representative must be:

- Told that they are being asked to give consent on behalf of the incapacitated adult,
- Told that they are free to decide whether they wish to make this decision or not, and
- Told that they are being asked to consider what the adult would want, and to set aside their own personal views when making this decision.
- Given sufficient information, in an understandable form, about your trial to ensure that they can make an informed decision.

The participant themselves must also receive information, according to their capacity of understanding, about the trial and its risks and benefits.

Non-CTIMPs (other intrusive research)

You should seek advice from a consultee on whether an adult lacking capacity to consent would wish to be included in your research study or not.

Consultees are not asked to give consent on behalf of the adult, but rather to provide an opinion on the views and feelings of the potential participant.

Consultees for intrusive research other than Clinical Trials of Investigational Medicinal Products (CTIMPs), in England and Wales are:

- Personal consultee, i.e. a person who cares for the adult lacking capacity or is interested in that person's welfare, but is not doing so for remuneration or acting in a professional capacity;
- If not available or unwilling to give advice then a nominated consultee i.e. a professional who is independent of the study can do so.
- There is further provision for emergency situations, visit 'Emergency research'.

The consultee must be:

- Told that they are being asked to advise on the views and feelings they believe the adult would have towards participation in your study.
- Told that they are free to decide whether they wish to provide this advice or not.

- Given sufficient information, in an understandable form, about your study to ensure that they provide you with informed advice.

The advice given by consultees should be recorded on a Consultee Declaration form (rather than a consent form). A template is available to download from 'Examples & Templates'.

You should also provide the participant themselves with information, according to their capacity of understanding, about your study and its risks and benefits.

Participants regaining capacity during your study

If it is likely adult participants might regain capacity during the course of your study, you must plan how you are going to involve them in the on-going consent process.

In most cases it is appropriate to ask them to give their own consent when and if they are able. If you intend to ask participants who regain capacity for their on-going consent you should:

- Inform the legal representative (Clinical Trials of Investigational Medicinal Products (CTIMPs)) or consultee (other intrusive research) of this at the outset
- Prepare an appropriate Participant Information Sheet and consent form for the participants themselves that explains what has happened so far, and what you are seeking their consent for.
- Plan how you will handle a participant withdrawing consent at each stage of your study, and tell them what they can expect.

Losing capacity during participation in research

If you think there is a significant risk of participants' losing capacity during your study, you should consider discussing on-going options with them during the original consent and include information in the Participant Information Sheet.

CTIMPs

- Consent to participate in a study is presumed to remain legally valid after loss of capacity (provided your protocol does not change significantly).

Other intrusive research

- In most circumstances, it is expected that the original consent should be respected.
- However, you have a legal obligation to carefully consider a request made by a representative to withdraw someone from a study, after they have lost capacity. You must consider their current situation, including possible benefits and harms that might arise as a consequence of their continued participation.
- In situations where the potential for losing capacity was discussed as part of the original consent you should still review how best to proceed if the participant does subsequently lose capacity. The original consent given by participants should not automatically be considered absolute. The current circumstances of the participant must be considered (see above).

In all cases

- You should consult with carers and take note of any signs of objection or distress from the participant.
- You must consider withdrawing a participant if they raise any objections.
- If your protocol changes during your study or you plan to obtain further consent from participants during your study, you must ask the legal representative for their consent / or consultee for advice on behalf of any adults who have lost capacity.

Principles of consent: Adults with incapacity (Northern Ireland)

The legal frameworks that govern the inclusion of adults with incapacity in research in Northern Ireland are:

- Medicines for Human Use (Clinical Trials) Regulations – applicable to CTIMP research only
- Common law.

These frameworks cover many aspects of research; here we provide guidance on the principles of consent when involving adults not able to consent for themselves in Northern Ireland, in the following circumstances.

Clinical Trials of Investigational Medicinal Products (CTIMPs)

A legal representative can be asked to give consent on behalf of an adult who lacks the capacity to do so themselves.

Those who are able to act as a legal representative in Clinical Trials of Investigational Medicinal Products (CTIMPs), in Northern Ireland are:

- Personal legal representative i.e. a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the adult, and is available and willing to do so. If one is not available:
- Professional legal representative i.e. a doctor responsible for the medical treatment of the adult if they are independent of the study, or a person nominated by the healthcare provider.
- There is further provision for emergency situations, visit 'Emergency research'.

The legal representative must be:

- Told that they are being asked to give consent on behalf of the incapacitated adult,
- Told that they are free to decide whether they wish to make this decision or not, and
- Told that they are being asked to consider what the adult would want, and to set aside their own personal views when making this decision.
- Given sufficient information, in an understandable form, about your trial to ensure that they can make an informed decision.

The participant themselves must also receive information, according to their capacity of understanding, about the trial and its risks and benefits.

Non-CTIMPs

No specific legal provision is made in Northern Ireland for the involvement of adults not able to consent for themselves in non-CTIMP research.

You should seek informed assent from a close relative or friend of an adult lacking capacity to consent themselves.

The close relative or friend should be:

- Told that they are being asked to give consent on behalf of the incapacitated adult,
- Told that they are free to decide whether they wish to make this decision or not,
- Told that they are being asked to consider what the adult would want, and to set aside their own personal views when making this decision.
- Given sufficient information, in an understandable form, about your study to ensure that they can make an informed decision.

You should also provide the participant themselves with information, according to their capacity of understanding, about your study and its risks and benefits.

Participants regaining capacity during your study

If it is likely that adult participants might regain capacity during the course of your study, you must plan how you are going to involve them in the on-going consent process.

In most cases it is appropriate to ask them to give their own consent when and if they are able. If you intend to ask participants who regain capacity for their on-going consent you must:

- Inform the legal representative (Clinical Trials of Investigational Medicinal Products (CTIMPs)) or close relative/friend (for all other research) of this at the outset.
- Prepare an appropriate Participant Information Sheet and consent form for the participants themselves that explains what has happened so far, and what you are seeking their consent for.
- Plan how you will handle a participant withdrawing consent at each stage of your study, and tell them what to expect.

Losing capacity during participation in research

If you think there is a significant risk of participants' losing capacity during your study, you should consider discussing on-going options with them during the original consent and include information in the Participant Information Sheet.

CTIMPs

- Consent to participate in a study is presumed to remain legally valid after loss of capacity (provided your protocol does not change significantly).

Other research (non-CTIMPs)

- Legally there is no specific provision for adults who lose capacity while taking part in non-CTIMPs in Northern Ireland.

- Researchers and Research Ethics Committees (RECs) might expect that in most circumstances the original consent should be respected.
- However, a request by a representative to withdraw someone from a study after they have lost capacity, should be considered carefully to ensure that it reflects the wishes of the person before they lost capacity, and that their current situation is fully considered, including possible benefits and harms that might arise as a consequence of their continued participation.

In all cases

- You should consult with carers and take note of any signs of objection or distress from the participant.
- You must consider withdrawing a participant if they raise any objections.
- The legal representative may decide to withdraw an incapable participant from your study; it is important that they make this decision having considered the wishes of a participant before loss of capacity, in light of current circumstances.
- If your protocol changes during your study or you plan to obtain further consent from participants during your study, you must ask the legal representative for their consent / close relative or friend for this assent.

Principles of consent: Adults with incapacity (Scotland)

The legal frameworks that govern the inclusion of adults with incapacity in research in Scotland are:

- Adults with Incapacity (Scotland) Act, and
- Medicines for Human Use (Clinical Trials) Regulations – applicable to CTIMP research only.

These frameworks cover many aspects of research; here we provide guidance on the principles of consent when involving adults not able to consent for themselves in Scotland, in the following circumstances.

Clinical Trials of Investigational Medicinal Products (CTIMPs)

A legal representative can be asked to give consent on behalf of an adult who lacks the capacity to do so themselves.

Those who are able to act as a legal representative in Clinical Trials of Investigational Medicinal Products (CTIMPs), in Scotland are:

- Personal legal representative i.e.
 - Adult's Welfare Guardian or Welfare Attorney, or if not appointed:
 - The adult's nearest relative, if neither are reasonably contactable:
- Professional legal representative i.e. a doctor responsible for the medical treatment of the adult if they are independent of the study, or a person nominated by the healthcare provider.
- There is further provision for emergency situations, visit 'Emergency research'.

The legal representative must be:

- Told that they are being asked to give consent on behalf of the incapacitated adult,
- Told that they are free to decide whether they wish to make this decision or not,
- Told that they are being asked to consider what the adult would want, and to set aside their own personal views when making this decision.
- Given sufficient information, in an understandable form, about your trial to ensure that they can make an informed decision.

The participant themselves must also receive information, according to their capacity of understanding, about the trial and its risks and benefits.

Non-CTIMPs (other medical, surgical, nursing, dental and psychological research)

A legal representative can be asked to give consent on behalf of an adult who lacks the capacity to do so themselves.

Those who are able to act as a legal representative in research other than Clinical Trials of Investigational Medicinal Products (i.e. non-CTIMPs), in Scotland are:

- Adult's Welfare Guardian or Welfare Attorney, if not appointed:
- The adult's nearest relative.

The legal representative must be:

- Told that they are being asked to give consent on behalf of the incapacitated adult,
- Told that they are free to decide whether they wish to make this decision or not, and
- Told that they are being asked to consider what the adult would want, and to set aside their own personal views when making this decision.
- Given sufficient information, in an understandable form, about your trial to ensure that they can make an informed decision.

You should also provide the participant themselves with information, according to their capacity of understanding, about your study and its risks and benefits.

If the participant expresses a view that they do not wish to take part in your study, this view must be acted upon.

Participants regaining capacity during your study

If it is likely that adult participants might regain capacity during the course of your study, you must plan how you are going to involve them in the on-going consent process.

In most cases it is appropriate to ask them to give their own consent when and if they are able. If you intend to ask participants regaining capacity for their consent you should:

- Inform the legal representative of this at the outset.
- Prepare an appropriate Participant Information Sheet and consent form for the participants themselves that explains what has happened so far, and what you are seeking their on-going consent for.
- Plan how you will handle a participant withdrawing consent at each stage of your study, and tell them what they can expect.

Participants losing capacity during your research

If you think there is a significant risk of participants' losing capacity during your study, you should consider discussing on-going options with them during the original consent and include information in the Participant Information Sheet.

CTIMPs

- Consent to participate in a trial is presumed to remain legally valid after loss of capacity (provided your protocol does not change significantly).

Other medical, surgical, nursing, dental and psychological research (non-CTIMPs)

- Legally there is no specific provision for adults who lose capacity while taking part in non-CTIMPs in Scotland.
- Researchers and Research Ethics Committees (RECs) might expect that in most circumstances the original consent should be respected.
- However, a request by a legal representative to withdraw someone from a study after they have lost capacity, should be considered carefully to ensure that it reflects the wishes of the person before they lost capacity, and that their current situation is fully considered, including possible benefits and harms that might arise as a consequence of their continued participation.

In all cases

- You should consult with carers and take note of any signs of objection or distress from the participant.
- You should withdraw a participant if they raise objections.
- The legal representative may decide to withdraw an incapable participant from your study; it is important that they make this decision having considered the wishes of a participant before loss of capacity, in light of current circumstances.
- If your protocol changes during your study or you plan to obtain further consent from participants during your study, you must ask the legal representative for their consent.

Principles of consent: Children and Young People

There are many ethical and legal issues to consider when involving children and young people in research.

Please refer to our 'Style' guidance for information on designing Participant Information Sheets and Consent forms for research involving children and young people.

Links to further guidance are available in 'Examples & Templates' and from our 'Links' page.

Legal frameworks and national requirements.

The requirements for consent, where participants are children and/or young people, depend on:

- The type of study; and
- Where in the UK it is taking place.

The guidance in this section is organised according to UK nation.

If your study involves recruitment from more than one UK nation, you can explore other jurisdictions later.

Key points to consider are:

- Is my study a Clinical Trial of an Investigational Medicinal Product (CTIMP)?
To find out, you should visit CTIMP in our Glossary and use the MHRA algorithm. For CTIMPs the law is the same across the UK.
- If your study is not a CTIMP:
The law regulating how children and young people can be included in your research will vary, depending on where in the UK your research takes place.

The concepts of consent and assent.

Consent is a legally defined decision given by someone who is competent, who has been adequately informed (and has adequate understanding), and who is free from undue influence enabling them to make a voluntary decision. The person can provide consent themselves (provided they are competent). Otherwise someone else who is empowered by law can provide it (e.g. a parent in the case of children). A child who is not capable of giving consent alone can still be involved in the decision-making process with others who are able in law, to provide consent.

Assent is difficult to define and is used in diverse ways, e.g. compliance by a child as young as three, through to the active agreement of a young teenager etc. Assent is agreement given by a child / young person, or others who are not legally empowered to give consent. It is important to provide children / young people with information that matches their capacity when seeking assent.

Principles of consent: Children and Young People (England, Wales and Northern Ireland)

From here you can access specific guidance on consent by and on behalf of children and young people in England, Wales and Northern Ireland. We include information on involving children and young people in the consent process including when to seek assent.

[Consent for under 16s in Clinical Trials of Investigational Medicinal Products \(CTIMPs\)](#)

The Medicines for Human Use (Clinical Trials) Regulations prohibit children under the age of 16 from giving consent to take part in a Clinical Trial of an Investigational Medicinal Product (CTIMP).

Those who are able to give consent on behalf of children / young people, to take part in a CTIMP, in the UK are:

- Parent or someone with parental responsibility (agreement of only one parent is required).
- Personal legal representative i.e. a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the child / young person, and is available and willing to do so.
A legal representative should only ever be approached if someone with parental responsibility cannot be contacted prior to the proposed inclusion of the child / young person, by reason of the urgent nature of the treatment provided as part of the trial. If a personal legal representative is not available:
- Professional legal representative i.e. a doctor responsible for the medical treatment of the child / young person if they are independent of the study, or a person nominated by the healthcare provider.

You must ensure that parents or legal representatives:

- Understand that you are asking them to give consent on behalf of the child / young person.
- Understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
- Have been informed of the right to withdraw the child / young person from the trial at any time.
- Have a contact point where further information about the trial can be obtained.

Children and young people should be involved in the decision-making process whenever possible. You should ensure that they receive information about your trial, which is understandable to them (visit 'Children's / young people's wishes and assent' below).

[Consent for over 16s in Clinical Trials of Investigational Medicinal Products \(CTIMPs\)](#)

Young people over 16 are presumed to be capable of giving consent on their own behalf to participate in Clinical Trials of Investigational Medicinal Products (CTIMPs).

Any young person, over 16, who is not capable of giving consent, should only be included in a CTIMP in the UK in line with the adult provisions of the Medicines for Human Use (Clinical Trials) Regulations. For guidance visit 'Principles> Adults lacking capacity (England and Wales)> CTIMPs' or 'Principles> Adults lacking capacity (Northern Ireland)> CTIMPs

Consent in Non-CTIMPs

There is no statute in England, Wales or Northern Ireland governing a child's right to consent to take part in research other than a Clinical Trial of an Investigational Medicinal Product (CTIMP), i.e. consent for non-CTIMPs.

Consent for treatment

- However common law presumes that young people aged between 16 and 18 are usually competent to give consent to treatment.
- Case law suggests that if a young person has sufficient understanding and intelligence to understand fully what is proposed, and can use and weigh this information in reaching a decision (i.e. they are 'Gillick competent'), he or she can give consent to treatment.
- When a child or young person is not competent, the Children Act and the Children Act (Northern Ireland) Order permits parents (and those with parental responsibility) to consent to medical treatment on their behalf. Consent of only one parent is required.
- When a young person is believed to be competent, consent from those with parental responsibility is not legally necessary. However, the involvement of parents in decision-making is encouraged in most circumstances.

Consent for research

- In the absence of law relating specifically to research, it is commonly assumed that the principle of 'Gillick competence' can be applied not only to consent for treatment, but also to consent for research.

A child / young person's right to give consent is dependent upon their capacity to understand the specific circumstances and details of the research being proposed, which in turn will relate to the complexity of the research itself.

Children and young peoples' competence may well be reflected in their ability or otherwise to understand and assess risk.

Competence to understand will be heavily influenced by how the information is presented to the child or young person, and the language used. You must ensure that you maximise a child / young person's chances of understanding what is involved in your study.

Even when a child or young person is competent, it is still normally good practice to involve the family in the decision-making process: however, if the young person objects, you should respect their privacy.

You should be aware that the voluntariness of a child's or young person's decision making is difficult both to determine and to secure.

Providing information in a format that is understandable to children and young people, and doing so in a manner that fosters true voluntary decision-making, are skills that require specific experience and expertise.

If a child or young person is not deemed to be sufficiently competent to give consent themselves to participate in non-CTIMP research; you are encouraged to inform them to the fullest of their understanding and enable them to participate in an assent process whenever this is appropriate.

Children's / young people's wishes and assent

Even when a child or young person is deemed not competent to make a decision for themselves, or in situations where they are not legally empowered to do so (e.g. in a Clinical Trial of an Investigational Medicinal Product (CTIMP)), it is important that:

- You give the child / young person information about your study, which is understandable to them and which explains what is involved and the potential risks and benefits.
- Staff with experience of working with children / young people should provide this information.
- If the child or young person is capable of assessing the information provided you must consider their explicit wishes. This includes their refusal to take part, or desire to withdraw from the study.
- It is usually inappropriate to ask very young children (e.g. under 5's) to sign an assent form, however their views should be considered.

Whenever practical and appropriate, a child's assent should be sought before including them in your research.

When is it appropriate to seek assent from a child? You have to make an informed judgment to determine when seeking assent is appropriate; the age of a child can only be taken as a guide. We would usually consider it inappropriate to obtain written assent from very young children.

Consider also the child's developmental stage, knowledge of illness and experience of health care.

How are decisions usually made in the family? How much autonomy does the child normally exercise? From observation does the child wish to be involved in the discussions?

What are the parents' views and can they help with this decision? They know the child best.

Although there is a danger that children can be asked to exercise greater autonomy than normal, this must be balanced with the potential loss of trust associated with denying their assent.

Such judgment needs a framework of considerations for analysis, a record of observations and discussions and a documented decision.

In circumstances where seeking assent at the outset is not appropriate, you could provide the child with information as and when required (i.e. 'drip feeding').

[Consent for 16 and 17 year olds who lack capacity](#)

Clinical Trials of Investigational Medicinal Products (CTIMPs)

If a young person, aged 16 or over, is deemed not to be competent to give consent to participate in a Clinical Trial of an Investigational Medicinal Product (CTIMP); you must proceed in line with the Medicines for Human Use (Clinical Trials) Regulations. For guidance visit 'Principles> Adults lacking capacity (England and Wales)> CTIMPs' or 'Principles> Adults lacking capacity (Northern Ireland)> CTIMPs

Other intrusive research (non-CTIMPs)

If a young person, aged 16 and over, is deemed not to be competent to give consent themselves to participate in a non-CTIMP; you must proceed in line with the Mental Capacity Act (in England and Wales) or common law (in Northern Ireland). For guidance visit 'Principles> Adults lacking capacity (England and Wales)> non-CTIMPs' or 'Principles> Adults lacking capacity (Northern Ireland)> non-CTIMPs'.

Principles of consent: Children and Young People (Scotland)

From here you can access specific guidance on the principles of consent by and on behalf of children and young people in Scotland. We include information on involving children and young people in the consent process including when to seek assent.

[Consent for under 16s in Clinical Trials of Investigational Medicinal Products \(CTIMPs\)](#)

The Medicines for Human Use (Clinical Trials) Regulations prohibit children under the age of 16 from giving consent to take part in a Clinical Trial of an Investigational Medicinal Product (CTIMP).

Those who are able to give consent on behalf of children / young people under 16, to take part in a CTIMP, in the UK are:

- Parent or someone with parental responsibility (agreement of only one parent is required).
- Personal legal representative i.e. a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the child / young person, and is available and willing to do so.
A legal representative should only ever be approached if someone with parental responsibility cannot be contacted prior to the proposed inclusion of the child / young person, by reason of the urgent nature of the treatment provided as part of the trial. If a personal legal representative is not available:
- Professional legal representative i.e. a doctor responsible for the medical treatment of the child / young person if they are independent of the study, or a person nominated by the healthcare provider.

You must ensure that parents or legal representatives:

- Understand that you are asking them to give consent on behalf of the child / young person.
- Understand the objectives, risks and inconveniences of the trial and the conditions under which it is to be conducted.
- Have been informed of the right to withdraw the child / young person from the trial at any time.
- Have a contact point where further information about the trial can be obtained.

Children and young people should be involved in the decision-making process whenever possible. You should ensure that they receive information about your trial, which is understandable to them (visit 'Children's / young people's wishes and assent' below).

Consent for over 16s in Clinical Trials of Investigational Medicinal Products (CTIMPs)

Young people over 16 are presumed to be capable of giving consent on their own behalf to participate in Clinical Trials of Investigational Medicinal Products (CTIMPs).

Any young person, over 16, who is not capable of giving consent, should only be included in a CTIMP in the UK in line with the adult provisions of the Medicines for Human Use (Clinical Trials) Regulations. For guidance visit 'Principles> Adults with incapacity (Scotland)> CTIMPs'.

Consent in Non-CTIMPs

There is no specific provision in Scots law governing a child's right to consent to take part in research, other than a Clinical Trial of an Investigational Medicinal Product (CTIMP), i.e. consent for non-CTIMPs.

Consent for treatment

- Young people aged 16 and over are deemed to be competent to give consent for medical treatment unless proven otherwise.
- Children and young people under 16 have a statutory right to give consent to surgical, medical or dental procedures or treatments if they are deemed, by a medical practitioner, to be competent to do so.
- The Children (Scotland) Act permits parents (or those with parental responsibility) to give consent on behalf of a young person under 16 who is not competent. Consent of only one parent is required.

Consent for research

- It is commonly accepted that we can extrapolate a child / young person's right to give consent for treatment, to give them the right to give consent to take part in non-CTIMP research.
- It is commonly assumed that they also have a legal right to object to participation.

A child / young person's right to give consent is dependent upon their capacity to understand the specific circumstances and details of the research being proposed, which in turn will relate to the complexity of the research itself.

Children and young peoples' competence may well be reflected in their ability or otherwise to understand and assess risk.

Competence to understand will be heavily influenced by how the information is presented to the child or young person, and the language used. You must ensure that you maximise a child / young person's chances of understanding what is involved in your study.

Even when a child or young person is competent, it is still normally good practice to involve the family in the decision-making process: however, if the child / young person objects, you should respect their view.

Case law suggests that a parent may not be able to overrule the decision of a competent child / young person in Scotland.

The Children (Scotland) Act states that children from the age of 12 are considered sufficiently mature to form a view, even if they are not considered fully competent to give consent.

You should be aware that the voluntariness of a child / young person's decision making is difficult both to determine and to secure.

Providing information in a format that is understandable to children and young people, and doing so in a manner that fosters true voluntary decision-making, are skills that require specific experience and expertise.

If a child or young person is not deemed to be sufficiently competent to give consent themselves to participate in non-CTIMP research; you are encouraged to inform them to the fullest of their understanding and enable them to participate in an assent process whenever this is appropriate.

Children's / young people's wishes and assent

Even when a child or young person is deemed not competent to make a decision for themselves, or in situations where they are not legally empowered to do so (e.g. in a Clinical Trial of an Investigational Medicinal Product (CTIMP)), it is important that:

- You give the child / young person information about your study, which is understandable to them and which explains what is involved including potential risks and benefits.
- Staff with experience of working with children should provide this information.
- If the child or young person is able to assess the information provided, you must consider the explicit wishes expressed by them. This includes their refusal to take part, or their desire to withdraw from the study.
- Whenever practical and appropriate, a child / young person's assent should be sought before including them in research.
- If parents provide consent, the aim of informing the child or young person to obtain assent may be more about comprehension rather than completeness in information provision.
- It is usually inappropriate to ask very young children to sign an assent form.

When is it appropriate to seek assent from a child? In Scots law, children over the age of 12 are usually considered to be sufficiently mature to form a view, even if they are not considered fully competent to give consent.

You have to make an informed judgment to determine when seeking assent is appropriate; the age of a child can only be taken as guide.

Consider also the child's developmental stage, knowledge of illness and experience of health care.

How are decisions usually made in the family? How much autonomy does the child normally exercise? From observation does the child wish to be involved in the discussions?

What are the parents' views and can they help with this decision? They know the child best.

Although there is a danger that children can be asked to exercise greater autonomy than normal, this must be balanced with the potential loss of trust associated with denying their assent.

Such judgment needs a framework of considerations for analysis, a record of observations and discussions and a documented decision.

In circumstances where seeking assent at the outset is not appropriate, you could provide the child with information as and when required (i.e. 'drip feeding').

Consent for 16 and 17 year olds who lack capacity

Clinical Trials of Investigational Medicinal Products (CTIMPs)

If a young person, aged 16 or over, is deemed not to be competent to give consent to participate in a Clinical Trial of an Investigational Medicinal Product (CTIMP); you must proceed in line with the Medicines for Human Use (Clinical Trials) Regulations. For guidance visit 'Principles> Adults with incapacity (Scotland)> CTIMPs'.

Other medical, surgical, nursing, dental or psychological research (non-CTIMPs)

If a young person, aged 16 and over, is deemed not to be competent to give consent themselves to participate in a non-CTIMP; you must proceed in line with The Adults with Incapacity (Scotland) Act. For guidance visit 'Principles> Adults with incapacity (Scotland)> non-CTIMPs'.

Principles of consent: Emergency research

Emergency research poses its own set of challenges in terms of providing information about the research and obtaining consent.

Emergency research is when:

- Treatment needs to be given urgently, and
- It is necessary to take urgent action for the purposes of the study.

In some emergency situations:

- Potential participants may lack capacity to give consent themselves, and
- Obtaining consent from a legal representative / consulting others is not reasonably practicable.

Guidance is provided here on how to proceed in such situations. It is organised according to UK nation.

Key points to consider are:

- Is my study a Clinical Trial of an Investigational Medicinal Product (CTIMP)?
To find out, you should visit CTIMP in our Glossary and use the MHRA algorithm.
For CTIMPs the law is the same across the UK; although the details of who can give consent may vary between nations.
- If your study is not a CTIMP:
The law regulating how children or adults can be included in your emergency research will vary, depending on where in the UK your research takes place.

Principles of consent: Emergency Research (England and Wales)

From here you can access guidance on the inclusion of both adults lacking capacity and children / young people in emergency research in England and Wales.

[Adults not able to consent for themselves in emergency Clinical Trials of Investigational Medicinal Products \(CTIMPs\)](#)

In the UK the law allows adults not able to consent for themselves to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if:

- Treatment needs to be given urgently;
- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by a NHS Research Ethics Committee;
- Consent is sought from a legal representative as soon as possible.

Adults recruited in such a manner may regain their capacity to give consent; for further guidance visit 'Principles> ALC(England and Wales)> Regain capacity'.

Adults not able to consent for themselves in other intrusive emergency research

In England and Wales the law allows adults not able to consent for themselves to be recruited into other intrusive research (i.e. research other than Clinical Trials of Investigational Medicinal Products) without prior advice from a consultee, in emergency situations if:

- Treatment needs to be given urgently;
- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to seek advice from a consultee;
- The procedure is approved by a NHS Research Ethics Committee; and
- A consultee is consulted as soon as possible to seek advice on the participant's likely views and feelings.

Adults recruited in such a manner may regain their capacity to give consent; for further guidance visit 'Principles> ALC(England and Wales)> Regain capacity'.

Children / young people in emergency CTIMPs

The law allows children and young people (under the age of 16) to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if:

- Treatment needs to be given urgently;
- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by a NHS Research Ethics Committee; and
- Consent is sought from a person with parental responsibility or a legal representative as soon as possible.

Young people over the age of 16 are considered to be adults in terms of the law governing the conduct of clinical trials. For further guidance on adults not able to consent for themselves in Clinical Trials of Investigational Medicinal Products visit 'Principles> ALC(England and Wales)> CTIMPs'

Children / young people in other emergency research

Common law would appear to enable research involving children and young people in emergency situations without prior consent, if:

- You first obtain NHS Research Ethics Committee approval, and
- You cannot address the same research question by recruiting from a non-emergency environment, and
- Your research is of potential benefit to the child / young person themselves, and

- Someone with parental responsibility for the child / young person is informed about the research as soon as possible, and
- Consent (and assent) is sought as soon as possible, and
- You make clear to the child / young person or their parent (if the child / young person is not competent) that the child / young person can withdraw (or be withdrawn by their parent) at any time without penalty.

If you cannot guarantee a potential direct benefit, the law is unclear. In such a case, The Council of Europe recommends that you must be able to ensure that your research will benefit others with a similar condition, and the risk to participants is minimal.

Principles of consent: Emergency Research (Northern Ireland)

From here you can access guidance on the inclusion of both adults lacking capacity and children / young people in emergency research in Northern Ireland.

[Adults not able to consent for themselves in emergency Clinical Trials of Investigational Medicinal Products \(CTIMPs\)](#)

In the UK the law allows adults not able to consent for themselves to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if:

- Treatment needs to be given urgently;
- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by a NHS Research Ethics Committee;
- Consent is sought from a legal representative as soon as possible.

Adults recruited in such a manner may regain their capacity to give consent; for further guidance visit 'Principles> AWI (Northern Ireland)> Regain capacity'.

[Adults not able to consent for themselves in other emergency research](#)

There is no specific provision for including adults not able to consent for themselves in other emergency research in Northern Ireland; apart from in Clinical Trials of Investigational Medicinal Products (CTIMPs).

[Children / young people in emergency CTIMPs](#)

The law allows children and young people (under the age of 16) to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if:

- Treatment needs to be given urgently;

- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by a NHS Research Ethics Committee; and
- Consent is sought from a person with parental responsibility or a legal representative as soon as possible.

Young people over the age of 16 are considered to be adults in terms of the law governing the conduct of clinical trials. For further guidance on adults not able to consent for themselves in Clinical Trials of Investigational Medicinal Products visit 'Principles> AWI (Northern Ireland)> CTIMPs'

[Children / young people in other emergency research](#)

Common law would appear to enable research involving children and young people in emergency situations without prior consent, if:

- You first obtain NHS Research Ethics Committee approval, and
- You cannot address the same research question by recruiting from a non-emergency environment, and
- Your research is of potential benefit to the child / young person themselves, and
- Someone with parental responsibility for the child / young person is informed about the research as soon as possible, and
- Consent (and assent) is sought as soon as possible, and
- You make clear to the child / young person or their parent (if the child / young person is not competent) that the child / young person can withdraw (or be withdrawn by their parent) at any time without penalty.

If you cannot guarantee a potential direct benefit, the law is unclear. In such a case, The Council of Europe recommends that you must be able to ensure that your research will benefit others with a similar condition, and the risk to participants is minimal.

Principles of consent: Emergency Research (Scotland)

From here you can access guidance on the inclusion of both adults lacking capacity and children / young people in emergency research in Scotland.

[Adults lacking capacity in emergency Clinical Trials of Investigational Medicinal Products \(CTIMPs\)](#)

In the UK the law allows adults with incapacity to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if:

- Treatment needs to be given urgently;
- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by a NHS Research Ethics Committee;
- Consent is sought from a legal representative as soon as possible.

Adults recruited in such a manner may regain their capacity to give consent; for further guidance visit 'Principles> AWI (Scotland)> Regain capacity'.

Adults lacking capacity in other emergency research

The law in Scotland demands that consent be in place before research other than Clinical Trials of Investigational Medicinal Products can begin. The law does not provide any 'exemptions' or alternatives for the involvement of adults not able to consent for themselves in non-CTIMP research, even in emergency situations.

Therefore, to include an adult not able to consent for themselves in emergency non-CTIMP research in Scotland, you must obtain consent before the adult can be involved in your study from:

- Welfare Attorney / Welfare Guardian, if not appointed
- Adults nearest relative

Adults recruited in such a manner may regain their capacity to give consent; for further guidance visit 'Principles> AWI (Scotland)> Regain capacity'.

Children / young people in emergency CTIMPs

The law allows children and young people (under the age of 16) to be recruited into Clinical Trials of Investigational Medicinal Products (CTIMPs) without prior consent in emergency situations if:

- Treatment needs to be given urgently;
- It is also necessary to take urgent action to administer the drug (IMP) for the purposes of the trial;
- It is not reasonably practicable to obtain consent from a legal representative;
- The procedure is approved by a NHS Research Ethics Committee; and
- Consent is sought from a person with parental responsibility or a legal representative as soon as possible.

Young people over the age of 16 are considered to be adults in terms of the law governing the conduct of clinical trials. For further guidance on adults not able to consent for themselves in Clinical Trials of Investigational Medicinal Products visit 'Principles>AWI (Scotland)> CTIMPs'.

Children / young people in emergency non-CTIMPs

The involvement of children and young people in research without prior consent in emergency situations would be considered ethical, if:

- You first obtain NHS Research Ethics Committee approval, and
- You cannot address the same research question by recruiting from a non-emergency environment, and
- Your research is of potential benefit to the child / young person themselves, and
- Someone with parental responsibility for the child / young person is informed about the research as soon as possible, and

- Consent (and assent) is sought as soon as possible, and
- You make clear to the child / young person or their parent (if the child / young person is not competent) that the child / young person can withdraw (or be withdrawn by their parent) at any time without penalty.

If you cannot guarantee a potential direct benefit, the law is unclear. In such cases, The Council of Europe recommends that you must be able to ensure your research will benefit others with a similar condition, and the risk to participants is minimal.

Principles of consent: Deceased people

Consent given prior to death, is believed to extend beyond death.

However, relatives may have a different opinion, once their relative has died. This should be handled sensitively with relatives being encouraged to respect the deceased person's wishes (or in certain cases, their nominated representative / nominee, see below).

In legal terms, the Data Protection Act no longer applies to identifiable data that relate to a person once they have died.

However any duty of confidence established prior to death does extend beyond death. It is important to maintain confidentiality to ensure that trust in services and institutions are not undermined. Disclosure of confidential information post mortem therefore requires consent to extend the duty of confidence.

If you intend to collect tissue from a deceased person, to use tissue removed from the deceased or to conduct a post mortem purely for research purposes consent is required across the UK.

Tissue removed as part of a Coroner's / Procurator Fiscal's post mortem can be used for research, once they are no longer required for such legal purposes, however consent for use in research must be in place.

Although legal details may vary between the nations within the UK, the same basic legal and ethical principles apply in terms of the consent required:

- The person themselves can give consent for their tissues to be used for research prior to their death. If the person was not able to consent for themselves prior to death (due to lack of capacity), someone else may have been asked to provide consent, assent or advice on their behalf (visit 'Principles > Adults who are not able to consent for themselves').
- Consent given before death should be respected, even when relatives may initially disagree.
- If consent is not in place, and the person has not specifically refused prior to their death:
 - In **England, Wales and Northern Ireland** an adult can nominate someone to represent them after their death and to give consent on their behalf. The nominated representative's consent cannot be overridden by other individuals, including those in a qualifying relationship.
 - In **Scotland** a person can be nominated by anyone (aged 12 or over) before their death, to represent them after death. A nominee can then give authorisation (equivalent to consent) on behalf of the deceased person.
- If consent has not been sought from the above, the following can provide legally appropriate consent (or 'authorisation' in Scotland) on behalf of the deceased person:
 - In **England, Wales and Northern Ireland**, those in a qualifying relationship.
 - In **Scotland**, nearest relative.

For further guidance visit the HTA consent code of practice.

Style: What makes a good Participant Information Sheet

In this section we cover general guidance on design and style of a Participant Information Sheet (PIS). We highlight what to consider when your research involves: Adults not able to consent for themselves, Children and Young people and/or Emergency research.

The right style will engage the reader, and help to establish a rapport by fully respecting their perspective and exploring all of the issues that are important to them. If designed well, a PIS is a valuable tool which facilitates effective communication and supports shared decision making.

This guidance is designed to be comprehensive, so not all of it will be relevant to your specific research.

General style guidance for all/most studies:

One size does not fit all

Not all research studies are the same. The information required to enable potential participants to decide if they wish to take part will therefore vary.

Different populations will have different information needs, different levels of understanding of medical terminology and different reading abilities.

The level of detail should be appropriate to the nature and burden of the study.

For example:

- You can explain a questionnaire study may be summarised on the front of the questionnaire itself, and completion of the questionnaire would be regarded as consent:

Whilst

- The Participant Information Sheet for a Clinical Trial of an Investigational Medicinal Product (CTIMP) will need to be significantly more detailed.

Proportionality: how long should a Participant Information Sheet be?

We advocate a proportionate approach. Consent arrangements must match the study's burden and risk/benefit profiles as well as the complexity of the protocol. A Participant Information Sheet (PIS) should be as long as it needs to be.

If your PIS is too long, there is a risk that potential participants will not read all of it.

Careful layout can make a big difference in how easy a PIS is to read. Adding a contents page may add length, but it can help the reader to locate relevant information.

If the PIS is likely to be lengthy (e.g. more than a few pages) then we suggest splitting your PIS into three sections (e.g. introduction, what's involved and supporting / further information), and using subheadings to break up content further.

Importance of your study title

The study title is part of the explanation of your research: you should never underestimate its importance. When well designed, the title provides a concise summary of your study in language most potential participants would understand.

A consistent study title should appear on all of your documents and be comprehensible to your potential participants.

For interventional studies you could consider the acronym - I.P.O.C. - Intervention, Population, Outcome, Comparator to help you structure a meaningful title.

Further guidance on study title is provided in our 'Links' page.

Invitational style

The Participant Information Sheet (PIS) should be a polite invitation to take part in your research; setting out the possible advantages and disadvantages, placing participation in the context of other options available and describing what potential participants can expect.

You should employ a polite tone throughout your PIS.

Do not use the passive voice

Conversational style in the active voice is found to be more effective than using the passive voice; so use the active voice and the pronoun 'we' throughout.

For example use:

- 'We would like to invite you to take part in...'
- 'We intend to collect an additional blood sample when you attend your next clinic...'
- 'We will post a questionnaire to you...', instead of 'questionnaires will be posted ...'
- '... We will send your samples to colleagues in America for analysis ...', instead of '... Samples will be sent to America for analysis ...'

Use plain English and avoid jargon

- Remember who is going to be reading your Participant Information Sheet (PIS).
- Use short, familiar words and short sentences.
- Write in simple, non-technical terms that a lay person will easily understand.
- The language used should be no more difficult to read than information leaflets for medicines or tabloid newspapers.
- You can use the readability statistics function available in Microsoft Word to calculate a readability score.
- Potential participants should be able to understand the PIS on the first reading.
- All of your potential participants should be able to understand your PIS.

- Remember that some patients might be very familiar with certain technical terms, but not with all medical terminology. Other groups (the newly diagnosed or the general public) may not be familiar with many relevant technical terms.
- When technical terms have to be included you may wish to provide the lay term first followed by the technical term in brackets. For example:
 - Feeling sick (nausea)
 - Blood clot on your leg (deep vein thrombosis or DVT)
- When preparing a PIS for an international study, remember that there are terms which have quite specific regional use, for example A&E (UK) instead of ER (USA).

The Cochrane Collaboration suggests that when writing for the general public you should:

- Limit sentences to no more than approximately 20 words, when possible.
- Don't introduce more than one idea/point in a sentence. If your next sentence does not directly follow the previous one, start a new paragraph.
- Avoid potentially misunderstood words (more obscure or commonly misunderstood) or phrases or words with dual or nuanced meanings (e.g. drugs; diet); especially those likely to cause difficulty to those who have English as a second or third language.
- Hard words are technical words, jargon, not commonly used words, or words that are long or with many syllables.
- Avoid more than 2 hard words in a sentence unless it is a term that is explained (consider introducing an acronym or shorter term for repeated use).

Instead of using Microsoft Word to calculate readability scores, you could calculate the Flesch Reading Ease score or Fog Score (or an equivalent) and consider how you might improve it. To find out how to calculate the Flesch or Fog Score visit 'Examples & Templates'.

Format

You should use the format best suited to the nature of the information that you wish to give potential participants, and which supports understanding.

In terms of written information, the following are worth considering:

- Use short headings that stand out.
- A question and answer format is often effective.
- Use type as large as possible - size 16 font if you intend to recruit elderly subjects.
- Leave 'white space' - avoid large sections of unbroken text or long lists.
- Use bullets for lists.
- Use non-justified text.
- Use bold lower case for emphasis.
- Consider the appropriate page size – it may be that A5, or another paper-size and layout would be more suitable than A4.
- In some cases, it might be more appropriate to use other media to support the consent process; for example DVDs, CDs, a script etc.

Using different ways of explaining

There are many ways of describing to potential participants what to expect. You could consider using flow diagrams or pictures if you feel they bring more clarity to the information

you are providing. However, consider their use carefully as they do not necessarily help in all cases.

If you are consenting people who cannot read, we would suggest the Participant Information Sheet is still used; read to the potential participant as a 'script'.

Participants' perspective

The purpose of a Participant Information Sheet (PIS) is to set out in writing what taking part in your study will involve for the participant. Including how participation may impact on their treatment and/or their lives and the lives of others close to them.

You must consider the potential participants' perspective. There are issues that might be very important to some people, like:

- How many times will I have to come to the hospital / research clinic?
- Will my partner, carer, friend be able to come with me?
- Will I have to take time off work to take part in this research? Etc.

Consult patients or members of the public to find out the types of issues that might be relevant to your potential participants.

Clarity about expected risks and benefits

In order to facilitate fair decision-making, you must state clearly what the risks and benefits of your study realistically are.

Risk is not easy to describe in a meaningful way. You should give potential participants an honest appraisal of how likely an event is to happen during the course of your study: together with an estimate of the likely impact such an event might have on them.

Potential risks and benefits are estimated from what is currently known about the treatment or intervention used. Potential participants should be made aware of the context in which you are estimating potential risk (e.g. this drug has been given to x people so far and... or this drug is commonly prescribed to people with y and....)

Consulting others from your potential pool of participants (patient groups or other lay people) will help you to describe risk effectively, and identify what is likely to be important to potential participants.

Different groups - different information sheets?

If you intend to recruit two or more different groups of people to your study, you might consider if you need to provide each group with their own Participant Information Sheet (PIS).

In many cases each group may:

- Have a different set of alternatives available to them;
- Have different levels of understanding of some technical terms;
- Understand or perceive risk in a different way;
- Have very different expectations in terms of the possible benefits of taking part;

- Have different visual or other accessibility needs etc.

Attempting to write a single PIS that is appropriate to all groups can lead to confusion, lack of clarity and increased length.

Test with relevant people - check you have got it right

You should test your Participant Information Sheet with an appropriate group of people (patient groups or other members of the public) to get help with:

- Your use of language;
- Describing risk/benefit and advantages/disadvantages from the potential participants' perspective;
- Choosing the most appropriate format (including font size, paper size, layout preferences, use of pictures and /or diagrams etc.)

You do not need to obtain NHS Research Ethics Committee (REC) approval to test your consent documents.

Style guidance for specific types of study:

Adults not able to consent for themselves

When approaching legal representatives, consultees, close relatives or close friends and asking for their consent, advice or assent you must address the Participant Information Sheet (PIS) to them, as the reader.

The PIS should:

- Invite them to act as legal representative or consultee, making it clear that they are not obliged to take on this role; and
- Ask them to consider the information you provide on your study, in light of their relative's / friend's views and needs, rather than their own, so that they can make an informed decision or give informed advice; and
- In England and Wales where advice is sought from a consultee, this should be recorded on a Consultee Declaration form.

If you are unclear on the law and/or terminology used in each UK nation, please visit 'Principles> Adults lacking capacity'.

Children and young people

A Participant Information Sheet (PIS) should be designed for each appropriate age/competence range.

These age ranges may differ depending on the type of study, the condition or the population being approached.

When seeking assent, an information sheet for children and young people should be much shorter and simpler than a PIS designed for obtaining consent.

When seeking assent, it is perhaps more important that the child / young person understands what is involved in general terms rather than attempting to ensure that they fully understand every detail of what is being proposed. For younger potential participants you could consider the careful use of pictures, if you believe they will support understanding.

Consider the child / young person's world. It is important to indicate how the study will affect them at home, school and in his/her social activities.

Studies with little or no intervention and posing minimal risk are likely to need a much shorter information sheet. You will not need to cover all of the issues given in this guidance

If appropriate, the risks of pregnancy and requirements for contraception should be handled sensitively (visit 'Content > PIS > Young people and pregnancy')

Information provided by a series of workshops held with young people from the NIHR Medicines for Children Research Network (MCRN) Young Persons' Advisory Group (YPAG). Further guidance is provided on our 'Links' page.

Emergency research

The style of Participant Information Sheet (PIS) delivered in an emergency situation should be designed with that specific use in mind.

It should be short, easy to read but contain sufficient detail to enable an informed decision to be made.

You might consider preparing a summary PIS, as well as an accompanying full length PIS.

Participants or those giving consent/advice on their behalf, could consider the full length PIS when the urgency has passed, and when they have time to fully consider the details of what is involved.

Content

This section focuses on the content of consent documents: Participant Information Sheet (PIS) and Consent Form. It is designed to act as a framework, not a rigid template (if guidance isn't relevant to your research, don't include it - remember one size doesn't fit all). You should consider what you do, and do not, need to include in your own PIS and consent form whilst reading through the guidance.

The purpose of consent documentation is to provide appropriate information to support potential participants in making a decision that is right for them and then to record their decision.

- > Participant Information Sheet
- > Consent form

Content: Participant Information Sheet

The content of your Participant Information Sheet (PIS) should describe clearly what a potential participant should expect if they agreed to take part in your study. You should simply provide sufficient and appropriate information on which they can base an informed decision.

We would suggest that you consider covering the following areas in your PIS. These areas are designed to act as a framework, not a rigid template (remember one size doesn't fit all - only include what is appropriate for your research). You should also consider how your layout and language might help to optimise understanding (further guidance is provided in 'Style').

Content: Participant Information Sheet Title

Document should be headed: 'Patient information sheet', 'Participant information sheet' or 'Information about the research'.

A consistent study title should appear on all the documents which is understandable to the intended audience. The title should explain the study in simple English.

To help you construct a meaningful title, you could consider using the acronym – I.P.O.C:

- Intervention
- Population
- Outcome
- Comparator (if appropriate)

Further guidance on study title is provided on our 'Links' page.

Content: Participant Information Sheet - Invitation and Summary

The purpose of the first section of your Participant Information Sheet is to enable potential participants to decide if they wish to learn more about your study or not. It should briefly give some background and invite their participation.

There are two elements to be included.

Invitation

You should make it clear that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary.

You should explain briefly how potential participants have been identified and why they have been selected.

Example text:

We'd like to invite you to take part in our research study. Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We'd suggest this should take about XX minutes. Please feel free to talk to others about the study if you wish.

The first part of the Participant Information Sheet tells you the purpose of the study and what will happen to you if you take part.

Then we give you more detailed information about the conduct of the study.

Do ask if anything is unclear.

Inviting Adults not able to consent for themselves

When recruiting adults who lack the capacity to consent to your research, you will need to invite either their legal representative or consultee to give consent / provide advice (For more guidance visit 'Content > PIS > Adults not able to consent for themselves').

You must ensure that you inform legal representatives / consultees:

- What you are asking them to do. (i.e. provide consent or advice?)
- Why you are asking them.
- What they must consider when making their decision / providing advice.
- That their role is voluntary; they are not obliged to take on the role.

Further guidance on the legal and ethical principles involved is provided in our 'Principles' section.

Summary

You should provide a short summary of the proposed research, which covers the following:

- Why?
 - What research question is being addressed?
 - How is it of relevance and importance to participants / patients and public?
- What?
 - Broadly what areas (disease, therapy or service) are being studied?
 - What drug, device or procedure is being tested?
 - What will the participant have to do?
 - What will it mean to participants to take part?
- Who?
 - Who would be eligible?
- Where?
 - The sites where the study will be conducted

- How, when?
- How long will the study last; when will it start and end?

Do not to go into too much detail but try to ensure that potential participants can get a clear but concise picture of the research you are asking them to take part in.

To see an example of how you might improve your study summary we recommend that you see the Participant Information Sheet for Newland Hill before and after in 'Examples & Templates'. We would also recommend that you read the guidance in our 'Style' section.

Content: Participant Information Sheet - What's involved

This section should introduce more detailed information that will allow potential participants to make a decision: to agree to take part in your research or to decline.

It should provide clear information on the essential elements of the study, such as:

- The condition or treatment under study;
- For studies involving therapeutic interventions, clarity on which elements of your study are research and which constitute standard care;
- Alternatives to participation (particularly important in therapeutic trials involving patients);
- What will happen to participants during and after the research study;
- The potential benefits and risks / inconveniences or restrictions they might expect;
- Any treatment(s) that may be withheld;
- The participant's responsibilities.

The information that you provide will be dependent on the specific type of research study and/or the specific types of people you are recruiting (remember one size doesn't fit all - only include what is appropriate for your research).

The following headings are common areas that need specific thought when preparing your Participant Information Sheet; not all of this guidance will be appropriate for all studies.

For all/ most studies:

Explanation: purpose of and background to the research and invitation

This should cover:

- What is the nature and purpose of your research?
- What is already known (or not known) and how will this study help you learn more? (Be clear and succinct in your explanation).
- What interventions are additional to standard care (i.e. research elements), making it clear what potential participants are being asked to consider giving their consent to.
- Is your research study primarily educational? It is entirely reasonable for research studies to be primarily educational, but this should be made clear to potential participants at the outset.

- Is your research a therapeutic study? Therapeutic studies may require an explanation of the condition and other possible treatment alternatives.
- How many others will be in the study?
- Re-iterate the invitation to take part and explain why they specifically are being approached.

What would taking part involve?

Before anyone decides if they wish to take part in your research study, they need to be made aware of what would be involved.

You should make clear which interventions are additional to standard care (i.e. the research elements) and ensure potential participants know what they are being asked to give their consent to. You can describe these elements in the context of what patients should expect in terms of standard care. Make it clear that their research consent only covers proposed research elements.

You should try to describe involvement from the potential participants' perspective – what should they expect to happen if they agree to take part?

This may include describing:

- How long the participant will be involved in the research?
- How long the research will last? (If this is different);
- If and how often they will need to meet a researcher, attend a research session, visit a clinic or their GP?
- How long will these visits last?
- What exactly will happen and what information is to be collected e.g. access to personal information samples / questionnaire, interview, discussion group, measurement, sample collection, blood tests, x-rays (carried out in addition to standard care or treatment), etc?
- Will participants be asked for information on particularly sensitive issues? Knowing whether an issue may be considered sensitive demands an understanding of your research population and what they might consider to be sensitive.
- For patients, how will participation in the research study affect or blend with their standard, clinical care?
- Any plans for long-term monitoring/follow-up?
- Whether your study will involve video/audio-taping or photography? Specific consent will be needed if published material would identify participants etc.

Potential participants must be made aware that if they agree to take part in your research you will be collecting data / information about them, their health and/or treatment. You must make it clear to them:

- The types of information you will be collecting;
- Who will have access to this information and how you will protect their confidentiality;
- Your future plans for ensuring that the data you collect will be used optimally; for example, data storage and re-use after the completion of this specific study, together with possibility of sharing anonymous information with others in order to support science more generally. It is important that potential participants are informed of the importance of data sharing.

The use of tables or flow diagrams can help provide clarity when describing a complex series of interventions. It can often help to describe each stage of your proposed study, with its inherent risk, in chronological order in the 'What's involved' section of your Participant Information Sheet.

If appropriate, you should explain that participants should take study medication regularly as directed and whether they can continue to take their regular medication or other prescribed or over-the-counter medicines.

It should also be explained that they will need to consider whether they should participate if they are in other Clinical Trials of Investigational Medicinal Products (CTIMPs), or have been in the recent past (specify how long).

What are the possible benefits of taking part?

It is usually not possible to promise any direct benefits of taking part to potential participants, even though sometimes participants can end up benefiting directly.

You need to ensure that potential participants are aware that you do not know what the outcome will be, and this is why you are conducting the research.

Consultation with the community, service users or patient groups may help you identify indirect benefits that could come from taking part in the research, such as:

- Empowering participants to learn more about their condition,
- Supporting or adding to existing diagnoses where more may be learnt about their condition,
- Being seen more often and/or feeling more supported as a consequence of their involvement in the research etc.

The most likely benefits will be experienced by others with a similar condition, in the future, rather than the participants themselves, as a consequence of discovery through research.

What are the possible disadvantages and risks of taking part?

A fair and honest evaluation of the consequences of research, including possible significant benefits and harms and their relative likelihoods, must be described to potential participants.

You should consider that:

- Explaining risk to potential participants in a meaningful way is not easy. However potential participants must be given an honest assessment of the likelihood that something might go wrong, and the consequent level of harm that might be caused.
- Assessing risk is a subjective judgment based on what you already know about this intervention.
- Consultation with the community, service users or patient groups can help you to determine what is likely to be a significant risk, and to design effective ways of presenting risk to potential participants (including careful use of graphic presentation).
- We often don't know the precise level of risk that research carries. You may only be able to present uncertainty or qualified estimates of risk to potential participants. These can often be placed in context e.g. how often has this drug been given to people, or what experience is there of using a certain technique etc.

- Each research study will have its own inherent risks, specific to the interventions involved, the types of participant recruited, the methods of assessment used etc.

Further guidance is provided on our 'Links' page.

Distinguishing risks

You should ensure that potential participants understand the separation, between the risks:

- Of having a specific condition;
- Associated with standard clinical care;
- Inherent in the research itself.

A fair assessment of research risk needs to be placed in an appropriate context for potential participants to consider. Some risks are set out below.

Risk of physical harm

Give potential participants an assessment of likelihood of harm and the likely impact.

- For example:
- 1 in 10 people are likely to suffer from a minor stomach upset or
- 1 in 10 people are likely to suffer from severe diarrhoea or
- 1 in 1000 people are likely to suffer from severe diarrhoea or
- 1 in 1000 people are likely to suffer from a mild stomach upset.

Risk to confidentiality

You should also inform potential participants of any potential risk to their confidentiality:

- What is the realistic risk of identifiable information being accidentally disclosed and what measures are you going to take to keep their information safe?
- Who is going to have access to this identifiable information (e.g. within the research team)?
- Are auditors, inspectors or monitors likely to need to have access to identifiable information?
- Will you be passing identifiable information on to participants' GP, for example to check inclusion criteria during screening etc?
- Are you intending to access information from other sources (e.g. the Office for National Statistics (ONS) / National Records of Scotland (NRS) or NHS central register etc)?
- Are you working with collaborators elsewhere who will access information about participants? How will you ensure participant confidentiality is maintained despite wider information sharing?
- What are your long term plans with respect to the data you collect? Will you be keeping research data beyond the life of this project: reusing it and/or sharing it with others; ensuring that it is optimally used? How will you manage the risks to participant confidentiality? Potential participants should be told about the importance of data sharing in research.
- What are your plans in terms of publication of research findings? How will you ensure that the confidentiality of participants is maintained?
- In some circumstances you may consider there to be significant risk of uncovering abuse, neglect or potential harm to others during the course of your research. It is a matter of judgment whether you wish to explicitly inform potential participants of this possibility, and any action you may have to consider making with respect to information given to you in confidence.

Psychological risk

Some research may also pose specific psychological risk to participants, in particular where research directly addresses difficult experiences and challenging issues in peoples' lives.

Potential participants should be informed of the issues to be discussed, the types of questions that might be asked and the sort of information you wish to collect, to ensure that they appreciate what is involved and what this might mean for them.

Potential participants should be made aware of any support that will be made available to them during or after their involvement in your study.

For some specific types of study, you may also need to cover the following:

Adults not able to consent for themselves

If you intend to recruit adults not able to consent for themselves into your study, you will be:

- Seeking consent from legal representatives, or
- Gaining advice from consultees, or
- Seeking assent from close relatives or friends.

Further details on which of these is applicable can be found in " Principles>Adults Lacking Capacity ".

In all circumstances, you should include the following in your Participant Information Sheet (PIS):

- Why you are approaching them (e.g. as legal representative or consultee etc)?
- What you are asking them to do (e.g. to give consent on behalf of another adult, to provide advice on what another adult may wish or feel or to give assent)?
- Their role in your study is voluntary; they do not have to provide consent, advice or assent if they do not wish to do so.
- They are asked to consider the potential participants views and feelings and to set aside their own.
- Details of your study, including any risks or benefits, as outlined in the remaining 'Content' guidance and as appropriate to your study.
- What they should do if they change their mind.
- If there is a significant chance that participants might regain capacity during the course of your study, how are you going to involve them in the on-going consent process?
- If you intend to collect on-going consent from any participant who regains capacity, you will need to provide a PIS suitable for this. Bear in mind what decision you will be asking the participant to make and the stage of research they might already be at.

Pregnancy and breast-feeding

If there could be harm to an unborn child and/or risk to an infant when breastfeeding then the Participant Information Sheet (PIS) should provide specific advice to potential participants about the risks of becoming pregnant, of fathering a child, or of breast-feeding whilst taking part in your research. Clear information should be provided for men and women.

For women:

You must give a clear warning to potential participants when there is a risk of harm to an unborn child or risk when breast-feeding. The information should include the need for pregnancy testing, contraceptive requirements, and how to report a pregnancy during the study.

The PIS should also provide information about what will happen if a participant becomes pregnant, including whether and how you will monitor the pregnancy. This would include access to mother's and/or child's notes, and any possible follow up of the child including post-natal examinations.

For men:

You must provide clear warnings and advice if the research treatment could damage sperm and consequently pose a risk to possible pregnancies. 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.

For more guidance visit 'Young people and pregnancy' below.

[Young people and pregnancy](#)

The risk of harm caused during pregnancy is most likely if you are recruiting young people to a Clinical Trial of an Investigational Medicinal Product (CTIMP).

In this case, the law requires consent from someone over the age of 16, therefore:

You must discuss the risk of pregnancy, pregnancy testing and the use of appropriate contraception with their parents (or others with parental responsibility) as part of the consent process.

You must discuss the risk of pregnancy, pregnancy testing and the use of appropriate contraception with young potential participants as part of the assent process (in the case of a CTIMP).

It is particularly important that you consider the following being sensitive to local social beliefs:

- What are the likely religious beliefs and cultural expectations of your potential research population?
- What are the perceived consequences of under-age sex? How are you going to handle confidentiality if you discover under-age sex?
- What is the risk of young people (men and women) not telling the truth?
- How can you minimise embarrassment and engender honesty: e.g. by talking with young people privately, away from their parents, or by asking them to complete a written questionnaire?
- How are you going to handle the results of any pregnancy test? How are you going to ensure a young woman's privacy?
- Will young people have access to sexual health advice, in private?
- At what age is it appropriate to be asking questions about sexual activity etc?

You should:

- Involve paediatricians and NHS Research Ethics Committees (RECs) in preliminary discussions if this is a concern,
- Consult young people when designing consent / writing information,
- Respect the young person's autonomy but encourage involvement of the parents,
- Be aware that in CTIMPs it is the parents of children under 16 who legally provide consent, and this will include consent to pregnancy testing and discussion of contraception, and
- Information needs to go beyond "We will do a pregnancy test..." to include, what in broad terms, will happen.

Therapeutic research - clinical alternatives

If you are asking patients to consider taking part in your study, you should make them aware of other clinical alternatives available to them. It is important that potential participants understand the context in which you are asking them to make their decision.

You must make clear to potential participants what they are being asked to consider giving their consent to. It is important that you highlight the additional or research elements of your study. You should avoid presenting standard care and additional research elements as optional, both to be considered during the research consent process. Potential participants should be aware that either they will receive standard care with additional research elements (which are clearly described), or that they will receive standard care minus specific research elements (again, with omitted elements clearly described).

When you are randomising participants to two or more treatment arms in order to directly compare treatment alternatives, you should explain to potential participants that there is no evidence of greater benefit or greater harm being associated with any of the alternatives being offered (For more guidance visit 'Randomisation and blinding' below).

Side effects of treatments / therapies in trials

For trials of treatments/therapies you should include a short description of the drug, device or procedure being tested, and describe the stage of its development.

You should explain all reasonably foreseeable side effects. Rare side effects are relevant if they are likely to result in serious or permanent harm.

For new treatments, you should explain the possibility of unknown side effects. You should place the estimated risk in the context of how many people have taken the drug or describing the experience of using a certain technique etc.

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

The risk of side effects should be described in terms of likelihood and severity, again using language that an average participant can understand (For more guidance visit 'What are the possible disadvantages and risks of taking part' above). Any adverse events that have been

noted in previous studies and that are thought most likely to be due to the underlying condition should not usually be listed as likely side effects.

Potential participants need to be given clear guidance on how to report any side effects they might suffer. You should provide contact numbers/details for the reporting of any side effects.

Randomisation and blinding

If your study involves randomising participants to different treatment groups, interventions or assessment methods you need to explain this to potential participants.

Randomisation is not a concept that many people find easy to understand. So it is important to explain that:

- You do not know which treatment/ assessment method is best and this is why you are conducting your research study, i.e. explain why you are randomising.
- If potential participants take part in your research then they will not be allocated to treatment/assessment in line with usual clinical decision-making.
- Neither the participant nor their doctor will decide which treatment/assessment will be given.
- They will be randomly allocated to a treatment/assessment, akin to drawing lots, tossing a coin or rolling a die.
- Sometimes specific details about the participant (e.g. age or gender) are used to make sure each group in the trial are as similar as possible.
- They may or may not receive the treatment/assessment and what the relative likelihood is of being in a particular group. For example, they are just as likely to receive treatment/assessment 1 as treatment/assessment 2.

Blinding

If your trial is blinded (double or single blind) you should explain that participants and/or their doctor/research team will not know which treatment they are receiving. Where appropriate, it may help to explain to potential participants that all treatments, including any placebo, will look the same as each other.

You should also explain that in an emergency you will be able to find out what treatment a participant has been receiving.

Participants should be told if they will not be informed which treatment they have received at the end of their participation (e.g. as the study as a whole may still be on-going).

Screening and exclusion

If you are asking potential participants to consider taking part in a study, where screening procedures determine eligibility, you must make this clear in the Participant Information Sheet.

Potential participants need to know what they should expect during the screening procedure:

- What tests will be involved?
- When will these tests be carried out?

- Are there any risks associated with the screening procedures themselves? How likely are these, and how severe? (Further guidance is available in 'What are the possible disadvantages and risks of taking part' above).
- What is the likelihood of you discovering significant health related findings during screening and how will these be handled? (Further detail is available in 'Discovering health related findings' below).

You should also explain to potential participants what will happen if the screening procedure either includes or excludes them, so that the path from either scenario is clear.

Therapeutic studies - what happens when the research study stops?

The Participant Information Sheet (PIS) should describe the arrangements for care after research, particularly if this differs from standard care.

You must be clear whether participants will have continued access to any benefits or intervention that they may have obtained during their participation in your research, once the research study stops.

Unless specific arrangements have been put in place for the supply of a treatment after research, the clinical decision about what happens after the study will come under the normal limitations of the NHS commissioning arrangements so this element of the PIS should explain:

- Whether participants will, or may be, offered continued access;
- Any waiting time between the end of participation in the research and any start of continued access (where this is possible);
- Any uncertainty in what may happen after research;
- When any remaining decisions are likely to be made.

If you are running a blinded trial, you should inform potential participants whether or not they will be told which treatment they have been receiving when their participation in your trial ends.

Tissue samples

If your study involves taking tissue samples your Participant Information Sheet should cover the following:

- Are you asking potential participants if you could access excess samples left over after a routine clinical procedure?
- Are you asking potential participants to donate new samples (perhaps in addition to routine clinical samples)?
- What types of samples would you like to collect (blood, urine, surgical samples etc)?
- How often do you intend to collect such samples from them?
- What is/are the likely size(s) of these samples?
- When and where will the samples be collected? For example will they be collected during routine visits to a clinic or will you be inviting participants to attend research clinics?
- How are you going to collect the samples (needle biopsy, blood draw etc)?

- Are there any risks associated with the collection of your research samples? You should give potential participants some idea of what they can expect in terms of the likelihood of something going wrong and how severe such an event might be.
- Is there any likelihood of discovering significant health related findings during analysis of these samples? If so, how will this be handled? (Further guidance is available in 'Discovering health related findings' below).
- What are you intending to do with the tissue samples?
- What type of consent are you asking potential participants for:
 - Specific consent to use their samples in a specific, described study;
 - Generic consent, which covers many possible uses. (More detail is available in 'Generic consent' below); or
 - Tiered consent where you are asking for their agreement to a variety of discrete activities; (further guidance can be found in 'Generic consent' below).
- Do you intend to transfer any of these samples out of the UK for analysis? If so, you should provide potential participants with some details of what would be involved.

Research databases and tissue banks

When establishing a research tissue bank or research database, it is likely that you will be seeking generic consent from potential participants / donors. Generic consent is non-specific consent, where potential participants are informed of the possible breadth of potential uses any donated samples might be put to in the future. This might include some studies that are already planned, but also some future research that cannot yet be described in detail. (Further guidance is available in 'Generic consent' below).

You may choose to seek tiered consent where you describe a number of discrete research activities that the tissue could be used for, and enable potential donors to agree to some but not necessarily all. Some of these elements may be well defined whilst others are relatively undefined as yet. You should only offer tiered consent if you are confident that you will be able to deliver on all aspects of consent in any combination the donor specifies.

There are many further issues explored in this guidance that you should consider including in your Participant Information Sheet, for a research database or research tissue bank, in particular on this page: Tissue samples, Generic consent, Discovering health related findings, Genetic research.

Further guidance can also be found in Supporting Information: Will my data be kept confidential?, What will happen to the samples I give? etc.

Expenses and payments

If you are providing expenses (e.g. travel, meals, child-care, compensation for loss of earnings, etc) to participants and/or others who might accompany them, you should explain this to potential participants.

It is important that potential participants understand how these payments might be influenced by their duration of involvement in your study or by factors such as the completeness of diaries they provide etc.

Further guidance is available from our 'Links' page.

Discovering health related findings

Research studies may reveal health related or incidental findings of which participants were unaware (clinically significant or otherwise). For help in considering the issues involved, and in assessing the risks and benefits of acting upon health related findings, please refer to further guidance on our 'Links' page.

If you determine that there is a significant likelihood of uncovering health related findings during the course of your research, you should ensure that potential participants are made aware:

- That you might discover something about their health of which they are currently unaware (perhaps with some indication about how likely you think this is, and how significant such a finding might be for participants).
- Whether you intend to feedback any such health related findings to participants (you may choose not to).
- If you do intend to feedback, how will you do this and who will feedback. For example, are you asking for consent to contact the participant's GP directly with the new health information, or will you provide participants themselves with feedback and encourage them to seek further advice?
- Will you be advising participants to seek confirmation of any findings through NHS diagnostic services?
- Will you be providing any additional support or contact with other services (e.g. Patient Support Groups etc)?

This information may well not appear as a separate section within the Participant Information Sheet (PIS), but you might include details in the sections covering benefits and risks in the first part of your PIS.

Genetic research

You need to inform potential participants of the risks and benefits of taking part in your study, in a manner that is both sensitive to commonly expressed public concerns about genetic research, yet is still commensurate with the risks involved. You should clearly explain:

- What is the background and purpose of your genetic study?
- What samples are you going to collect and what analyses are planned?
- Could any of your results be clinically significant to participants?
- Are you planning to feedback these findings to participants? (For more guidance visit 'Discovering health related findings' above)
- If appropriate, explain that you are not planning on feeding back any genetic information to them.
- If you are planning to conduct genome-wide analyses, you should inform potential participants that due to the nature of the analyses, you might look at or analyse genes related to the specific condition under investigation as well as unrelated genes.
- If you are planning a genetic sub-study to a main study, potential participants should be able to refuse participation in the sub-study whilst still being able to take part in the main study. This should be made clear to potential participants.
- How are you going to safeguard confidentiality? (For more guidance visit 'Content > PIS > Supporting Information').

Impact on insurance

Potential participants should be told if their participation in your study might affect any insurance cover that they may have (e.g. travel insurance, protection insurance (life insurance, income protection, critical illness cover) and private medical insurance) and advise that they seek expert advice on these issues, where necessary.

Radiation: Ionising Radiation (Medical Exposure) Regulations (IRMER)

If ionising radiation is going to be used as part of your research study or to support your research study, information must be provided to all potential participants about the radiation exposure(s) involved and dosage to be administered.

You should include information on all exposures, both those delivered as part of standard care as well as any additional, research specific exposures. You should make it clear which are additional to standard care.

You should describe the level of risk associated with the planned exposures, in terms of likelihood and impact, in a form of words that will be understood by most of your potential participants.

More information about ionising radiation is provided in our 'Links' page.

Accessing ONS, NRS and other registry data

You should include details of the information resources that you intend to access e.g. Office for National Statistics (ONS), National Records for Scotland (NRS) / General Register Office for Scotland (GROS), NHS Central Registers or other registries including those managed by Health and Social Care Information Centre (HSCIC), or Information Services Division (ISD), in Scotland. For further information, please visit our 'Links' page.

You should describe what types of information you would like access to, and how this information is going to be used.

You will also need to inform potential participants about issues around their confidentiality and how these will be managed (For more guidance visit 'Supporting Information').

Potential participants should be asked specifically to consider the use of their data that are held centrally, in the consent process. Both HSCIC and ISD have provided a form of words that they like to see in consent forms. The suggested wording is as follows:

I understand that the information held and maintained by The Health and Social Care Information Centre (or amend as appropriate) and other central UK NHS bodies may be used to help contact me or provide information about my health status.

Generic consent

If there is any intention to use data or samples from your study for future research and/or if you intend to collect data or samples in order to establish a data or tissue bank/collection,

you should seek generic consent. In this scenario the Participant Information Sheet (PIS) needs to inform potential participants in very general terms of your future intentions which may still be ill defined. This may include describing:

- What are the potential types of research questions the donated tissue / data might be used to address; what areas of research might they be put to?
- Are you intending to share your data and/or tissue with others (here or overseas)?
- Are you establishing a local resource that will only be used by your direct research team?
- How will you decide who has access to your collection? How are you going to decide what research priorities your collection is going to support?
- How will you ensure confidentiality is maintained?
- Is there any likelihood that you, or others with whom you might collaborate in the future, might discover health related findings relevant to individual donors? If there is, how will you handle these? (For more guidance visit 'Discovering health related findings' above).
- There are certain uses of tissue that some people feel particularly strongly about, for example genetic testing, animal testing, commercial exploitation. You should inform potential participants of any such uses that you think are likely.
- Will any tissue or data be disposed of at any time? If so, when and by what means?

You should be careful if you offer potential participants options in specifying what they can agree to and what they might decline (i.e. tiered consent). You should only offer options if you are sure you will be able to deliver on all potential participants' wishes, in any combination.

In true generic consent, potential participants are asked only to give their consent if they agree to be involved in all of the activities described in your PIS and during consent (i.e. consent for all activities or none at all).

Further guidance is available from our 'Links' page.

Content: Participant Information Sheet - Supporting Information

The first part of your Participant Information Sheet (PIS) provides potential participants with:

- A background to your study;
- An overview of what is involved and what they might expect, if they decided to participate in your research;
- The potential risks and possible benefits associated with agreeing to participate in your study.

In supporting information you can include further information and a little more detail so that interested potential participants can obtain a wider understanding of some of the more detailed implications before making a decision.

For more straight forward studies you may find you do not need to split the information up into the two sections, but can explain everything adequately and clearly in a single 'What's

involved' section of a PIS. However, you should ensure that the issues discussed here are adequately covered, when appropriate, somewhere in your PIS.

We have provided you with a list of common issues that all / most PIS will have to address, and a list of issues that only some studies will pose (remember one size doesn't fit all - only include what is appropriate for your research).

For all/ most studies:

What if something goes wrong?

The Participant Information Sheet (PIS) should describe how any complaints will be handled and what compensation may be available in the event of anyone being harmed. This information must be applicable to the setting in which the research will be conducted e.g. university, NHS, commercial or other public research facility etc.

Complaints – Contact details of where a complaint can be made should be given to potential participants.

- First point of contact might be your contact details, or that of someone else within the research team.
- You should also provide a contact independent of the research team for more formal complaints.

An example of possible wording that could be used is as follows:

If you have a concern about any aspect of this study, you should ask to speak to 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 by contacting [insert details e.g. NHS Complaints Procedure or Private Institutional arrangements]. Details can be obtained from [insert details]

Harm – You should provide potential participants with details of what redress and/or compensation should be available to them in the event that they are harmed as a consequence of taking part in your research.

Details of insurance/indemnity schemes should be given, including whether compensation is dependent on demonstrating negligence or otherwise.

If you are unsure what indemnity or insurance is available to you, you should speak to your R&D/ research / research governance office.

NHS based research – NHS bodies are liable for clinical negligence and other negligent harm to individuals covered by their duty of care.

NHS Institutions employing researchers are also liable for negligent harm caused by the design of studies they initiate.

NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, but they may offer an ex gratia payment.

If NHS indemnity is in place for your study, you could include the following possible wording:

In the event that something does go wrong and you are harmed during the research 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).

Universities – Universities employing researchers are liable for their employees' actions (undertaken as part of their job) and are expected to insure against the risk of claims relating to research studies that their staff design and undertake.

They may have 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 Participant Information Sheet (PIS), which describe what insurance cover is being provided, in terms that a lay person would understand.

Commercial research – For a Pharmaceutical industry sponsored study, where there are Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements, you should include the following form of words in your PIS:

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 or where the protocol wasn't followed.

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

Potential participants must be told that the decision to take part in your research is entirely voluntary, and that they can change their minds at a later stage.

Potential participants will need to be assured that any such decision they may make to withdraw (or to decline the invitation to be involved in the first place) will not affect the care they receive from any relevant service (e.g. for patients, from the NHS).

You should make it clear at the outset what they should expect if they were to withdraw their consent. Some of the issues that may need to be addressed include:

- Does withdrawal simply mean that participants will no longer be attending further research clinics or taking any further active part in the research?

- Would participants wish that all their data be destroyed? Will it be possible to extract their data and destroy it, if this is what they request?
- Could participants withdraw their samples from further analysis?
- If your study includes medium to long term follow up, how can participants withdraw from this element? For example, if you intend to access registry data over time, how could participants withdraw from this?
- Could withdrawal post intervention pose a safety issue? If so, how would you manage this (e.g. with an exit check-up)? Participants should be able to ask that any information collected at an exit check-up be included or excluded from the study.
- Can participants withdraw both data and tissue samples from subsequent tissue or data banking?

It is important to make your intentions clear to the participant, and not to make promises that you cannot fulfil. For example:

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.

Will my information be kept confidential?

You should tell potential participants how their confidentiality will be safeguarded during and after the study. You may wish to tell potential participants how your procedures for handling, processing, storing and destroying their data match the Caldicott principles and/or appropriate legislation.

The potential participant should be told:

- If you intend to keep the data you collect for use beyond a specific research study/trial.
- Is it possible that you might share anonymous information with others in the future? Potential participants should be informed of the importance of data sharing with other researchers; to ensure that research is open to peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making.
- What arrangements are you going to make to ensure the information is kept secure? For example, will you keep direct identifiers, and separate them from health information? Will you destroy all direct identifiers and store only fully anonymised data in the longer term?
- Who will have responsibility of acting as the data controller? This is the organisation legally responsible for the security and validity of the information held under the Data Protection Act. This is usually the organisation that physically holds the data either on their servers or in their filing cabinets.
- Who is going to act as data custodian (i.e. who is going to manage access to identifiable/non-identifiable data)?
- Do you intend to ask for further ethics committee approval for each re-use of the data, or not?
- Do you envisage sharing any of the information with others in the future, including those abroad (especially outside the European Economic Area (EEA)) or commercial

companies? If so, how are you going to ensure participants' confidentiality is maintained?

- If identifiable data will be shared with others outside the EEA, you should make potential participants aware that such countries might not offer the same level of protection of peoples' privacy as that demanded by law in the UK. However, you can inform potential participants of the steps you will take to ensure that any such transfer of information abroad will not compromise their confidentiality.

You should avoid repeating information you provided earlier in your Participant Information Sheet. How much information and the nature of the information appearing in 'Supporting information' will very much depend on the type of study you are planning and the potential risks involved.

What will happen to the results of this study?

You should inform potential participants of your intentions with respect to publishing research findings, as well as how you intend to feedback findings to participants themselves. (This might include how you are going to handle individual health related findings, as well as overall outcomes of the study). Further guidance on health related findings is available from 'Content > PIS > Discovering health related findings'.

You should also provide relevant assurance that individual participants will not be identifiable from any report or publication placed in the public domain. If you think there is a risk that identifiable information may be published, you must ask potential participants for their explicit consent for this, having ensured that they understand the potential implications of agreeing to this.

Who is organising and funding this study?

You should tell potential participants which organisation(s) is/are sponsoring and which is/are funding your research (e.g. medical research charity, pharmaceutical company, academic institution, NHS organisation etc).

Potential participants should be told whether their doctor is being paid for their role in the study and if any conflicts of interest exist. 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.

How have patients and the public been involved in this study?

You should explain how you have involved patients and the public in the design of your study and how they will be involved in the conduct of the research. The following are examples of how you might have involved patients / the public:

Service users helped develop the research topic and what research questions should be asked and one of them is a co-applicant who will continue to be involved in the study.

Potential participants were involved in reviewing the Participant Information Sheet.

In designing this study we have taken into account patient opinions on the frequency of participant visits and the tests that we will carry out.

Potential participants were involved in describing the inclusion and exclusion criteria for people taking part in this study.

Knowing how patients or the public have been involved in planning your study can give potential participants greater confidence in taking part, as it provides them with the assurance that what they are being asked to do is acceptable.

More information on how to involve patients or the public in your study can be found on the HRA website and from INVOLVE (further guidance is available from our 'Links' page).

Who has reviewed this study?

You should include some form of assurance to potential participants that your study has been reviewed and approved by a research ethics committee.

The following is suggested wording:

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by _____ Research Ethics Committee.

Further information and contact details

You should provide potential participants with places where they can access more information, for example:

- General information about research: there are a number of web resources and booklets available, produced by research organisations, which explain why research is conducted, define some technical terms, and provide ideas as to the sorts of questions potential participants might like to ask before deciding if they will take part in research or not. Further guidance is available from our 'Links' page.
- Specific information about this research study: usually this would be provided by someone who is part of the research team; this could be you or some other member of your team. Potential participants should be given a name and contact details. If you also have a study website, details of where to find this should be included.
- Advice as to whether they should participate: this is usually a person who is independent of your study. It could be the potential participant's health care professional or a person you nominate who can provide support and who is independent of your study.
- Who they should approach if they are unhappy with the study: this would be a contact if participants have any concerns about your study and their involvement in it. For some studies, you may need to provide an emergency contact number that is manned 'out-of-hours'.

If you are conducting a study over a number of different sites, you should make sure that all of the contacts you provide are appropriate for each of the sites involved.

Version control

Your Participant Information Sheet should be dated and given a version number (referring to a protocol number if necessary). This can be done in a header, footer or within the body of the document.

Version numbers will not only help you and your research team to manage consent paperwork during the on-going study (including handling any subsequent amendment), but it will also be used by the research ethics committee, regulators or research governance offices when referring to 'approved' documents.

Consent process

You should explain how potential participants should expect the consent process to proceed. You should inform them if you are intending to obtain a record of their consent in writing, by means of a consent form, and that they will be given a copy of the Consent Form and Participant Information Sheet to take away with them.

Recruiting adults lacking capacity in England and Wales to non-CTIMPs.

Consultees should be informed that the advice they provide (i.e. advice on whether an adult lacking capacity should be included or excluded from your study) will be recorded on a Consultee Declaration form. A template is available to download from 'Examples & Templates'. This is because they are not being asked to give consent on behalf of the adult.

You must fully explain early in your Participant Information Sheet what you are asking them to do, why you are asking them to act as a consultee, what they need to consider when providing you with their advice and that they do not have to act as a consultee if they do not wish to do so. (Further guidance is available from 'Content> PIS> Adults not able to consent for themselves' and 'Principles> Adults Lacking Capacity').

For some specific types of study, you may also need to cover the following:

What if relevant new information becomes available?

During a participant's involvement in your study, significant findings might emerge that impact upon the risk / benefit balance that was originally explained to them. Potential participants need to be assured at the outset that if this happens you will let them know.

- You must give them further assurance that they can change their mind about their involvement and that this will not affect their care (in the case of patients). The following is an example:
Sometimes we get new information about the treatment being studied. If this happens, your research doctor will tell you and discuss whether you 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 he may ask you to sign an agreement outlining the discussion.
- Potential participants should also be told at the outset if it is possible that they might be withdrawn from the study because of information that comes to light that relates specifically to them and their health. For example:

If this happens, your research doctor might consider that you should withdraw from the study. He/she will explain the reasons and arrange for your care to continue.

- Similarly potential participants to some studies (in particular trials) should be made aware that the study may be stopped for safety reasons or if it becomes clear that one of the study treatments is much better than the other(s).

If the study is stopped for any other reason, we will tell you and arrange for your continuing care.

- In all cases it is also important that potential participants are told of any further implications of their withdrawal, for example any safety, exit check-ups that might be necessary, post-study arrangements etc.

Involvement of General Practitioner / other healthcare practitioner

The Participant Information Sheet should make it clear if your study necessitates contact with a participant's General Practitioner (GP) or other health care professional. In such cases, you should explain to potential participants that if they agree to take part in your study you would need to contact their GP (or other health care practitioner). You should provide potential participants with an explanation of why this contact is necessary and what information would be exchanged.

What will happen to the samples I give?

You should give potential participants more information on your medium to long-term plans for any samples remaining after your specific piece of research has ended. This should include consideration of the following:

- Will participants' samples be destroyed at the end of this study, or do you intend to keep them for future use?
- How will you ensure confidentiality is maintained during medium to long-term storage?
- Do you intend to share samples with others, including transferring samples elsewhere, maybe even outside the UK?
- Could this future use include genetic testing, the use of animals, commercial involvement?
- How will you manage access to samples in the future? Will all future use require additional ethical approval?
- Is it possible that you might share anonymous information with others? Potential participants should be informed of the importance of data sharing; to ensure your research is open to peer scrutiny, to optimise the use of good quality research data and to support policy and other decision-making.
- Could any future use produce health related findings that might be significant to individual participants? If so, how will this be handled, what should potential participants expect? (For further guidance visit 'Content> PIS> Discovering health related findings').
- Are you making any specific provision for destruction of any remaining samples?

There are a number of options to consider when asking potential participants for consent to collect samples. These include obtaining:

- Generic consent – is non-specific consent, where potential participants are informed of the possible breadth of potential uses any donated samples might be put to in the

future. This might include some studies that are already planned, but also some future research that cannot yet be described in detail.

- Tiered consent – is where you describe a number of discrete research activities that the donated tissue could be used for, and enable potential donors to agree to some but not necessarily all. Some of these elements may be well defined, whilst others could be relatively undefined as yet. You should only offer tiered consent if you are confident that you can deliver all aspects of consent in any combination the donor specifies.
- Specific consent – is when donors are asked only to give consent to specific use(s) of their samples, and when no future, as yet unspecified research is likely. You should think about offering this option only if you are sure that you have no intention of any further storage or use of the donated samples.

Further guidance is available on our 'Links' page.

Commercial exploitation

If your research or collection of samples/data is likely to directly feed into a discovery of commercial value, you need to make it explicit to potential participants that:

1. Your study may have commercial benefit.
2. Participants will not benefit financially in any way, if commercialisation of any research findings are successful.

Content: Consent Form

A consent form should normally be used to record the consent process and a participant's agreement to take part in your study.

A signature on a consent form alone does not constitute legal or ethical consent, for more guidance please visit our section on 'Principles'.

When designing your consent form you should consider what precisely you are asking potential participants to give their consent for (remember one size does not fit all). You must again consider how to optimise understanding. (For more guidance please visit our section on 'Style').

General content

A consent form should normally be used to record the consent process and a participant's agreement to take part in your study.

The consent form should be produced on headed paper.

Ensure that the study title is clearly displayed. You may also wish to include a study identification number.

You may wish to include spaces for site or centre ID and/or participant ID.

If you are producing a number of consent forms for your study (e.g. for different types of participant, or to be used in different UK nations), ensure that each consent form is clearly identified.

When producing your consent form you should consider what is appropriate for your type of study and the participants who will be involved.

For many studies the following paragraphs will be sufficient to accurately record agreement to take part. You may not need to include all, think about what you are asking potential participants to give their consent to (remember one size doesn't fit all - only include what is appropriate for your research):

- I confirm that I have read 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.
- 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.
- (If appropriate) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
- (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

- (If appropriate) I agree to my General Practitioner being informed of my participation in the study.
- (If appropriate) I understand that the information held and maintained by the Health and Social Care Information Centre (or amend as appropriate) and other central UK NHS bodies may be used to help contact me or provide information about my health status.
- I agree to take part in the above study.

You should provide a box after each item on your form for potential participants to initial, tick or provide the answers 'yes' or 'no', to indicate their specific agreement with each statement.

If you are producing consent forms to be used by legal representatives, ensure that the language used addresses them appropriately. Make it clear you are asking them for consent on behalf of, or advice with respect to a child / young person or adult lacking capacity.

Some example templates are available from our 'Examples & Templates' page.

Itemising specific elements

For some studies you may choose to provide an itemised or tiered consent form covering specific issues, especially where additional elements are optional for the participant. This is not obligatory but may include:

- Additional invasive tests or samples required for study purposes only;
- Consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs;
- Transfer of data/samples to countries outside of the European Economic Area (EEA) with less data protection;
- Agreement to receive individual feedback from testing.

Only offer potential participants options if you are confident that you can deliver all combinations of accepted or rejected options.

Signatories, witnesses and legal representatives

The signatories on the consent form should be those who are involved in the consent process, e.g. the participant, the researcher or the participant's legal representative / consultee.

You must ensure that the signatory is appropriate for the circumstances (e.g. recording consent given on behalf of an adult not able to consent for themselves to a non-CTIMP in Scotland should ask for the signature of a Welfare Attorney / Welfare Guardian / nearest relative etc).

Consent forms for a participant's legal representative should address them directly and should be written appropriately. The consent form must be clear that they are being asked for consent on behalf of the research participant.

An independent witness is not routinely required except in cases where potential participants are not able to read or write, or who are visually impaired etc.

Adults lacking capacity (England and Wales) - consultee declaration form (non-CTIMPs only)

When recruiting adults lacking capacity in England or Wales, to a research study that is not defined as a Clinical Trial of an Investigational Medicinal Product (CTIMP), you will be asking a consultee to advise on whether to include the adult in your study or not. The advice they provide should be recorded on a Consultee Declaration Form.

An example of a Consultee Declaration form can be found in 'Examples & Templates'.

Version control

You must ensure that all consent forms carry appropriate version control (either a date and/or a number). This will help you manage consent documentation throughout the life of your study, and will be referenced by others who review and/or approve specific study-related paperwork (e.g. Research Ethics Committees, NHS R&D Offices etc).