

Guidance for Researchers

Participant Information Sheet and Consent Form Templates

The information provided to participants is crucial for a number of reasons: It explains to individuals everything that will happen to them, should they consent to participate; it allows them to weigh up the risks and benefits of taking part; and it ensures that the information provided to them is fully documented from a legal perspective. All of the above should be achieved in as concise a way as possible, without compromising clarity.

This template is a guide to help researchers design study information sheets and consent forms. It has been designed with reference to HRA Participant Information Sheet Preparation Guidance (<http://www.hra-decisiontools.org.uk/consent/>)

- *Sample text is italicised.* Alter or delete as required as you produce the draft.
- Standard required text is underlined. This includes complaints contacts and statements provided by our insurer. Please remove underline when you incorporate into your document.
- **Main headings are in bold.** Headings can remain in this format if desired. Some headings may be deleted or added as relevant for your study.

All advisory text should be deleted before finalising the document.

Repetition of information throughout the participant information sheet is not necessary; it may be useful to cross-reference to other section(s) to avoid repetition.

Although the PIS and Consent form templates are in one file here, please make them separate documents when you develop yours.

Should you require assistance, contact either CTRG (University) or R&D (OUH) as early as possible in the planning stage:

<http://www.admin.ox.ac.uk/researchsupport/ctrq/>

<http://www.ouh.nhs.uk/researchers/default.aspx>

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Add contact details of the local research team and either the Chief or Local Investigator

PARTICIPANT INFORMATION SHEET

<Study Title>: The title could be the same as in the protocol or a simplified version understandable to a lay person. If the latter, this should be used as the short title in the IRAS form. The titles must be consistent throughout the documentation.

Invitation paragraph: It must be clear that you are inviting potential participants to consider taking part in your research and that participation is entirely voluntary.

Example:

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study?

Provide a brief outline of the purpose of your study in lay language. Do not cut and paste directly from the protocol.

Why have I been invited?

- Explain specifically why the participant has been invited (e.g. because they have a specific condition, or because they are healthy individuals)
- State how many participants you are intending to involve and their characteristics (e.g. healthy volunteers, people with x condition).

Do I have to take part?

- The answer is 'No': It should be clear that taking part is entirely voluntary.
- Participant can withdraw if he/she later changes his/her mind, without giving a reason;
- Withdrawal will not affect clinical care (if participants are patients).

What will happen to me if I decide to take part?

This section details what will be involved in your research study from a participant's point of view, and in the order they will experience it. If there are multiple study visits, describe them in turn.

- If research is taking place in the context of clinical care, make clear which parts are research and which standard care.
- A table or flow chart can provide clarity when describing a complex series of interventions).

Consider:

- How long the participant will be involved in the research; how often they will need to attend a research session; and how long visits will be.

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- If you will be allocating participants randomly to study medication(s) and/or placebo, describe what it means in lay terms.
- If you will be collecting samples, give an idea of amounts. Blood volume may be more meaningfully expressed in tablespoons: 5ml is equivalent to 1 teaspoon, 15ml is 1 tablespoon. Biopsies may be compared to grains of rice.
- If you will be using tissue samples, state whether the tissue will already be collected as part of clinical care. Are you requesting use of tissue surplus to diagnostic need, or collecting additional samples?
- Outline any plans for long-term monitoring/follow-up.
- If the study involves the use of any ionising radiation (e.g. x-rays) or non-ionising radiation, such as MRI scans, please add *template consent form point 10* (appended) to your consent form.

What should I consider?

You should explain:

- Conditions which may exclude individuals from participation;
- Whether they can continue to take their regular medication or other prescribed or over-the-counter medicines;
- Any requirements for contraception;
- Whether they can participate if they are involved in other research studies.

Are there any possible disadvantages or risks from taking part?

Provide a fair and honest evaluation of the possible consequences of key research procedures and drugs: risks and their relative likelihoods, as well as what you will do to mitigate these risks. For example:

Procedures:

- Blood samples: the possibility of bruising and/or fainting
- Biopsies: the possibility of bruising, infection (mitigated by antiseptic, trained staff).
- Additional radiation when the study involves any ionising radiation: the implications of doses in addition to standard care.
- Questionnaires or interview questions that may cause distress: give indication of kinds of questions you will be asking, and outline would happen if a participant becomes upset.

Study Drugs:

- State whether the drug is commonly used for the indication being researched or for other conditions, or whether it is 'first in man'
- State known side effects of study drugs. You could use a table such as:

Side Effect	Frequency
	Very common (in more than 1 in 10 participants)
	Common (more than 1 in 100 but fewer than 1 in 10)
	Uncommon (more than 1 in 1000 but fewer than 1 in 100)

What are the possible benefits of taking part?

- Sometimes participants can benefit directly. If this is so, be clear; if not, be equally clear that there is no benefit.
- 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.

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Will my General Practitioner/family doctor (GP) be informed of my participation?

- GPs should be notified if study participation could affect clinical care of participants. (GPs should be provided with a letter and the study information sheet.)
- There may also be instances where GPs will be contacted to follow up incidental findings that may be of clinical significance, such as high blood pressure or indications of depression.
- If the GP will be informed of participation or may be notified of findings requiring follow up, make this clear and add a version of *template consent form point 6* to your consent form.

Will my taking part in the study be kept confidential?

- Explain arrangements made to ensure that information is kept secure.
- Explain in what form you will hold information. For example, will participants be identified by study code only? Will you destroy all direct identifiers and store only fully anonymised data? Note that if you anonymise during the study, it will not be possible for participants to withdraw their data. They should be informed of this here and/or in the section discussing withdrawal.
- Include the following text:

Responsible members of the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations. (There is a related mandatory point on the consent form template)

Other considerations:

- If you are not part of the clinical care team of patients, you cannot access their medical notes without their consent. For screening/identification for recruitment, see information about invitation letters in “Guidance for Researchers Seeking Sponsorship.”
- If you are intending to check contact details or health status in future (e.g. for follow up) using NHS Digital or the NHS Central Register (Scotland), state this, and *add template consent form point 7* to your consent form.
- If your study will involve video/audio-recording, outline what will happen to these recordings in the longer term; and, if transcribed, whether the recordings will be destroyed. If video or audio recording, please *add template consent form point 5* to your consent form.

Will I be reimbursed for taking part?

- Make clear whether they will be compensated for their time, inconvenience for having to take medications or for having to donate blood or tissue samples. It is important that potential participants understand how these payments might be influenced by their duration of involvement in your study (whether pro rata) or by factors such as the completeness of diaries they provide.
- Make clear whether they and/or others who might accompany them will be reimbursed for their expenses such as: travel, meals, childcare. It should not cost participants to contribute to research; at a minimum, travel should be reimbursed. This expense may sometimes be avoided by having research visits coincide with regular clinical appointments.

What will happen to the samples I give?

- State how they will be used in the research (where they will be transferred or held, what analysis will take place) and in what form (anonymous, linked anonymous). *Add template consent form point 4* to your consent form.
- If your study involves the analysis or use of DNA, limits on anonymity should be made clear to participants. For example:

Your DNA and blood sample will be assigned a code and your data will also be identified only by this number. The material given to researchers will not have information that identifies you. However, your DNA is unique to you so it can never be completely anonymous.

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- You should also give potential participants information on your plans for any samples remaining after your specific piece of research has ended, such as whether they will be destroyed or stored, with consent, for future use.
 - If kept for future use, it is worth ‘future proofing’ by indicating that this research may happen outside of the UK. Consider whether they may be used by commercial companies. For instance: *Your anonymised samples will be used mainly by local researchers (if applicable), but ethically approved research projects may take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide.*
 - Please add *template consent form point 13* to your consent form.
 - It will also be necessary to retain the consent form (personal data) until the sample has been depleted or destroyed, in order to meet the traceability requirements of the Human Tissue Act. Please add a statement in the PIS – e.g. *If you agree to your samples being used in future research, your consent form will be held until the samples have been used up.*

What will happen to my data?

- General Data Protection Regulations (GDPR) require mention of data controller (Oxford University Hospitals NHS Foundation Trust) and more explicit details about what personal data will be held by whom, for what purposes, and for how long. For example:
- *We will be using information from [source: e.g. you and your medical records] in order to undertake this study. Research is a task that we perform in the public interest. Oxford University Hospitals NHS Foundation Trust, as sponsor, is the data controller. This means that we, as Oxford University Hospitals NHS Foundation Trust researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for [time as per IRAS A43] after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the Oxford University Hospitals NHS Foundation Trust for [time as per IRAS A44] after the end of the study. [can add reason it is held, e.g as part of the research record]*
- If there is a site processing details also add the following:
- *The [local NHS Trust or local study team] will use your [list details, e.g. name, NHS number, home address, and contact details], to [give reason: e.g. contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study]. They will keep identifiable information about you from this study for [time as per IRAS 43] after the study has finished. [If consent forms or other personal details will be archived at site, this will need to be mentioned]*
- If you are receiving information from another source (e.g. NHS digital) please indicate what you will be collecting, and for what purpose.
- *Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. [Can also include: Further information about your rights with respect to your personal data is available at <https://www.ouh.nhs.uk/privacy/default.aspx>*
- *You can find out more about how we use your information by contacting [CI or study team email].*
- It may be possible here to refer to the section on confidentiality.
- If you intend to keep the data you collect for use beyond a specific research study/trial or if anonymised data may be shared in future, state this and add
- If personal data will be shared with others outside the EU, you should make potential participants aware that such countries might not offer the same level of protection of privacy as that demanded by

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law in the UK. Inform potential participants of the steps you will take to ensure that any such transfer of information abroad will not compromise confidentiality, and obtain explicit consent for the transfer of personal data.

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

Make clear that:

- Participation is voluntary and participants may change their minds at a later stage.
- Withdrawal will not affect the care they receive from any relevant service (e.g. for patients, from the NHS).
- What procedure is in place in case of withdrawal?
 - Are there any safety implications? Will participant be followed up and a final visit arranged?
 - Will samples and data collected to point of withdrawal be retained for the study, removed, or will the participant have a choice?
 - If the study intends to bank tissue or data for future research, specify the effect of withdrawal on future use.

Examples:

- *If you withdraw from the study, we will destroy all your identifiable samples, but will use the data collected up to your withdrawal. Or;*
- *If you withdraw from the study, unless you state otherwise, any blood or tissue samples which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples are destroyed at any time during or after the study. Or;*
- *You can withdraw from the study 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.*

What will happen to the results of this study? Alternatively: What happens at the end of the study?

- Reassure potential participants that they will not be identified from any report or publication placed in the public domain. If they will be (for instance, with images of faces) it will be necessary to obtain specific consent for this.
- You should inform potential participants of your intentions with respect to:
 - Publishing research findings;
 - Presenting your findings at conferences;
 - Feeding back findings to participants themselves. Will you provide them with a summary, or add in a link to a website from which they could get the information, or ask them to contact you?
- Indicate whether the study is part of an educational project, such as fulfilment of requirements for a DPhil. For example:
Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis).

What if we find something unexpected?

Consider whether analysis of images, samples, or questionnaire responses might produce findings of clinical significance for participants or (in cases of some genetic analysis) their relatives. If so, specify the management pathway of these incidental findings. This will typically involve clinical verification and/or referral to the participant's GP.

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What if there is a problem?

if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should contact <name of investigator><contact details (phone number & email)

There are no special compensation arrangements. Oxford University Hospitals NHS Foundation Trust will provide indemnity for this study. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it.

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

You will also be able to contact the Patient Advice and Liaison Service (PALS) in the first instance (01865 221473).

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

- Patient and public involvement (PPI) is increasingly encouraged by funders and regulators. Potential participants may have greater confidence in taking part if they know that patients or the public have been involved in planning your study. Guidance and resources are available at www.invo.org.uk/

Examples may include:

- *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.*

It may be useful to include one or both of the following links to general information about taking part in research:

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Who is organising and funding the study?

- Inform potential participants which organisations are sponsoring and which 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. For example:

Researchers 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.

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Who has reviewed the study?

Provide details of the research ethics committee who has reviewed and approved the study.

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

Participation in future research:

If you are intending to approach participants in the future, make it clear where their personal details will be kept - for instance, *Your contact details would be held separately from this study on [describe arrangements – eg, a password protected computer in the Department of XY]* and that agreeing to be contacted does not oblige them to take part in future research.

Add *template consent form point 12* to your consent form.

Further information and contact details:

Please contact < > by < > (telephone, e-mail, in writing)

*Thank you for reading this information. Or;
Thank you for considering taking part.*

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Add contact details of the local research team and either the Chief or Local Investigator

Study Code:

Site ID Code:

Participant identification number:

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CONSENT FORM

<Study Title>: the title could be the same as in the protocol or a simplified version understandable to a lay person

Name of Researcher:

If you agree, please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities [and from the NHS Trust(s)], where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. (If appropriate) <i>I agree to provide a sample(s) as part of my involvement in this study and I understand I will not gain any direct personal or financial benefit from them.</i>	
5. (If appropriate) <i>I agree to audio/video recording and the use of anonymised quotes in research reports and publications.</i>	
6. (If appropriate) <i>I agree to my General Practitioner being informed of my participation in the study.</i>	

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7. (If appropriate) <i>I understand that the information held and maintained by the NHS Digital / NHS Central Register (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>	
8. (Genetic research, if appropriate,) <i>I understand and agree that my samples will be used in research aimed at understanding the genetic influences on disease and that the results of these investigations are unlikely to have any implications for me personally.</i>	
9. (MRI studies, if appropriate): <i>I understand that this is a research scan that is not useful for medical diagnosis, and that scans are not routinely looked at by a doctor. If a concern is raised about a possible abnormality on my scan, I will only be informed if a doctor thinks it is medically important such that the finding has clear implications for my current or future health.</i>	
10. I agree to take part in this study.	
Additional:	
11. (If appropriate) <i>I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies.</i>	
12. (If appropriate) <i>I agree for my anonymised samples to be used in future research,* here or abroad, which has ethics approval. (*if some future use may be commercial, state this)</i>	

Name of Participant *Date* *Signature*

Name of Person taking Consent *Date* *Signature*

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes (if participant is a patient).*

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