NOTES FOR RESEARCHERS:

This template forms the minimum requirement for a participant information sheet for researchers across the University, from all disciplines, and should be completed in conjunction with reading the [submission guidelines](http://www.surrey.ac.uk/research/integrity/Research%20Ethics/Guidelines%20for%20submission%20to%20UEC.pdf) on the ethics website. Please ensure you are familiar with the obligations of your profession, discipline and participant group. Most studies should include some information under each of the sub-headings below. To avoid repetition you can place the information under different headings according to the nature of your study. If you come across text that is not relevant to your subject area, you can either delete it or adapt the wording to suit the requirements of your study. When rephrasing please ensure that participants still receive accurate and complete information.

It should also be made clear to participants which elements of the study are compulsory and which, if any, are optional.

If your project has more than one phase or is particularly complex, you can also split the information sheet into sub-sections or provide a summary and further information. However researchers choose to organise the information, it should be written in plain English, be clear, understandable and suitable for the participants in question and remain accessible.

Further advice on drafting participant information sheets, including how to tailor them to different types of participant can be found on the [consent section of the Health Research Authority website](http://www.hra-decisiontools.org.uk/consent/).

If you are preparing to submit your proposal to an NHS Research Ethics Committee you may be asked to use the [HRA headings and contents suggestions](http://www.hra-decisiontools.org.uk/consent/docs/Consent%20and%20PIS%20Guidance%20Mar3rd2014.pdf) for participant information sheets and consent forms.

{…} Sentences that may be particularly study specific and optional.

[…] Insert the wording relevant to your study.

\* Delete an option as appropriate.

Further notes throughout the template are provided in boxes.

{Logo collaborator****}

**Participant Information Sheet** **[version x, dd/mm/yy]**

[study title]

**{participant type/group}**

**[PROJECT TITLE]**

**Introduction**

I/we\* would like to invite you to take part in a research project. Before you decide you need to understand why the research is being done and what it will involve for you. Please take the time to read the following information carefully and ask questions about anything you do not understand. Talk to others about the study if you wish.

**What is the purpose of the study?**

**Why have I been invited to take part in the study?**

You have been invited to take part in this [study/donate human tissue samples] because [reason]

{To be eligible to take part in the study, you must meet the following criteria:}

About [X] participants / donors\* in [Y] countries will take part in this study. [Z] participants / donors\* will be from the UK.

The above section asks you to specify how many participants you are planning to recruit and, if it is a multi-national study, how many of those participants are located in the UK.

**Do I have to take part?**

No, you do not have to participate. There will be no adverse consequences in terms of your legal rights and your care / treatment / employment status / education, that is, there will be no impact on your assessment or class of degree\*, if you decide not to participate or withdraw at a later stage. You can withdraw your participation at any time. You can request for your data to be withdrawn until [date, e.g. submission of online questionnaire] / until publication of the data\* without giving a reason and without prejudice.

If you withdraw from the study this will mean the following for your participation and data\*:

All identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained {because we cannot trace this information back to you}. No further data/tissue\* would be collected or any other research procedures would be carried out on or in relation to you. {For safety reasons we will ask you to attend an exit check up /…\*}.

OR

Identifiable data already collected will be retained if you allow us to. Anonymous data already collected will be used {because we cannot trace the latter information back to you}. No further data/tissue\* would be collected or any other research procedures would be carried out on or in relation to you. {For safety reasons we will ask you to attend an exit check up /…\*}.

OR

Both identifiable and anonymised data will be destroyed. No further data/tissue\* would be collected or any other research procedures would be carried out on or in relation to you. {For safety reasons we will ask you to attend an exit check up /…}.

{If you were to lose capacity during the study

It is not practicable for the research team to monitor capacity and your continued capacity will be assumed / if you were to lose capacity during the study, the same procedures would apply as if you were to withdraw from the study / you would continue to be included in the study\*}

**What will my involvement require?**

If you agree to take part, we will then ask you to sign a consent form. If you do decide to take part you will be given this information sheet to keep and a copy of your signed consent form. The research will last [study duration] but your involvement would only be [duration for each donor / participant\*]. During this time, you will be asked to [number of study visits, details of any study procedures, length of visits].

**What will I have to do?**

**What will happen to data{/samples} that I provide?**

Please differentiate between anonymous data and personal data (those that render someone identifiable, such as name, contact details, audio/video recordings, photographs, rare conditions, small groups). Please note that the University recommends NOT to share personal data outside the research team or at least to provide the participants the option to opt out of this. Please see the submission guidelines for further guidance

Research data are stored securely for at least 10 years following their last access and project data (related to the administration of the project, e.g. your consent form) for at least 6 years in line with the University of Surrey policies.

If you are conducting a clinical trial, please note that different data retention requirements hold for your study. Please refer to the appropriate guidelines. You may adopt part of the following suggested wording where relevant to your study.

1. Data **not** used for a marketing authorisation: data including your medical records needs to be retained for at least 5 years after the completion of the trial
2. Data used for a marketing authorisation: data including your medical records needs to be retained for at least 15 years after the completion of the trial or for at least 2 years after the last marketing authorisation in the EC.

All other documentation pertaining to the trial needs to be kept as long as the product is authorised

1. Records relating to the full traceability of the investigational medicinal product for advanced therapies: documentation including your medical records needs to be retained for at least 30 years

Personal data will be handled in accordance with the {UK} Data Protection Act (1998).

{With your consent, to make the most of your participation and support efficient advancements in science, any anonymised data/samples may be used for future research. We cannot tell you at this moment in time what this research will entail or what analyses will be carried out but we can assure you that all appropriate legal, ethical and other approvals will be in place. For practical reasons your consent will not be sought again {unless you indicate you wish us to do this}. Your data/samples will not be used for [commercial purposes/genetic testing/…\*].

**What are the possible disadvantages or risks of taking part?**

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

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

**What if there is a problem?**

Any complaint or concern about any aspect of the way you have been dealt with during the course of the study will be addressed; please contact [insert name of Principal Investigator], Principal Investigator on [work contact number, email address] in the first instance {or my Supervisor [students, please insert name and contact details of Supervisor(s)]}. You may also contact [someone who is independent of the research team, e.g. Head of School]. {If you remain unhappy you can file a complaint using the [complaint procedure, e.g. Clinical Research Centre, NHS]}.

{*If the University provides insurance cover for your study*

The University of Surrey holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation. This does not affect your legal rights to seek compensation.

1. If your study is clinical research or a clinical trial, according to the definitions below, it will potentially be covered by the University’s clinical trials insurance and you should include the wording in black:

**Clinical Trials**: only statutorily defined Trials are included: “any clinical research requiring clinical trials authorisation from the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004”

**Clinical Research**: Research that directly involves a particular person or group of people, or that uses materials from humans, such as their behaviour or samples of their tissue:

If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

1. If your study does not fall under either of the categories above, and will therefore potentially be covered by the University’s public liability insurance, you should use the wording below:

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above.

{If, in addition, NHS indemnity is in place for your study, usually when one or more members of your research team have NHS contracts and/or where participants are NHS patients, please use the wording below)

If you are harmed due to someone's negligence then you may have grounds for legal action for compensation against [NHS Trust, Private Clinic] and/or the University of Surrey but you may have to pay your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should follow the instructions given above }

{If your study involves commercial research, for a Pharmaceutical industry sponsored study, where there are Association of the British Pharmaceutical Industry (ABPI) or other no-fault compensation arrangements are in place, the following wording is recommended by the Health Research Authority:

The Sponsor of this study is required to 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).

Compensation will be paid where the injury results 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 to have more information on this). The Sponsor is not 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.}

{Your participation in this study might affect insurance cover that you may already have [travel insurance / protection insurance (life insurance, income protection, critical illness cover) / private medical insurance\*]. We advise that you seek expert advice on these issues before consenting to take part in the study, where necessary.}

**Will my taking part in the study be kept confidential?**

Please note that the University recommends NOT to share personal data outside the research team or at least to provide the participants the option to opt out of this. If identifiable data will be shared with others outside the EEA, which includes publishing on the internet, you must 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. (Please see submission guidelines for further information).

Yes. Your details will be held in complete confidence and we will follow ethical and legal practice in relation to all study procedures. Personal data [name, contact details, audio/video recordings] will be handled in accordance with the {UK} Data Protection Act 1998 so that unauthorised individuals will not have access to them.

Your {personal} data will be accessed, processed and securely destroyed by [members of the research team {including external collaborators}/principal and co-investigators/student and supervisors\*]. In order to check that this research is carried out in line with the law and good {research/clinical/other\*} practice, monitoring and auditing can be carried out by independent authorised individuals. {Relevant sections of your medical notes and} data collected during the study, may be looked at by authorised individuals from the University of Surrey, [company name, government, pharma, other], from regulatory authorities [or from the NHS Trust], where it is relevant to your taking part in this research. All will have a duty of confidentiality to you as a donor/ participant\* and we will do our best to meet this duty. {We will anonymise any documents or records that are sent from the University of Surrey, so that you cannot be identified from them. The exceptions to this are any letters or information that we send to your GP.}

{The data/samples\* you provide will be anonymised and} your personal data will be stored securely {separately from those anonymised data} . You will not be identified in any reports/publications resulting from this research and those reading them will not know who has contributed to it / with your permission we would like to use {anonymous} verbatim quotation/photographs/audio recordings/videos\* in reports.

If identifiable data will be shared with others outside the EEA, you must 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.

{In certain exceptional circumstances where you or others may be at significant risk of harm, the researcher may need to report this to an appropriate authority, in accordance with the {UK} Data Protection Act 1998. This would usually be discussed with you first.

Examples of those exceptional circumstances when confidential information may have to be disclosed are:

* The researcher believes you are at serious risk of harm, either from yourself or others
* The researcher suspects a child may be at risk of harm
* You pose a serious risk of harm to, or threaten or abuse others
* As a statutory requirement e.g. reporting certain infectious diseases
* Under a court order requiring the University to divulge information
* We are passed information relating to an act of terrorism}

**Full contact details of researcher {and supervisor}**

**Who is organising and funding the research?**

This research is organised by [the University of Surrey / …\*] and funded by [government or EU funding / charity / pharmaceutical company\*]. The funder is [interested in / looking at / aiming to / has no conflict of interest…\*]

{The sponsors of this study will pay [name of hospital department or research fund] for including you in this study}.

Or

{Your doctor will be paid for including you in this study}.

**Who has reviewed the project?**

This research has been looked at by an independent group of people, called an Ethics Committee, to protect your interests. This study has been reviewed by and received a favourable ethical opinion from \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Research Ethics Committee/ University of Surrey {full name of Faculty} Ethics Committee \*.

**Thank you for taking the time to read this Information Sheet.**