**PARTICIPANT INFORMATION SHEET NHS**

**Title of Study: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**IRAS ref: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PLEASE KEEP A COPY OF THIS INFORMATION SHEET FOR YOUR RECORDS**

**Instructions:** *All blue italics is for guidance only and once section complete the blue italics must be deleted.*

*If a section is not pertinent to your study it can be amended/deleted, extra sections may be added if necessary.*

*Red text should be selected and changed to black or deleted depending on the study design.*

**Section: Taking Part**

**Invitation Paragraph**

We would like to invite you to participate in this research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please discuss the study with others if you wish. If you have any questions you can contact us using the contact details at the end of this information sheet.

*Aim: to explain who is undertaking the research, the purpose of the information sheet, to invite participants to take part, to explain why they were invited to take part and that participation is voluntary.*

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

The aim and objectives of this study………………

We are specifically interested in……………….

This will involve ……………………………………

*Aim: to* *provide a brief and clear outline of the aim of the study (i.e. the overall purpose of the research) and the objectives, (i.e. the steps that address how the research aim will be achieved).*

**Who is responsible for this study?**

This study is the responsibility of …………….at the University of Surrey and also involves collaborators at …………….

*Aim:* *To provide information on who is responsible for the conduct of the project, together with any collaborators external to the University of Surrey and explain what their role is too.*

*.***Why have I been invited to take part?**

You are invited to participate in this study because……

*Aim: to explain why you have approached the participants, how they were identified and the inclusion/exclusion criteria.*

**Do I have to take part?**

Participation is voluntary and you do not have to take part. We will describe the study in this information sheet and will give you ………days to read this, so you can decide whether you wish to take part in this study. Please contact us if there is anything that is not clear, or if you have any questions, or if you would like more information.

*Aim:* *emphasise that participation in the study is voluntary. State how long the participants will have to read the information sheet and decide whether to participate.*

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

If you decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form to confirm your agreement to participate. You will be given a copy of this consent form to keep. We will then …………….

*Aim: this section should be used to detail in lay language what is expected from the participant while they take part in the study.*

**For studies with human tissue samples:**

You will be asked to provide a sample of blood, urine, stool, tumour. This will be collected by [nurse, researcher, surgeon] at [clinic visit, during your planned surgery].

We will not collect more than x amount of blood in y amount of time.

**What happens if I do not want to take part or if I change my mind?**

You are free to withdraw from the study at any time, without giving a reason.

**For studies with human tissue samples:**

If you withdraw from the study any samples already collected will be destroyed. If the sample has already been analysed and the results anonymised it will not be possible to withdraw the data already obtained from the study.

*Aim: details of how the participant can withdraw their participation, data and samples from the study. Explain if there are any limitations to the withdrawal of data, e.g. not being possible to remove data once anonymised.*

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

The information we will get from the study will……………….

*Aim: to explain if there are any benefits for participants involved in the research. If applicable, provide a clear statement of arrangements for reimbursement.*

**Are there any potential risks involved?**

A possible disadvantage to taking part in the study is that ……………

In order to reduce any potential risks, the researchers will…………

**For studies with human tissue samples:**

* with blood samples: the possibility of bruising and/or fainting.
* with tissue biopsies: the possibility of bruising, infection.
* if taking blood samples with a cannula, mention if they will be replaced and indicate how often this will occur and the likelihood of problems.
* explain that despite checking veins at the screening visit it is not possible to predict how the participant will react following multiple sample collections.
* if the tests conducted on the sample could potentially reveal unexpected or incidental findings, please state this, outlining the process you would follow if this were to happen.

*Aim: this section can be used to explain if there are any risks for participants involved in the research. Consider any limits to confidentiality or disclosure to third parties if appropriate.*

**How is the project being funded?**

This research is being funded by……….

Or

This research is a student project as part of ……

*Aim: give details of the funder and any possible conflict of interest.*

**Will my participation be kept confidential?**

We are responsible for making sure your participation is kept confidential and any data is kept secure and used only in the way described in this information sheet.

Your information may be subject to review for monitoring and audit purposes, by individuals from the University of Surrey and/or regulators who will treat your data in confidence.

*Aim: to give the details of what measures you will take to ensure confidentiality.*

**Will my data be shared or used in future research studies?**

We would like your permission to share……

*Aim: to explain what will happen to the study data after the end of this study and whether all or some of it may be used in other research projects or de-identified and shared publicly. If the data will be used outside of the UK, please provide details of the measures in place to handle data. State if you will be keeping non-identifiable study data and/or personal data for use in future studies or sharing it.*

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

We will produce a final report summarising the main findings………

This research may be published in ………….

You can contact the study team to find out the results of the research…

*Aim: explain how the anonymised findings will be summarised, how the participant can request a copy and how findings will be disseminated. Add funder requirements such as open access etc.*

*Giving participants information about the findings of a research study is an important part of good public engagement and a key aspect of research transparency. It respects participants and acknowledges their contribution. It is also an expectation in the*[*UK Policy Framework for Health and Social Care Research*](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

**Who has reviewed this study?**

This research has been reviewed by an independent group of people, called an Ethics Committee. This study was reviewed and given a favourable ethical opinion by the……

*Aim: Please provide details of which NHS REC has reviewed the project*

**Section: Your personal data**

*This section contains mandatory text required by the HRA, do not change other than the options in red.*

**What is personal data?**

‘Personal Data’ means any information that identifies you as an individual. We will be collecting and using some of your personal data that is relevant to the study and this section gives information on that. This personal data collected will include [your name, email address, phone number, ID number, location data, other identifiers etc.], which is regarded as ‘personal data’ and [race, ethnic origin, religion, physical or mental health, biometric data, genetic data etc.], which is regarded as a ‘special category personal data’.

*Aim: a simple statement to explain to participants what personal data is and what information will be collected in this study.*

**Who is handling my personal data?**

The University of Surrey, the sponsor of this research and responsible for looking after your information,, will act as the ‘Data Controller’. The research team will process your personal data on behalf of the controller and are responsible for looking after your information and using it properly. We will use this information as explained in the ‘What is the purpose of the study’ section above*.*

*Aim: to make clear who the Data Controller is. Include details of any other collaborators and other data processors.*

**What will happen to my personal data?**

As a publicly-funded organisation, we have to ensure that when we use **identifiable personal** information from people who have agreed to take part in research, that this data is processed fairly and lawfully. The University of Surrey processes personal data for the purposes of carrying out research in the **public interest** and special category data is processed on an additional condition necessary for **research purposes.** This means that when you agree to take part in this research study, we will use and look after your data in the ways needed to achieve the outcomes of the study.

**How will we use information about you?**

We will need to use information from [you] [from your medical records] [your GP] [OTHER] for this research project.

This information will include your [initials/ NHS number/ name/ contact details/ provide a bullet list of identifiers held by site and/or sponsor for the research]. People will use this information to do the research or to check your records to make sure that the research is being done properly.

OPTION where applicable: People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

DELETE one option in square brackets: We will keep your study data for the minimum period of time required by [state the conditions that will be used to determine this time period] OR [we will keep your study data for a maximum of XX years]. The study data will then be fully anonymized and securely archived or destroyed.

**International transfers**

[IF NO TRANSFERS OUT OF UK WILL OCCUR] Your data will not be shared outside the UK.

OR

[IF TRANSFERS OUT OF UK WILL OCCUR, WHICH IF IT REMAINS A POSSIBILITY E.G. IN THE FUTURE – INCLUDING SHARING IN DE-IDENTIFIED FORM WITH OTHER RESEARCHERS - SHOULD BE INCLUDED AND ABOVE DELETED]

We may share data about you outside the UK for research related purposes to:

In bullet points, concisely list the reasons why you will send data out of the UK

If this happens, we will only share the data that is needed. We will also make sure you can’t be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations:

* [insert list e.g. our partners who analyse your data, companies to pay your expenses, organisations who store your data]

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following [DELETE AS APPLICABLE]:

* (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
* we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details [visit the Information Commissioner’s Office (ICO) website](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/)
* we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
* we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
* we have procedures in place to deal with any suspected personal data breach.  We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules [visit the Information Commissioner's Office (ICO) website](https://ico.org.uk/for-organisations/report-a-breach)
* You can find out more about how we use your information <https://www.surrey.ac.uk/information-management/data-protection> and/or by contacting [dataprotection@surrey.ac.uk](mailto:dataprotection@surrey.ac.uk)
* [OTHER]

**What are your choices about how your information is used?**

* you can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have
* OPTION if follow up data will be collected after withdrawal: If you choose to stop taking part in the study, we would like to continue collecting information about your health from [central NHS records / your hospital / your GP]. If you do not want this to happen, tell us and we will stop
* you have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
* OPTION if data will be used for future research: If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. [Insert details of any specific bank / repository]

**Where can you find out more about how your information is used?**

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

* our leaflet [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch) and website information <https://www.surrey.ac.uk/information-management/data-protection> or study specific documents
* by asking one of the research team
* by sending an email to [email of research team] or [dataprotection@surrey.ac.uk](mailto:dataprotection@surrey.ac.uk)
* by ringing us on [phone number of research team].
* OPTION if the sponsor has appointed a UK representative: By contacting our UK representative at [provide name and contact details of the UK representative]

*NOTE: At least one of these sources must be able to point people directly to the sponsor’s Data Protection Officer.*

**Section: Further information**

**What if you have a query or something goes wrong?**

If you are unsure about something you can contact the research team for further advice using the contact details at the bottom of this information sheet.

However, if your query has not been handled to your satisfaction, or if you are unhappy and wish to make a formal complaint to someone independent of the research team, then please contact:

Head of Assurance

Research, Innovation and Impact

University of Surrey

Senate House, Guildford, Surrey, GU2 7XH

Email: assurance@surrey.ac.uk

The University has in place the relevant insurance policies which apply to this study. 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.

*Aim: to inform participants of the procedure to follow if they would like to complain and that insurance cover is in place.*

**Who should I contact for further information?**

If you have any questions or require more information about this study, please contact me using the following contact details:

Chief Investigator: Name, email, phone number (University details, not NHS or personal)

Principal Investigator: Name, email, phone number (not personal)

Project manager: Name, email, phone number (University details, not NHS or personal)

University of Surrey

Stag Hill

Guildford

GU2 7XH

**Thank you for reading this information sheet and for considering taking part in this research.**