**PARTICIPANT INFORMATION SHEET**

**Template**

**General Guidance**

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.

Information sheets should be written in simple, non-technical terms and be easily understood by a layperson. Use short words, sentences and paragraphs with clear sub-headings to make the text manageable, and a font size for easy reading. As a general guide the language level used should be no more difficult than that used in tabloid newspapers. Large sections of unbroken text should be avoided and bullet pointed lists used where appropriate.

The tone should be invitational and not coercive or overly persuasive.

All consent forms and information sheets should be version dated in the header/footer to ensure that the most recent version is used and the pages numbered e.g. 2 of 3.

The participant should be given a copy of the information sheet for further reference and a copy should be retained by the investigator with the study documents.

**Information for children**

When designing information sheets for children, investigators need to consider the likely attention span of the child and any possible fear/apprehension of the procedures involved.

Consideration should be given to the possible need for reading out the information or the use of pictures to help explain certain details.

**WHEN SUBMITTING YOUR PARTICIPANT INFORMATION SHEET FOR REVIEW PLEASE ENSURE THAT YOU SUBMIT THE FINAL VERSION EG DELETE THIS GUIDANCE SHEET AND delete/edit ANY GUIDANCE WITHIN THE TEMPLATE BELOW.**

**Text highlighted in yellow is advisory – sections will need to be completed appropriately for your study then the advisory text deleted or highlighting removed.**

**Optional statements are highlighted turquoise – delete or revise as required.**

**LIVERPOOL JOHN MOORES UNIVERSITY**

**Participant Information Sheet For [*insert target group e.g. child, service user, service provider etc.*]**

**LJMU’s Research Ethics Committee Approval Reference**:

**YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET**

**Title of Study** *[If the title is not self-explanatory to a lay person then a secondary title should be given to clarify]*:

*[Insert an introductory paragraph e.g.:]*

You are being invited to take part in a study. Before you decide it is important for you to understand why the study us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

1. **Who will conduct the study?**

**Study Team** *[Include name and contact details and status [e.g. PhD student, supervisor, co-investigator]*

**Principal Investigator**:

**Co-investigator:**

**School/Faculty within LJMU**:

**Collaborating Institutions:**

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

*[Why the study is important, the background and aim of the study should be given in language understandable to a lay person. This section should be brief but informative and should not be misleading. Where the study is a student led project being conducted for the purpose of completing a degree programme, this should be made clear]*

This study hopes to answer the following questions

1. **Why have I been invited to participate?**

You have been invited because…

The exclusion / inclusion criteria are…

*[Please explain how the participant was identified as a potential participant and how many other participants will be recruited to the study]*

1. **Do I have to take part?**

*[You should explain that taking part in the study is entirely voluntary and that refusal to agree to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. The participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.*

*Example paragraph:]*

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw at any time by informing the investigators without giving a reason and without it affecting your rights/any future treatment/service you receive.

1. **What will happen to me if I take part?**

*[If applicable:]* We will talk you through the study procedures and give you the chance to ask any questions.

*[Please include appropriate required information in language appropriate for a layperson. You should give potential participants an idea of what they should expect if they agree to take part, in the order they will experience. If there are multiple study visits, describe them in turn. It is important that you consider their perspective and likely view of any impacts on them, their lives and those close to them. For example:*

* *If a study is taking place in the context of clinical care, make it clear which parts are the study and which standard care.*
* *How long the participant will be involved; how often they will need to attend; how long the visits will be.*
* *How many visits, to where, when, to whom and how long will visits take*
* *How groups will be allocated*
* *Exactly what the participant will be asked to do (what will happen during participation - how, where, when, with whom, how often, for how long etc.). Where questionnaires are to be returned by members of the public as part of the study the ethics committee would advise investigators to consider the use of collection boxes at third party locations.*
* *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?*
* *If not already covered, what the investigator will do (how, where, when, with whom, how often, for how long etc.)*
* *Whether participants will be given the opportunity to consent for any significant findings directly related to the participant (e.g. abnormal findings) to be reported back to them – how this would be done – by whom – and the limitations of the findings*
* *Detail payments/reimbursements/prize draws etc.*

*[Where there are a large number of procedures involved it is recommended that these also be depicted as a flow chart for clarity].*

1. ***[If applicable]* Will I be recorded and how will the recorded media be used?**

You are free to decline to be audio/video recorded. You should be comfortable with the recording process and you are free to stop the recording at any time

The audio/video recording is essential to your participation but you should be comfortable with the recording process and you are free to stop the recording at any time

The audio and/or video recordings of your activities made during this study will be used only for analysis. No other use will be made of them without your written permission.

Interviews will be audio recorded on a password protected audio recording device and as soon as possible the recording will be transferred to secure storage and deleted from the recording device.

[If collecting special category personal data] Interviews will be audio recorded on an encrypted audio recording device and as soon as possible the recording will be transferred to secure storage and deleted from the recording device.

1. **What should I consider?**

*[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;

• Whether they can participate if they are involved in other studies.

1. **Are there any possible disadvantages or risks from taking part?**

*[State the any reasonable foreseeable discomforts, disadvantages, adverse reactions, distress and risks of harm. Try to describe the likelihood of adverse things happening as well as the severity in language all potential participants are likely to understand. State how the risks will be minimised/mitigated and managed, both by the investigator and the participant. Ask the participant to inform you if they experience an adverse event]*

* Blood samples: *the possibility of bruising and/or fainting etc.*
* Biopsies: *the possibility of bruising, infection (mitigated by antiseptic, trained staff) etc.*
* Radiation for DEXA: *the implications for doses etc.*
* Questionnaires or interview questions that may cause distress: *give implication of kinds of questions you will be asking, whether the participant can skip questions and outline what would happen if a participant becomes upset.*

Study supplements/nutrition/drugs etc.

* Dose:
* Side effects:
* Contraindications:

If you are personally affected by participation in this study, you may wish to seek support/advice from…

1. **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. It is important not to exaggerate the possible benefits to the particular participant during the course of the project. This could be seen as coercive.]*

The benefits of taking part are

Whilst will be no direct benefits to you for taking part in the study, but it is hoped that this work will….

1. ***[if applicable]* What will happen to my tissue samples?**

*[The following information must be included:*

* + *details of why the tissue samples are being collected*
	+ *brief details of the proposed tests and analyses to be performed*
	+ *details of how/where the tissue will be stored and how/when the tissue will be disposed of*

*Where applicable participants must be given specific information relating to the following potential uses of tissue samples or personal data:*

* + *Study involving human embryos and stem cells*
	+ *study into termination of pregnancy or contraception*
	+ *Study involving genetic analysis]*

It will 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.

[If applicable] Your DNA and blood sample will be assigned a code and your data will also be identified only by this number. You will not be identifiable from reading the code, however, your DNA is unique to you so it can never be completely anonymous.

[If applicable] Your samples might be shared anonymously with other investigators (if applicable), in ethically approved studies that take place in hospitals, universities, non-profit institutions or commercial laboratories worldwide. If you agree to your samples being used in future studies, your consent form will be held until the samples have been used up.

1. **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.) and/or if the participant has been administered and anaesthetic]*

1. **What will happen to the data provided and how will my taking part in this project be kept confidential?**

The information you provide as part of the study is the **study data**. Any study data from which you can be identified (e.g. from identifiers such as your name, date of birth, audio recording etc.), is known as **personal data**.This includes more sensitive categories of personal data (**sensitive data**) such as your race; ethnic origin; politics; religion; trade union membership; genetics; biometrics (where used for ID purposes); health; sex life; or sexual orientation.

Your participation in this study will not involve the collection of personal data

When you agree to take part in a study, we will use your personal data in the ways needed to conduct and analyse the study and if necessary, to verify and defend, when required, the process and outcomes of the study. Personal data will be accessible to the study team and. *[e.g. the study team, a transcription service, any other recipient]* … *[State whether personal identifiable data/information/tissue will be transferred outside of the European Economic Area, (provide details of where) and how appropriate or suitable safeguards will be achieved (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)]*

When we do not need to use personal data, it will be deleted or identifiers will be removed. Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed). However, your consent form, contact details, audio recordings etc. will be retained for X years.

Responsible members of Liverpool John Moores University [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the study to ensure that the study is complying with applicable regulations.

Personal data collected from you will be recorded using a linked code – the link from the code to your identity will be stored securely and separately from the coded data

Personal data will be used in machine learning or other technologies that will result in solely automated decision-making about the individual. There are no significant or envisaged consequences of such processing for the data subject / The envisaged consequences of such processing for the data subject are… This is significant because…

We will not tell anyone that you have taken part in the focus group, although there is of course a possibility that another member of the group might recognise you. We will also not name you in any of our reports or publications. In addition, all participants in the focus group will be asked to respect the confidentiality of their fellow participants.

You will not be identifiable in any ensuing reports or publications.

We will use pseudonyms in transcripts and reports to help protect the identity of individuals and organisations unless you tell us that you would like to be attributed to information/direct quotes etc.

With your consent, we would like to store your contact details so that we may contact you about future opportunities to participate in studies.

The interview recordings will be sent to an independent company who will produce a transcript

De-identified data might be used for additional or subsequent studies and we might share de-identified data with other investigators running other studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or private companies in this country or abroad). All personal information that could identify you will be removed or changed before information is shared or results are made public. This information will not be combined with other information in a way that could identify you.

When you agree to take part in a study, the information collected may be provided to investigators running other studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or private companies in this country or abroad. Your information could be used for research and could be combined with information about you from other sources held by investigators, the NHS or government.  Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information may be used to contact you about future opportunities to participate in studies. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified your data will only be used in studies that has been independently reviewed by an ethics committee.

*[For research studies conducted in the NHS or approved by the HRA and/or NHS REC – please include information according to the HRA recommended transparency wording* [*https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/*](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-public-sector/)*]*

1. **Limits to confidentiality**

Please note that confidentiality may not be guaranteed; for example, due to the limited size of the participant sample, the position of the participant or information included in reports, participants might be indirectly identifiable in transcripts and reports. The investigator will work with the participant in an attempt to minimise and manage the potential for indirect identification of participants.

The Investigator will keep confidential anything they learn or observe related to illegal activity unless related to the abuse of children or vulnerable adults, money laundering or acts of terrorism.

The investigator has a professional obligation to inform relevant agencies if they learn about…

In certain exceptional circumstances where you or others may be at significant risk of harm, the investigator may need to report this to an appropriate authority. This would usually be discussed with you first. Examples of those exceptional circumstances when confidential information may have to be disclosed are:

* The investigator believes you are at serious risk of harm, either from yourself or others
* The investigator 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
1. ***[if applicable]* Use of Deception**

Study designs often require that the full intent of the study not be explained prior to participation. Although we have described the general nature of the tasks that you will be asked to perform, the full intent of the study will not be explained to you until after the completion of the study (at which point you may withdraw your data from the study).

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

The investigator intends to … *[complete a dissertation to satisfy their degree programme / publish the results in a PhD thesis / journal article]*

1. **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 advising the participant to speak to their GP.*

1. **Who is organising and *[If applicable]* funding/commissioning the study?**

This study is organised by Liverpool John Moores University and funded/commissioned by… [The funder/commissioner is *[interested in / looking at / aiming to / has no conflict of interest…]*

*[Commercial studies:* I*t should be made clear to participants that in the event of the development of a new product or service there will be no personal financial gain]*

1. **Who has reviewed this study?**

This study has been reviewed by, and received ethics clearance through, the Liverpool John Moores University Research Ethics Committee (Reference number: xxx).

1. **What if something goes wrong?**

If you have a concern about any aspect of this study, please contact the relevant investigator who will do their best to answer your query. The investigator should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact the chair of the Liverpool John Moores University Research Ethics Committee (researchethics@ljmu.ac.uk) and your communication will be re-directed to an independent person as appropriate.

*[For intervention studies]*

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.

*[If, in addition, NHS indemnity is in place for your study, usually when one or more members of your research team have NHS contracts]* 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 LJMU but you may have to pay your legal costs.

1. **Data Protection Notice**

Liverpool John Moores University is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study *[If LJMU is not the sole Data Controller this will need to be revised and the other data controller added. An explanation provided in the ethics application].* This means that we are responsible for looking after your information and using it properly. Liverpool John Moores University will process your personal data for the purpose of research. Research is a task that we perform in the public interest. Liverpool John Moores University will keep identifiable information about you for X years after the study has finished/ until X.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at URL and/or by contacting secretariat@ljmu.ac.uk.

If you are concerned about how your personal data is being processed, please contact LJMU in the first instance at secretariat@ljmu.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner’s Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: <https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/>

**16. Contact for further information**

*[Name, postal/email address and telephone**number of the principal investigator or that of another investigator in the project (In the interests of safety LJMU Research Ethics Committee would advise investigators not to include home addresses or personal telephone numbers (mobile or home) as contact details for participants)]*

**Thank you for reading this information sheet and for considering to take part in this study.**

*Note: A copy of the participant information sheet should be retained by the participant with a copy of the signed consent form.*

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