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|  cid:image006.jpg@01CE26F4.32127830 | Date received | Initials | LJMU REC Ref |
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**UREC Research Ethics Application Form – Studies Involving the Collection of Human Tissue**

**No research (studies on human participants or their data (including service evaluations, audit etc.)) must be started without full, unconditional ethical approval.** There are a number of routes for obtaining ethical approval depending on the potential participants and type of study involved – please complete the checklists below to determine which is the most appropriate route for your research study.

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| 1. **Pedagogic Research (ONLY complete if you are a member of staff undertaking pedagogic research – otherwise, please leave blank)**
 | **YES** | **NO** |
|  | Is the proposed study being undertaken by a member of LJMU staff? |  |  |
|  | Is the purpose of the study to evaluate the effectiveness of LJMU teaching and learning practices by identifying areas for improvement, piloting changes and improvements to current practices or helping students identify and work on areas for improvement in their own study practices? |  |  |
|  | Will the study be explained to staff and students and their informed consent obtained? |  |  |
|  | Will participants have the right to refuse to participate and to withdraw from the study? |  |  |
|  | Will the findings from the study be used **solely** for internal purposes?*e.g. there is no intention to publish or disseminate the findings in journal articles or external presentations* |  |  |
| If you have answered **YES to all 1a-e,** your study may be eligible for consideration under the University’s Code of Practice for Pedagogic Research. You should **not** complete this application form but seek further guidance at <https://www2.ljmu.ac.uk/RGSO/114123.htm> or by contacting researchethics@ljmu.ac.uk. |
| If you have answered **No to any of 1a-e,** please complete the checklists below |

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| 1. **Requirements for NHS Research Ethics Committee & Health Research Authority Approval**
 | **YES** | **NO** |
|  | Is the study defined as research by the HRA **AND** is there a regulatory or NHS policy requirement for the study to be approved by a NHS REC? (<https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/>\* Please note when completing the decision tool, (<http://www.hra-decisiontools.org.uk/ethics/>) LJMU researchers can store human tissue according to the LJMU HTA licence (<https://www2.ljmu.ac.uk/RGSO/93204.htm>) |  |  |
|  | Is the study defined as research by the HRA **AND** will the study involve NHS organisations in England where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers (references to participants include people whose data or tissue is involved in a research project)? <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/> |  |  |
|  | Is the study defined as research by the HRA **AND** will the study/project be led from Northern Ireland, Scotland or Wales and involves NHS/HSC sites? <https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx> |  |  |
| If you answered **NO to 2a** then your study can be ethically approved by UREC. Please complete the checklist below to determine whether your application is eligible for proportionate review (applications can be submitted at any time) or full review at UREC meetings (please refer to the deadlines for submission - <https://www2.ljmu.ac.uk/RGSO/93126.htm>)  |
| If you answered **YES to 2a, please DO NOT complete this ethics application form.** You must complete an IRAS form (<https://www.myresearchproject.org.uk/>) and seek NHS REC approval. <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/> |
| If you answered **YES to 2b**, you must complete an IRAS form (<https://www.myresearchproject.org.uk/>) and seek HRA approval (in addition to either NHS REC or UREC approval – as determined by your answer to **2a**). <https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/> |
| If you answered **YES to 2c**, you should apply for NHS/HSC R&D Permissions (in addition to either NHS REC or UREC approval (as determined by your answer to **2a**) through the appropriate NHS/HSC permission process for that lead nation (<https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx>) |
| If you answered **NO** to **2b** or **2c**, please seek ethical approval as determined by your answer to **2a**. |

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| 1. **Full versus Proportionate Review - will the proposed study:**
 | **YES** | **NO** |
|  | Expose participants or researchers to activities that pose a significant risk of causing physical harm or more than mild discomfort, psychological stress or anxiety or levels of risks beyond those, which the participant is likely to experience whilst participating in their everyday activities? These risks may be related to psychological or physical health, social standing or connectedness, economic well-being, legal harm or devaluation of a person’s self-worth (*e.g. untrained volunteers exposed to high levels of physical exertion; participants purposefully exposed to stressful situations; exposure to pain; risk of injury or damage; research where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life; lone working at night; interviewing in the researcher’s or participant’s homes, observation in potentially volatile or sensitive situations etc.)* |  |  |
|  | Involve the discussion or disclosure of topics which participants might find sensitive or distressing? (*e.g. sexual activity; criminal/illegal activity; drug use; mental health; previous traumatic experiences; illness; bereavement; disclosure and analysis of findings based on sensitive personal information as defined by Data Protection Act e.g. racial or ethnic origin; political opinions; religious beliefs; trade union membership; physical or mental health; sexual life)* |  |  |
|  | Involve the administration of drugs, medicines or nutritional supplements as part of the research design? |  |  |
|  | Involve the collection of venous blood samples? |  |  |
|  | Involve the collection and/or use of human tissue from healthy volunteers? *Please note, samples collected for a research purpose and subsequently processed to leave it acellular with any residual cellular material immediately discarded is* ***NOT*** *considered human tissue and is therefore not regulated by the HT act or the LJMU Human Tissue License* |  |  |
|  | Include adults who may be classed as vulnerable? *e.g. drug/substance users; young offenders; prisoners/probationers; those in a dependent relationship with the researcher; those who have an impairment of, or a disturbance in, the mind or the brain. e.g. dementia, mental illness, learning disability, brain damage, intoxication, any other condition causing confusion, drowsiness or loss of consciousness (e.g. concussion, stroke, heart attack, epileptic fit, serious accident, delirium).* |  |  |
|  | Include children (below 16) NOT in an educational setting/accredited organisation OR where active, opt-in parental consent and child assent will not be sought? |  |  |
|  | Involve focus groups with children (below 16) with more than 8 participants in each focus group and/or the age range within the focus group is more than 3 years and/or the focus group will last more than 90 minutes in duration? |  |  |
|  | Include children (under 11) who will not be supported when undertaking the protocol? |  |  |
|  | Involve recruiting participants who have not been provided with a participant information sheet and asked to sign a consent form? *Please note that for questionnaire-based studies a consent form is generally not request as consent is implied by the completion of the questionnaire. Applicants conducting* ***questionnaire-only*** *studies should answer NO* |  |  |
|  | Involve conducting observations (including ethnography) in a non-public place? |  |  |
|  | Involve participatory/action research? |  |  |
|  | Involve deliberately misleading participants in any way? |  |  |
|  | Involve cash payments to participants for anything other than the reimbursement of reasonable expenses or reasonable incentives that are not pro-rata or are unequal between participants (including participants who withdraw)? |  |  |
|  | Be conducted outside of normal working hours or at a time and place inconvenient to participants? |  |  |
|  | Be conducted outside the EU or in one of the 3 non-EU EEA member countries? |  |  |
|  | Involve accessing and analysing existing datasets that will not be anonymous to the researcher? |  |  |
|  | Involve the sharing of directly or indirectly identifiable data with other organisations outside of LJMU or with people outside of the research team? |  |  |
|  | Involve the dissemination of directly or indirectly identifiable data/information without a participants consent (*e.g. the use of social media or the internet as a data source – unless the website or social media account is maintained by a public or commercial organisation*)? |  |  |
| If you have answered **No to all** **3a-s** your study is eligible for proportionate review. Complete this application form and submit as **ONE** pdf document (the application form and all supporting documents) **at any time** to**EthicsPR@ljmu.ac.uk**. Your application will be reviewed by a UREC sub-committee, all being well, within 10 working days. Please note, the UREC sub-committee finds that your application has been wrongly submitted for proportionate review, you will be notified and your application will be consideration at the next available UREC meeting.  |
| If you have answered **Yes to any of 3a-s** your study must be submitted for full review. Complete this application form and submit as **ONE** pdf document (the application form and all supporting documents) to **researchethics@ljmu.ac.uk** by the deadline advertise (<https://www2.ljmu.ac.uk/RGSO/93126.htm>). Your application will be considered at a UREC meeting. Guidance on completing the LJMU REC application form can be found at <http://www2.ljmu.ac.uk/RGSO/93044.htm>  |

<https://www2.ljmu.ac.uk/RGSO/93085.htm>

**Research Mode**

* **Undergraduate** – specify course

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* **Postgraduate** (Type **YES** in the boxes that apply)

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|  | MRes |
|  | MPhil  |
|  | PhD |
|  | Prof Doc e.g. EdD or DBA |
|  | Other taught Masters programme – specify course  |
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|  |  | Postdoctoral |
|  |  | Staff project |
|  |  | Other – please specify |

* **Has this application previously been submitted to the University REC for review? –** Yes / No

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* **If yes please state the original REC Ref Number**
* **Please confirm whether the Principle Investigator (PI) has successfully completed the LJMU Research Ethics Training and a copy of the certificate of completion emailed to the PI has been appended to this ethics application** (<https://www2.ljmu.ac.uk/RGSO/131507.htm>)

Please type **YES** or **NO** in the box below

(Please note all students MUST have completed the LJMU Research Ethics Training BEFORE they start to complete the ethics application form. Where student PIs have not completed the training, ethics applications will be rejected).

* **Student research - please confirm that an email/letter from the supervisor has been appended to this ethics application confirming that:**

a) the supervisor has read and reviewed this ethics application form and all supporting documents

b) the information included in the application and all supporting documents will allow UREC to decide whether all challenges to the principles of research ethics have been identified and addressed

Please type **YES** or **NO** in the box below

**Section A – The Applicant**

1. **Title of the Research**

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1. **Principal Investigator (PI)** *(Note that the in the case of postgraduate or undergraduate research the student is designated the PI. For research undertaken by staff inclusive of postdoctoral researchers and research assistants the staff member conducting the research is designated the PI.)*

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| Email |  | Telephone |  |

Relevant experience / Qualifications

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1. **Co-applicants** *(including student supervisors)*

**Co-applicant 1 / Academic Supervisor 1** *(where the application is being submitted by a student, either undergraduate or postgraduate, details of their main dissertation supervisor must be included. The form must be submitted with a letter or email from their named supervisor indicating that they have read the application and are willing to supervisor the student undertaking the proposed study –* ***STUDENT APPLICATIONS WILL NOT BE REVIEWED UNTIL NOTIFICATION OF REVIEW BY THE NAMED SUPERVISOR IS RECEIVED***

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Relevant experience / Qualifications

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**Co-applicant 2 / Academic Supervisor 2**

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| Title |  | Forename |  | Surname |  |

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Relevant experience / Qualifications

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Where there are more than two co-applicants, please append an additional page to your application containing the relevant details

**SECTION B – PROJECT DETAILS**

1. **Proposed date for commencement of participant recruitment** *(Please enter the date when you propose to start recruiting participants – note that no recruitment can take place without full, unconditional ethical approval)*

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| **Start date:** |  |

1. **Scientific justification – please provide an overview in plain English - please avoid abbreviations and explain technical terms. State the background and why this is an important area for research** *(Note this must be completed in language comprehensible to a layperson. Do not simply refer to the protocol. Maximum length – 1 side of A4)*

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1. **Give a summary of the purpose, design and methodology of the planned research. What do you propose to do and how do you propose to do it? Provide information as appropriate in plain English (comprehensible to a layperson) to help the REC understand and approve your application.**
2. *Participants – who are they? What will happen to them? How many times? In what order? Where? When? How? How long will take them? Etc.*
3. *Interventions/procedures - Give details (How? When? Where? How often? For how long? Etc.) of all interventions/procedures that will be received by the participants as part of the research protocol (intervention/procedures might include seeking consent, screening questionnaires, interviews, questionnaires for data collection, exercise, measurement variables etc.)*

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1. **State the principal research question**

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1. **Give details of the proposed intervention(s) or procedure(s) and the groups of people involved (***including psychological or physical interventions, interviews, observations or questionnaires)*

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| **intervention(s) or procedure(s)** *(e.g., interviews, questionnaires, Vo2max test, blood sampling, force platform, health-screening questionnaire etc.)* | **Participants***(e.g. LJMU students, athletes, general public, children etc.)* | **Number of participants required** | **Avg. time to complete** | **Where will the intervention / procedure take place***(LJMU classroom, LJMU laboratory, participant’s homes, public places etc.)* |
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*To include additional interventions place your mouse cursor in the last cell of the final column and press the tab button on your keyboard. A new row will be created for the above table.*

1. **Studies involving questionnaires to collect data. Please confirm that you have**:
2. Appended the questionnaire as it would be presented to the participants. This might include an introduction, instructions for completing the questionnaire, instructions for returning/submitting the questionnaire and any signposting to support services where applicable.
3. Included at the start of the questionnaire, a statement of implied consent and a tick box for participants to confirm implied consent, which you can copy from the consent form template.
4. Included at the start of the questionnaire, a statement that makes it clear that participants have the option of not answering questions they do not want to answer.
5. Requested the age of the participant at the start of the questionnaire, stated the age requirement and included instructions that those younger than the age requirement should not complete the questionnaire.

Please type **YES or NA** in the box below

**Have the questionnaires previously been validated?**

Please type **YES**, **NO** or **NA** in the box below

**If YES, please include the references and state the population in which the questionnaire was validated**

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1. **Where interviews or focus groups (structured or semi-structured) are proposed you must append an outline of the questions you are going to ask your participants. Please confirm that you have attached an outline of your interview / focus group questions.**

Please type **YES** or **NA** in the box below

1. **How will the findings of the research be disseminated?***(e.g. thesis, dissertation, peer-reviewed articles, conference presentations, reports)*

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**SECTION C – THE PARTICIPANTS**

**Please give separate details for different study groups where appropriate.** *Participation in a research project must be entirely voluntary, and no one must be coerced to participate in a research project against his/her will.  Researchers should avoid exerting undue influence when approaching potential participants.  No sanctions should follow if the participant decides to withdraw from the research at any time.*

***Gatekeepers*** *- A gatekeeper is any person or institution that acts as an intermediary between a researcher and potential participants (e.g., school authorities, sports club, treatment service providers, a coach, instructor etc.). The use of a gatekeeper may be necessary:*

* *To help identify participants where a researcher does not have legitimate access to personal data of potential participants (names and contact details or information related to identifying participants in relation to the inclusion/exclusion criteria of the study)*
* *Where it may also be more appropriate or good etiquette to ask a gatekeeper to make the first approach to potential participants – and in specific circumstances to take an active role in recruiting the participants*

*To minimise and manage potential risks (e.g. to gain permissions to access facilities, use a gatekeeper’s resources such as their facilities and their staff and to undertake the research within certain hours etc.)*

1. **How will the participants been selected, approached and recruited?** *(Where different groups of participants have been identified in section B5a above provide details on how each group will be selected, approached and recruited.)*
2. **Please indicate how individuals will be identified as potential participants.**
* If the researcher will need to access an individual’s personal data, please explain why they would have legitimate access to the personal data (according to the data protection act).
* If using a third party, such as a gatekeeper, to identify participants, records or samples please explain why and provide details of their relationship with the potential participants. (e.g., school authority, coach, treatment provider etc.)

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1. **How, where and by whom will the potential participants be initially approached/contacted?** (e.g. *face-to-face, by email/letter, telephone, referrals (e.g. by a gatekeeper or by snowballing etc.), social media, poster, flyers, presentation to a group of individuals etc.)*
* *Consider how to approach participants without revealing private information to others* *(e.g. an email sent to a group of individuals who have identified themselves as dyslexic to the gatekeeper but not to each other)*
* *Time & place – Is it easy for potential participants to say yes or no?*

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1. **Please confirm you have appended a copy of the recruitment emails/letters/posters/adverts etc**. Please type **YES** or **NA** in the box below

*If you wish to send a participant recruitment email/letter then in the text please state:*

1. *How the person was identified as a potential participant*
2. *How you have accessed their contact details / who has provided permission for you to access their contact details / who is emailing the potential participants on behalf of the researcher.*
3. *Something like “if you are interested in participating in the study please take time to read the participant information sheet (attached) and contact me with any questions. I can be contacted….”).*
4. *Inform the participant what they should do if they would like to participate*
5. **Participant recruitment** (the process of obtaining informed consent from participants). **Please explain (e.g. who, when, where, how) the process of fully informing participants, gatekeepers and parents/guardians about the purpose, methods and intended possible uses of the research, what participation in the research entails and what risks, if any, are involved.** *(Exclusively relying on simply handing out a participant information sheet should be avoided. Researchers should be able to verbally explain the study clearly to potential participants, provide a participant information sheet for participants to keep and be available to answer questions)*

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1. **How will the participant access the information sheet after they have consented?** *(e.g., will they be provided with a paper / electronic copy to keep? Online questionnaires - consider asking the participant to print/make an electronic copy of the participant information sheet)*

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1. **How long will the potential participants have to decide whether they would like to participate?** *(Potential participants need time to consider fully the implications of taking part in research.  They should be able to ask questions and reflect.  Participants should not be rushed into decisions - There are no fixed guidelines for the time to be allowed to participants.  It has been common practice to suggest a minimum of 24 hours, but this is not an absolute rule.  Each study should be considered on its own merits.  If you feel that a shorter period is reasonable in the circumstances and taking into account the nature of the study, please justify this in your answer)*

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1. **How was the number of participants decided?** *(e.g. was a sample size calculation performed)*

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1. **Will any of the participants come from any of the following groups?**
* *Whether children are considered vulnerable is dependent on the child’s circumstance, their susceptibility to coercion, the type of research being undertaken and how and where the research is being undertaken*
* *Please note that the Mental Capacity Act 2005 requires that all research involving participation of any adult who lacks the capacity to consent through learning difficulties, brain injury or mental health problems be reviewed by a NHS REC. For further information please see* [*http://www2.ljmu.ac.uk/RGSO/101579.htm*](http://www2.ljmu.ac.uk/RGSO/101579.htm)
* *Vulnerable adults & participants with a dependent relationship with the researcher: This question is designed to ascertain whether your participant groups are likely to need special consideration regarding issues of informed consent and the potential for perceived pressure to participate.*

**Type YES in all boxes that apply**

 Children under 16

 Children under 18 considered vulnerable

 Adults with learning disabilities

 Adults with mental illness (if yes please specify type of illness below)

Drug / Substance users

Young offenders

Those with a dependant relationship with the investigator (e.g. a coach etc.)

Other vulnerable groups please specify below

**Please provide details that might help the REC understand the ethical issues related to the characteristics of the participants and how they might be addressed.** *(e.g. age of participants; why participants might be considered vulnerable; ethical implications with regards to mental illness, drug users, young offenders; the dependent relationship between participant and researcher etc.)*

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**Please justify their inclusion:**

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1. **If you are proposing to undertake a research study involving interaction with children or vulnerable adults do you have current, valid clearance from the UK Disclosure and Barring Service (DBS)?**

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|  | **Yes** |  | **No**  |  | **Not Applicable** |

1. **What are the inclusion/exclusion criteria?**
* *The answers to the questions below will help the REC understand how you will ensure the quality of the study, how you will minimise any potential risks/hazards and whether there is the potential for any particular participant groups to be exploited or unfairly excluded.*
* *Participants need to be fully informed about the inclusion/exclusion criteria – please include the relevant information in any recruitment materials and information sheets*
1. **On what basis will individuals be included or excluded (eligible/ineligible) from your study in order to address the research question/objective?** *(Consider the characteristics of the target/study population)*

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1. **On what basis will individuals be included or excluded (eligible/ineligible) from your study in order to minimise/manage risk?** *(e.g. those with a food allergy, injury, mental or physical health issues etc.)*

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1. **How will you apply/implement each of the inclusion and exclusion criteria?** *(e.g. will potential participants self-include/exclude themselves based on the information provided on the participant information sheet – or will you assess the potential participants in some way – such as with a health screening questionnaire or physiological measurements – please explain)*

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1. **If applying the inclusion / exclusion criteria requires the collection of personal information about the participant then please detail the screening process that will ensure privacy and confidentiality.** *please consider the following:*
* *request only the minimal amount of information necessary for screening*
* *Screening should be done in private*
* *Immediate storage of data to ensure confidentiality*

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1. **Please confirm that where participants are screened and excluded from participating in the study, the researcher will NOT store screening information and give the screening questionnaire back to the individual**

Please type **YES** or **NA** in the box below

1. **Payment, reimbursements of expenses or any other benefit or incentives for taking part in the study.** *The REC will wish to be reassured that research participants are not being paid for taking risks or that payments are set at a level which would unduly influence participants and “cloud there judgement” about whether or not to participate.*
* *Research participants should not be substantially out of pocket because of taking part in a research study.*
* *Payment in cash or kind to participants must only be for costs such as travel expenses, child-care expenses, meals and demonstrable loss of earnings etc.*
* *Consideration should be given to any expense involved in returning postal questionnaires.*
* *If it is not possible to reimburse such expenses this should be explained before the research participant is recruited.  A clear statement should be included in the participant information sheet setting out the position on reimbursement.*
* *Payment/compensation for time and effort is a considered a wage payment model – and will only be considered by the REC if the tax implications have been considered by the researchers and communicated to the participants.*
1. **Will any payment or reward, such as an incentive or out of pocket expenses, be made to participants?**

Please type YES or NO in the box below

1. **If YES, How much is the payment or what is the reward?**

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1. **Please justify the payment/reward** *(consider whether this is a fair reimbursement or compensation or likely to coerce or apply undue pressure to participate. Is the payment/reward necessary to achieve a representative sample?)*

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1. **How will the payment/reward be made?** (*Vouchers are preferable as cash could have tax implications. If using a prize draw, how and when will the winners be notified of results and how and when winners will be notified and results be announced.)*

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1. **Will participants be able withdraw their participation without losing a payment/reward or entered into a prize draw?** Please type YES or NO in the box below.

**If NO, please explain why not** *(consider the principle that participants should be free to withdraw their participation without being penalised)*

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**SECTION D – CONSENT**

*For most types of research, it is both a legal and ethical requirement to obtain informed consent from participants able to consent for themselves. The researcher is responsible for obtaining an individual’s consent to participate. The participant should be fully informed about their participation (ideally verbally and in writing) and should be free to refuse to participate or withdraw their participation.*

* 1. **Will informed consent be obtained from: (Where applicable, please type YES in the box below)**

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| The research participants? The research participant’s carers or guardians? Gatekeeper? *(consent for their involvement in identifying/approaching/recruiting participants and/or permissions with regards to access and use of facilities/resources for recruitment and data collection purposes)* Not applicable  |

* 1. **Will a signed record of consent be obtained?** *(Please note that where the study involves the administration of a questionnaire or survey a signed record of consent is not required for completion of the questionnaire as long as it is made clear in the information sheet that completion of the questionnaire is voluntary. Under these circumstances, return of the completed questionnaire is taken as implied consent. Participation in any other interventions within the same study e.g. interviews, focus groups must be supported by obtaining appropriate written consent.)*
	2. Please type **YES**, **NO**, **implied consent** or **verbal consent** (*if written consent is not possible and implied consent is not appropriate*) in the box below.

*Where the study involves the use of more than one intervention for example interviews and a questionnaire please the space below to detail the method of consent to be used for each intervention e.g. Questionnaire – implied consent, Interview – written consent, Telephone interview – verbal consent*

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*If implied consent is to be assumed by return of questionnaires, the following statement (or similar) must be included on the questionnaire:*

*“I have read the information sheet provided and I am happy to participate. I understand that by completing and returning this questionnaire I am consenting to be part of this research study and for my data to be used as described in the information sheet provided” – please include a tick box so that the participant can confirm hey have read the statement.*

* 1. **If you propose NOT to obtain consent in writing (other than for questionnaires), please explain why not**. *(Where a participant is unable to sign or mark a document to indicate their consent, arrangements should be made for their consent to be witnessed and this should be documented)*

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**PLEASE APPEND COPIES OF ANY PROPOSED CONSENT FORMS TO THIS APPLICATION**

* 1. **All participants must be provided with written information detailing the purpose, procedures, risks and benefits of participating. An approved template for the participant information sheet can be found at** [**https://www2.ljmu.ac.uk/RGSO/93044.htm**](https://www2.ljmu.ac.uk/RGSO/93044.htm)**. Please check the box below to confirm that a participant information sheet has been appended to this application.**

**APPLICATIONS SUBMITTED WITHOUT A PARTICIPANT INFORMATION SHEET WILL NOT BE REVIEWED.**

* 1. **Will participants be able to withhold consent (refuse to take part)?**
	2. **Will participants be able to freely withhold consent (refuse to take part)?**

Please type **YES** or **NO** in the box below

If **NO** please explain why not

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* 1. **Will participants be able to freely withdraw from the study whilst it is ongoing?**

Please type **YES** or **NO** in the box below

If **NO** please explain why not

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* 1. **Will participants be able to freely withdraw their identifiable data from the study after data collection has ended?** *(if there are practical issues related to withdrawing a participants data once it has been amalgamated please explain below)*

Please type **YES**, **NO** or **NA** in the box below

If **NO** please explain why not

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**THE ABILITY OF PARTICIPANTS TO REFUSE TO TAKE PART OR TO WITHDRAW FROM A STUDY MUST BE MADE CLEAR IN THE WRITTEN INFORMATION PROVIDED TO PARTICIPANTS**

**SECTION E - RISKS AND BENEFITS**

***Risks*** *– the potential physical or psychological harm, adverse effects, discomfort, distress, intrusion, inconvenience or changes to lifestyle*

***Benefits*** *– as defined and perceived by the participant rather than the researcher. Benefits are sometimes “hoped-for”*

* 1. **Outline all potential risks to participants which are anticipated to be beyond those experienced in their everyday/normal life, how the risks will be minimised and managed**
* *Could be physical, psychological, social, economic, legal harm or damage to a person’s self-worth. e.g. side effects, incorrect dosage, injury, dangerous intervention/procedure, untrained volunteers exposed to high levels of physical exertion, participants purposefully exposed to stressful situations, research where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life, individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, breach of confidentiality, possible misunderstanding etc.*
* *Whether the risk will involve an increased likelihood or significantly higher risk of such negative events occurring than would be encountered in the participant’s everyday life, will depend on the context and a judgement as to the nature of the specific participant(s) and what constitutes their everyday lives.*

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|  | **Anticipated risks** | **How minimised** *(e.g. consider contraindications, checks, training, information to participants, procedures, equipment etc.)* | **How managed both during and after participation** *(what if something does happen during and after the study – what will/might you do) (e.g. stop, treatment, equipment availability, training, re-assess, refer, reschedule, carry-on, signpost to support services to help after-participation care of the participants etc.)* |
| 1. |  |  |  |
| 2. |  |  |  |

*To include additional interventions place your mouse cursor in the last cell of the final column and press the tab button on your keyboard. A new row will be created for the above table.*

* 1. **Reporting findings to participants**
	2. **Is there the potential for the research to reveal findings that might be considered abnormal or significant with regards to the participant’s health?**

Please type **YES** or **NO** in the box below

**If YES, please confirm that the participant will be informed on the participant information sheet that they will be given the option on the consent form to agree, or not agree, for abnormal results to be reported to them**.

Please type **YES** in the box below

* 1. **What advice/information will be provided to participants when passing findings onto participants- and who will provide the advice/information?**

*Consider the whether the methods are a proper diagnostic tool, the researcher’s qualifications to diagnose and disclose, whether the participant should consult with an appropriate authority such as their GP etc.*

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* 1. **Explain any potential or hoped for benefits of the study**.
* *PLEASE BE REALISTIC and do not over-emphasise the potential direct benefits to individual participants. Where there are no direct benefits to individual participants, provide brief details of the potential or hoped for broader benefits of the study for example to society or to future service users.*
* *Participation might be a positive experience but it is probably best to refrain from claiming any therapeutic benefit simply from participation)*

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* 1. **What are the potential risks for the researchers themselves? (if any)**

*Consider issues related to working outside of normal hours, off university premises (including a participant’s home), loan working, interacting with participants and members of the public who might pose a threat and potentially dangerous environments.*

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|  | **Anticipated risks** | **How minimised** | **How the risks will be managed should an event occur** |
| 1. |  |  |  |
| 2. |  |  |  |

*To include additional interventions place your mouse cursor in the last cell of the final column and press the tab button on your keyboard. A new row will be created for the above table.*

* 1. **For studies that involve transporting participants, will the transport be hired through LJMU Insurance officer?**

Please type **YES** or **NO** in the box below

**If NO, please confirm that the LJMU insurance officer has authorised the use of transport that is not hired through LJMU**

Please type YES in the box below

**SECTION F – DATA ACCESS AND STORAGE**

* ***Privacy*** *– an individual’s control over the extent, timing, and circumstances of sharing oneself (physically, behaviourally, or intellectually) with others.*
* ***Confidentiality*** *- the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.*
* ***Anonymity*** *– where individuals cannot be directly and indirectly identified – this could be related to participation (no way of anyone, including the researcher, knowing that an individual has participated), data/information (no way for anyone, including the researcher, to identify the individual from the data/information collected) and publication (no way for an individual to be identified from data/information that is published).*
* ***Link-codes*** *– used to help maintain confidentiality – data is coded so that that the data is unidentifiable simply by viewing the coded data but is identifiable when using the record that links the code to the identity of an individual. Data coded in this way is NOT anonymised, is still regarded as personal identifiable data and must be used/stored in accordance with the data protection act.*
* ***Personal identifiable Data/information*** *- Data/information that can be identified with a participant through identifiers such as names, link-codes, postal/email addresses, telephone numbers, date of birth, full postcode, medical records, academic records, audio/video recordings of individuals, images, voices etc.. The use of identifiable personal information in research should be reduced so far as possible consistent with achievement of the research aims. The "Caldecott Principles" set out an ethical framework for use of identifiable data:*
1. *Justify the purpose(s) for obtaining the information.*
2. *Do not use person-identifiable information unless it is absolutely necessary.*
3. *Use the minimum necessary person-identifiable information.*
4. *Access to person-identifiable information should be on a strict need-to-know basis.*
5. *Everyone with access to person-identifiable information should be aware of his or her responsibilities.*
6. *Understand and comply with the law.*
	1. **Personal Data Management.**
	2. **Please provide details of any personal, identifiable or sensitive information will be collected and stored** *(e.g. names, postal/email addresses, telephone numbers, date of birth, full postcode, medical records, academic records, audio/video recordings of individuals, images, voices etc.)*

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* 1. **How will personal identifiable data/information be collected/recorded to ensure privacy and confidentiality?**
* *Will data/information be anonymous? Will you use linked-codes/pseudonyms? Will you require codes/pseudonyms to be linked to the identity of the participant?*
* *How will you ensure that individuals are not identifiable from the codes/pseudonyms?*
* *Will recording devices be password protected and only accessible to the researchers? Will the data/information be deleted from a recording device once transferred to storage?*
* *For questionnaires (used for collecting data and screening participants), please explain how the method of submitting/delivering the completed questionnaire to the researcher will ensure confidentiality.*

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* 1. **How will personal identifiable data/information be securely stored to ensure privacy and confidentiality?** *(e.g. a locked filing cabinet in an LJMU office, managed client LJMU computers/laptops that require an LJMU username and password to use, an LJMU portal such as the M:drive).*

**Please note, personal identifiable data/information must not be stored on home or personal computer/laptop or a portable storage device (such as a USB drive)**

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* 1. **How will study findings be disseminated in order to ensure privacy and confidentiality?** *(e.g. participants will not be directly attributed to data/information that is disseminated – or will be attributed but only with explicit consent from the participant, use of pseudonyms etc.)*

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* 1. **Following attempts to ensure privacy and confidentiality, if there is the possibility that individuals could be indirectly identified once the study has been disseminated please explain what you will do (including involving the participant in the decision making process) to minimise the potential for indirect identification, and how you will manage the potential for indirect identification?**
* *participants with specific characteristics/certain profile or who belong to a specific group might be indirectly identifiable from the things they have said/done that are disseminated by the researcher).*
* *Care should be taken that the combination of incidental details e.g. details about occupation, location, age and ethnicity, do not lead to individuals being identifiable*
* *You might want to consult with the participant about how information will be disseminated and what information should not be disseminated.*

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* 1. **Will you share personal, identifiable data with other organisations outside of LJMU or with people outside of your research team?** *(e.g. supervisor, co-applicants)*
* *Unless there is a good reason, only anonymised data should be shared.  Where data has been effectively pseudo-anonymised (can be identified via a linked code) it should only be shared on the basis that the recipient cannot disclose pseudo-anonymised data to third parties and is not permitted to link the data with other data which might render the information more identifiable.*

**Please type YES or NO in the box below**

**If YES, please provide further information**

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**Please confirm that personal identifiable data/information will not be transferred out of the EEA without the explicit consent of participants *(include this information on information sheets and consent forms).***

* *In general, personal identifiable data should not be transferred outside of the European Economic Area (EEA). This is because other countries do not have the same legal framework or protections for patient data. Even where this is the case, it is difficult to manage and monitor the use of data to ensure it is safeguarded appropriately and is not misused.*
* *Such information should be handled with great care and only used in the way described in the way described in the participant information sheet.*

**Please type YES or NA in the box below**

* 1. **For how long will any personal, identifiable data collected during the study be stored?**

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* 1. **Limits of confidentiality**
	2. **Is it possible that criminal or other disclosures requiring action could take place during the study?** *(e.g. during an interview)*
* *A range of situations – across disciplinary domains – might prompt consideration of the need to breach confidentiality.*
* *Although it is generally the case that information resulting from research with human participants should remain confidential between the researcher and participant, there are limits to confidentiality and situations where research brings to light information that may mean that this confidentiality will need to be broken. In such cases, a third party (such as an appropriate/relevant authority or organisation) might need to be informed of the information in question.*

Please type **YES**, **NO** or **NA** in the box below

**If YES, please state under which circumstances confidentiality might be breached for ethically or legally justifiable reasons**. *For example*

* *When the researcher knows or suspects that there is serious, immediate or future harm to others with regards money-laundering, crimes covered by the prevention of terrorism legislation or child protection offenses/abuse of vulnerable adults.*
* *When the researcher knows or suspects that an individual is harming themselves or others or might harm themselves or others in the future.*

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* 1. **If YES, what might you do if you are confronted with the need to breach confidentiality**? *(e.g., stop the research and consult with relevant individuals/organisations).* *Please consider that breaching confidentiality will have legal implications.*

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* 1. **Please confirm that it will be clear to the participants (i.e. on the participant information sheet) as to the circumstances and process in which confidentiality may be breached.**

Please type **YES** or **NA** in the box below

**SECTION G – USE OF HUMAN TISSUE SAMPLES OR OTHER HUMAN BIOLOGICAL MATERIAL**

*Where human tissue is stored for the purpose of research The Human Tissue Act 2004 requires that either an appropriate license issued from the Human Tissue Authority is in place (such as the LJMU HTA licence) or that the research receives ethical approval from an NHS REC. Samples collected for a research purpose and subsequently processed to leave it acellular with any residual cellular material immediately discarded is not considered Human tissue and is therefore not regulated by the HT act or the LJMU Human Tissue License.* [*https://www2.ljmu.ac.uk/RGSO/93204.htm*](https://www2.ljmu.ac.uk/RGSO/93204.htm)

1. **Within a seven day period, do you propose to process tissue samples collected from a human in order to make it acellular** *(e.g. serum, plasma etc.).*

Please type **YES** or **NO** in the box below

1. **Do you propose to store a cellular tissue sample, without intending to process the sample to make it acellular in the short term** *(e.g. whole blood, muscle biopsy etc.)?*

Please type **YES** or **NO** in the box below

1. **Please confirm that you have undertaken relevant training in the requirements of the Human Tissue Act 2004 for the use of human tissue samples in research.**

**Yes,** I have received training. Please insert date of training received

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**No.** Please insert date of proposed training

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1. **What types of human tissue or other biological material will be included in the study?** *(e.g. blood, saliva, urine etc.)*

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1. **Who will collect the samples and are they certified to undertake this collection procedure?** *(please provide details)*

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1. **Consent**
2. **Will informed consent be obtained from the donors for the use of the samples in this research study?**

Please type **YES** or **NO** in the box below

1. **Will informed consent be obtained from the donors for the use of the samples in future research?**

Please type **YES** or **NO** in the box below

1. **Storage**
2. **Give details of where the samples will be stored, who will have access and the custodial arrangements**

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1. **Will the samples be stored** **in fully anonymised form?** *(No way of linking sample to donor)*

Please type **YES** or **NO** in the box below

1. **Will the samples be stored** **in linked anonymised form?** *(Samples coded – donor cannot be identified from the sample code, but there is a record linking the code to the donor)*

Please type **YES** or **NO** in the box below

**If YES, who will have access to the code and personal information about the donor?**

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1. **In a form in which the donor could be identifiable from the sample code**

Please type **YES** or **NO** in the box below

**If YES, please justify**

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1. **Analysis**
2. **What types of tests or analysis will be carried out on the samples?**

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1. **If the study will involve the analysis of human DNA in the samples, please confirm that the consent form required the participant to provide specific consent for this**

Please type **YES** or **NA** in the box below

1. **Findings**
2. **Is it possible that the research could produce findings of clinical significance for individuals***? (including relatives of donors)*

Please type **YES** or **NO** in the box below

**If YES, will arrangements be made to notify the individuals concerned?**

Please type **YES** or **NO** in the box below

1. **If donors or their relatives are not to be informed of any findings of clinical significance please justify.** If they are to be notified please say what arrangements will be made and give details of the support and counselling service

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1. **What will happen to the samples at the end of the study?** Where appropriate, please type **YES** in the boxes below

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|  Destruction Transfer to a research tissue bank licensed by the Human Tissue Authority Storage at LJMU pending ethical approval for use in another project |

**DECLARATION OF THE PRINCIPAL INVESTIGATOR**

* The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
* I undertake to abide by the ethical principles underlying the Declaration of Helsinki and LJMU’s REC regulations and guidelines together with the codes of practice laid down by any relevant professional or learned society.
* If the research is approved, I undertake to adhere to the approved study procedures and any conditions set out by the REC in giving its favourable opinion.
* I undertake to seek an ethical opinion from LJMU REC before implementing substantial amendments to the approved study plan. <https://www2.ljmu.ac.uk/RGSO/93205.htm>
* If, in the course of the administering any approved intervention, there are any serious adverse events, I understand that I am responsible for immediately stopping the intervention and alerting LJMU REC. <https://www2.ljmu.ac.uk/RGSO/93130.htm>
* I am aware of my responsibility to comply with the requirements of the law and relevant guidelines relating to security and confidentiality of personal data.
* I understand that any records/data may be subject to inspection for audit purposes if required in the future.
* I understand that personal data about me as a researcher will be held by the University and this will be managed according to the principals of the Data Protection Act.
* I understand that the information contained in this application, any supporting documentation and all correspondence with LJMU REC relating to the application will be subject to the provisions of the Freedom of Information Act. The information may be disclosed in response to requests made under the Act except where statutory exemptions apply.
* I understand that all conditions apply to my co-applicants and other researchers involved in the study and that it is my responsibility that they abide by them.

**Type YES to CONFIRM THAT YOU HAVE READ AND AGREE TO THE DECLARATION ABOVE**

**SUBMITTING YOUR APPLICATION FOR REVIEW**

Once you have completed the ethics application form appended all of the supporting documents and saved as **ONE** pdf document, please submit it electronically to **either** EthicsPR@ljmu.ac.uk (no submission deadline) for proportionate review or to researchethics@ljmu.ac.uk for full review (by the advertised submission deadline). <https://www2.ljmu.ac.uk/RGSO/93085.htm>

**APPLICATIONS MUST BE SUBMITTED VIA AN LJMU EMAIL ACCOUNT AND FOR STUDENT APPLICATIONS SUPPORTED BY AN EMAIL / LETTER FROM THE MAIN SUPERVISOR CONFIRMING THAT THEY HAVE READ AND APPROVED THE STUDY / APPLICATION.**

**CHECKLIST OF DOCUMENTS SUBMITTED ELECTRONICALLY**

(Please note that applications submitted without the required supporting documents will not be reviewed).

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|  | LJMU REC training certificate of completion (Mandatory for students) <https://www2.ljmu.ac.uk/RGSO/131507.htm>  |
|  | Ethics Application Form (MANDATORY) |
|  | Protocol (MANDATORY) see note below |
|  | Email / letter from supervisor confirming that a) the supervisor has read and reviewed this ethics application form and all supporting documents and b) the information included in the application and all supporting documents will allow UREC to decide whether all challenges to the principles of research ethics have been identified and addressed |
|  | Copies of any recruitment/advertisement material e.g. letters, emails, posters etc. |
|  | Participant Information Sheet <https://www2.ljmu.ac.uk/RGSO/93044.htm>  |
|  | Carer Information Sheet <https://www2.ljmu.ac.uk/RGSO/93044.htm>  |
|  | Gatekeeper Information Sheet <https://www2.ljmu.ac.uk/RGSO/93044.htm>  |
|  | Participant Consent Form <https://www2.ljmu.ac.uk/RGSO/93044.htm>  |
|  | Carer Consent Form <https://www2.ljmu.ac.uk/RGSO/93044.htm>  |
|  | Gatekeeper Consent Form <https://www2.ljmu.ac.uk/RGSO/93044.htm>  |
|  | Non-validated questionnaires |
|  | List of interview questions |
|  | Risk Assessment Form <https://www2.ljmu.ac.uk/RGSO/93044.htm>  |
|  | Other please specify |
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***Note***

***A research protocol is*** *a document describing in detail how a research study is to be conducted in practice, including a brief introduction or background to the study, the proposed methodology and a plan for analysing the results. For the purposes of your application for ethical approval, it is something that can be presented in a variety of formats dependent on its origin for example:*

* *for postgraduate research students it may be the programme of work embedded within their programme registration form (RD9R)*
* *for studies which have obtained external funding it is often the description of what they propose doing which they submitted to the funder*
* *for other students it is the study proposal they have written and had assessed/approved by their supervisor.*