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**UoM Template for Research Participant Information Sheets V9**

This is a template Participant Information Sheet which includes all essential information that you are obliged to provide to participants**.** It is recommended that you use the same section and sub-headings for your sheet(s) but you may add sections and change the order as appropriate for your study.

**Important note:** the information described in this template **should be adapted, where necessary,** including when participants are children, adults with learning difficulties or non-English speakers.

We have provided guidance notes in **purple** for you to consider, please ensure you **replace these** with your own text or delete sections if not appropriate to your project (e.g. DBS checks). In all the example text provided below you **must change the wording in purple** to reflect the details of your own specific project. **You should also delete this guidance section**.

You must ensure that the information you provide in this document matches with the statements in your consent form and the information listed in your data management plan.

Please ensure you **adjust the footer to the correct version number and date for your project**.

An example participant information sheet is included in **Appendix 1**. The corresponding example consent form can be found as Appendix 1 of the consent form template document for general studies.

There are no specific requirements about the

Please ensure you also **adjust the footer to the correct version number and date for your project**.

 INDividualised EXercise approach for people with chronic low back pain (INDEX study): The development of an enhanced EMG biofeedback app

**Participant Information Sheet (PIS)**

You are being invited to take part in a research study [**insert a brief description of the overall aim of the research and whether it will be for a degree**]. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part, and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

**About the research**

**Who will conduct the research?**

Carolina Costa Lopes, a Masters student from the University of Manchester. Supervised by Dr Alexander Casson from The University of Manchester, and Dr Janet Deane from ??

**What is the purpose of the research?**

Provide a brief and simple to understand explanation of what you, the researcher, are hoping to achieve by the research.

Provide a statement explaining how and why the participant was chosen and how many other participants you intend to recruit (if known).

You have been chosen because you are part of the VOCAL group and have experienced low back pain.

**Am I suitable to take part?**

You may wish to include information about any inclusion or exclusion criteria that are essential to participation.

**Will the outcomes of the research be published?**

Provide details of anticipated outcomes and if participants will be informed of the findings or if they will be published in journals, in a student thesis or online (i.e. blogs, websites or social media).

**Who has reviewed the research project?**

This research study has been reviewed by the University of Manchester Proportionate Research Ethics Committee, application number ??

**What would my involvement be?**

* **What would I be asked to do if I took part?**

Describe what will happen to the participant during the research as well as what they will be expected to do and, specifically, where this will occur (location and venue). This should be laid out in order, as a participant ‘journey’ and also include details of any possible risks/benefits to the participant.

Provide details of the duration of the study (e.g. 3x ½ hour interviews; 1x 30 minute questionnaire etc) including how long in total the participant will be involved in the study (from consent to final visit). Remember to also include time for checking processes or taking part in follow up interviews or multiple processes. It may be helpful to include a flow chart or diagram here.

* **Will I be compensated for taking part?**

No.

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

It is up to you to decide whether or not to take part. Give details here about how the participant should inform you whether they want to take part or not. If you do decide to take part you will be given this information sheet to keep and [will be asked to sign a consent form/will be asked to provide verbal consent/will be asked to tick a box to confirm consent]. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

For audio/video recordings you must explicitly state whether participants are free to decline the recording or whether it is essential to their participation in the study. You must also state that participants should be comfortable with the recording process at all times and they are free to stop recording at any time.

**Data Protection and Confidentiality**

* **What information will you collect about me?**

In order to participate in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically we will need to collect:

* Contact details: So that we can can arrange follow up sessions for feedback on updated designs for the application. These will be retained for ?
* Your age and gender so that we can report the demographics of our dataset in any papers or reports that are published as a result of this study. The data will be anonymised, connected only to your participant number and not to your name or contact details.
* Your electronic? Participation consent form

~~For~~ [~~audio/video recordings~~](http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=38446%20) ~~you must state:~~

* ~~what the recordings/photographs will consist of (e.g. voice only, facial features, full body, surrounding environment, other individuals, etc) and how they are obtained (e.g. during a focus group discussion, asking participants to take images or recordings of their lives, etc)~~
* ~~Example: Recordings of your voice during the focus group discussion~~
* ~~Example: Pictures that you take of your local community including the residents, buildings and any community events that are taking place.~~
* **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is “a public interest task” and “a process necessary for research purposes”.

* **What are my rights in relation to the information you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings or photographs.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095).

If using a hard copy version of the PIS with participants, you must ensure the full URL of the privacy notice is listed here or a hard copy is printed and appended with the information sheet.

* **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. [If UoM is not the sole Data Controller this will need to be revised and the other data controller added and you should seek further advice from the [Information Governance Office](mailto:information.governance@manchester.ac.uk) regarding these arrangements] This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Provide details of:

* + What measures you will take to ensure confidentiality, such as providing participants with an assigned ID number only known to the research team (known as pseudonymised)\*
  + Whether the data will be fully anonymised (you won’t be able to identify the participants) or pseudonymised (you have a key which would enable you to identify the specific participants if necessary).
  + Specifically when data will become fully anonymised (e.g. key link broken for pseudonymised data) so that participants know the exact timeframe in which they can request that their data is withdrawn.

(For each description below you should be clear whether the data will be identifiable or anonymous.)

* + Where data will be held and when/how it will be transferred between UoM and other sites or devices (including transcription services)
  + How long data will be stored\*\*
  + If data are transferred outside the EU or to any cloud services, what will happen to the data at the end of the study
  + If you will be sharing the data with any other organisation
  + If you will be keeping data or contact details\*\*\* for use in future studies
  + If you will be archiving the data in a repository

**\*For audio/video recordings or photographs you must state the following:**

* If the recordings will be used to create transcripts, state who will be performing the transcribing, for example a member of the research team, another UoM employee or a third party who is a UoM approved supplier. If they are another UoM employee, ensure they are reminded of the guidelines regarding confidentiality and ask them to sign a copy of the [Confidentiality Agreement](http://documents.manchester.ac.uk/display.aspx?DocID=38446)). If they are a third party they must be a UoM approved supplier as this ensures a confidentiality agreement is in place between their organisation and UoM.
* whether the personal identifiable information will be removed in the final transcript or not
* when and how the recordings/photographs will be destroyed or digitally altered to remove personal information (for example, by Pixellation / voice masking software).
* who will have access to the recordings/photographs (if different to the rest of the personal information).

If using **Zoom/Skype/Teams** to conduct your data collection then please ensure you add the following paragraph to the section related to **Confidentiality**:

Your participation in this research will be recorded in [Skype/Zoom] and your personal data will be processed by [Microsoft/Zoom]. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

If using Zoom, please also consult the [FAQs](http://documents.manchester.ac.uk/display.aspx?DocID=48888) for more information on recordings.

**\*\*Important note:** UoM requires identifiable data to be anonymised as soon as the objectives of the project allow. The standard retention period for data once anonymised is 5 years unless funders or regulators have specified longer retention requirements.

**\*\*\* Reminder:** If you are intending to add their contact details to a database for future contact you must provide a mechanism for them to opt out of this in each communication and consider how many times you will contact them if they have not responded. You must also state for how long their information will be kept for this purpose.

**General Example:** The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. The research team will have access to the key that links this ID number to your personal information. Your consent form will be retained for 5 years in a locked cabinet on UoM premises for audit purposes. With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.

**Example for sharing data:**

When you agree to take part in a research study and with your informed consent, the information about you may be provided to researchers running other studies here or at other organisations. With your consent your anonymised information will be shared in order to support additional research in accordance with The University of Manchester’s Research Privacy Notice**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of X, and cannot be used to contact you regarding any other matter. It will not be used to make decisions about future services available to you.

**For NHS REC studies, please refer to** 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/) instead of the Research Privacy Notice in the paragraph above.

Example for archiving: At the end of the project we will deposit a fully anonymised dataset [e.g. including de-identified interview transcripts] in an open data repository where it will be permanently stored. We will use [name of repository and location (e.g. Figshare at the University of Manchester Library)]. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

**Potential disclosures (if not applicable please delete):**

If the nature of the study means that individuals outside of the research team may need to be provided with details about the participant’s involvement in the study, this should be stated and also included in the **consent form. Examples include (but should be modified according to your study):**

If, during the study, we have concerns about your safety or the safety of others, we will inform your GP/care team/family member.

If, during the study, you disclose information about misconduct/poor practice, we have a professional obligation to report this and will therefore need to inform your employer/professional body.

If, during the study, you disclose information about any current or future illegal activities, we have a legal obligation to report this and will therefore need to inform the relevant authorities.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

**What if I have a complaint?**

You must include a way for the participants to contact someone if they have any complaints. If participants wish to direct their complaint to someone within the research team, they should be directed to yourself (staff projects) or **your supervisor (student projects)**.If they wish to direct their complaint to someone independent of the research team, this should be the RGEI Manager as listed below.

For international studies, it may be appropriate to provide details of a local contact who participants can speak with initially. However, you must also have a plan in place for how such complaints will be forwarded back to the research team and details of this should be included in your ethics application.

* **Contact details for complaints**

If you have a complaint that you wish to direct to members of the research team, please contact: **PROVIDE CONTACT DETAILS IN LARGE BOLD PRINT. Contact details must include email and telephone numbers; these contact points should be professional or project specific email and phone numbers not personal ones. Please ensure they are live contact points and that phone numbers have voicemail that is regularly checked.**

**STUDENTS CANNOT BE LISTED IN THE COMPLAINTS SECTION**

**If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact**

TheResearch Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk)  or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information Tel 0303 123 1113

If using a hard copy version of the PIS with participants, you must ensure the full URL of the ICO’s complaints procedure is listed here or a hard copy is printed and appended with the information sheet.

**Contact Details**

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s) **PROVIDE CONTACT DETAILS IN LARGE BOLD PRINT. Contact details must include email and where possible, telephone numbers; these contact points should be professional or project specific not personal. Please ensure they are live contact details and phone numbers have voicemail that is regularly checked. This section MUST appear last on the PIS as it will be the first place participants look to locate your contact details.**

**If your study involves face-to-face (in person) activities then you must also include the COVID section below. If your study does not involve these activities, then you do not need to include this section.**

Additional information in relation to COVID-19

Please see below for additional information that you may need to include in your participant information sheet if conducting research during the COVID-19 pandemic.

**Important notes:**

Please check the [research ethics website](https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/ethics/) for updates relating to how any restrictions mandated by government will impact the ability of research participants to travel to take part in your study.

Please also refer to the [Research FAQs](https://www.staffnet.manchester.ac.uk/coronavirus/faqs/research/) for updated information on any additional requirements or restrictions relating to research in general.

**The following additional information can be added as an addendum (separate page) to your participant information sheet or as a new section. Please note, if adding as a new section you MUST ensure that your contact details still appear last on the sheet.**

Due to the current COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice in relation to social distancing as well as taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

**Are there any additional considerations that I need to know about before deciding whether I should take part?**

Details should be included of any additional risks to the participants including possible infection through travelling to and from the venue, coming into contact with other research participants (e.g. focus groups) or through the method of data collection itself (e.g. using any equipment which the participant touches).

Should not take part if in a vulnerable group or if have symptoms.

**What additional steps will you take to keep me safe while I take part?**

Provide details of what steps you will take to reduce the chances of coming into contact with and/or spreading the virus. This may include details of disinfecting equipment, providing single use equipment (i.e. pens, post-its, etc), requirements for the use of PPE, changing the venue, reorganising the activities of data collection to limit repeat visits, limiting waiting times in between participants or other considerations.

**Is there any additional information that I need to know?**

Provide any additional requirements of participation (such as PPE) or any additional information that the participant needs to know before deciding if they still wish to take part. If applicable, remind them to please arrive on time (not early or late) to avoid too many participants gathering in the same area.

**Additional data use**

May have to provide contact details to NHS Track and Trace if it becomes necessary. Or equivalent details for other country.

**What if the Government Guidance changes?**

Provide details here about what you will do in these circumstances – which may include postponing contact.

**What if I have additional queries?**

Insert details of the research team

Appendix 1: Example PIS

**Before and After: The Impact of COVID**

You are being invited to take part in a research study looking at the impact of the COVID-19 pandemic on our lifestyles. Before you decide whether to take part, it’s important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

**Who is carrying out this research study?**

Dr Scarlet O and Dr Norbert Minion who are researchers in clinical psychology at the University of Manchester.

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

The COVID-19 pandemic forced us to make many changes to how we conduct our everyday lives, including what we do in our free time. We want to find out how significant these changes are and what improvements they have made to our lives as a result.

**Am I suitable to take part?**

We’d love to speak with you if you’re:

* At least 16 years or older
* Happy to talk about your lifestyle both before and after the COVID-19 pandemic
* Have access to a computer, tablet or mobile phone with video and a stable internet connection (for the Zoom conversation)

**What will I be asked to do if I take part?**

Take part in a one-to-one online interview with either Scarlet or Norbert (your choice) to talk through your lifestyle both before and after the COVID-19 pandemic. The interview would last approximately 1 hour, take place using Zoom and can be arranged at a date and time that is convenient for you.

**Will I be compensated for taking part?**

Yes, you’ll receive a £10 Love 2 Shop voucher (electronic) as a thank you for sharing your experiences.

**What are the risks if I take part?**

Although many people report a number of positive changes over the past 18 months, the pandemic impacted everyone differently and we recognise that this might include things that didn’t go so well. In sharing your story with us, we will ask you about things that were difficult or made you feel sad. We will also ask you about the impact on your family, friends, loved ones or pets. We understand that it might be difficult and potentially upsetting to talk about these things. If you begin to feel this way, we can take a break, arrange the interview for another time or stop altogether. You can also let us know if there’s any questions or subject areas that you don’t want to talk about.

**Who has reviewed this study?**

This study has been reviewed by the University of Manchester Research Ethics Committee 2.

**Who is funding this study?**

The Medical Research Council

**What happens if I don’t want to take part or change my mind?**

It is up to you to decide whether or not to take part. If you would like to, then get in touch with Scarlet or Norbert using the contact details at the end of this information sheet. If you do decide to take part, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. If you would like for us to delete the data that we have collected up until that point, we will do so. This does not affect your data protection rights. If you do decide not to take part, you do not need to do anything further.

**Data Protection and Confidentiality**

**What information will you collect about me?**

In order to participate in this research project we will need to collection information that could identify you, called ‘personal identifiable information’. Specifically we will need to collect:

* Your name
* Contact details
* Gender
* Ethnicity
* Age
* Details about your household
* A recording of your voice and face (zoom conversation)

**Under what legal basis are you collecting it?**

We are collecting and storing this personal identifiable information in accordance with data protection law which protects your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is ‘a public interest task’ and ‘a process necessary for research purposes’.

**What are my rights in relation to the information that you will collect about me?**

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you, including audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](http://documents.manchester.ac.uk/display.aspx?DocID=37095).

**Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

The study team will store your identifying information (name and contact details) securely and separately from your study data. Your data will be marked with an ID number and not your name. The key for linking your ID number to your identity will be accessible only to the research team. Once all of the data has been analysed, we will destroy the key, anonymising your data. Your consent form (including your name and signature) will be retained separately for 5 years after the end of the study in a locked filing cabinet on University premises. We will also ask for your permission to keep your contact details on file and contact you about future studies that you might be interested in.

In order to ensure that we have an accurate record of our conversation, we need record it using the Zoom software. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection.

The recording will include both your voice (audio) and your face (video). If you prefer, you can disable your camera so that only your voice is recorded. We will use the recording of our conversation to make a transcript and once we have checked that the transcript is correct, the recording will be deleted. We will remove any information from the transcript that might identify you.

In accordance with the University of Manchester’s Research Privacy notice and with your consent, we would like to be able to share your anonymised data with other University of Manchester researchers who are doing studies similar to ours.

At the end of the project we would like to deposit a fully anonymised dataset in an open data repository where it will be permanently stored. We will use Figshare at the University of Manchester Library. Researchers at other institutions and others can access the anonymised data directly from the repository and use it for further research or to check our analysis and results.

**Will the outcomes be published?**

The outcomes will be reported at scientific conferences and in peer-reviewed journals but you won’t be identifiable in any of these.

**Potential Disclosures**

If during our conversation you reveal any information which means you may be at risk of harming yourself or others, we will be required to break confidentiality in order to put you in touch with the correct support. This may involve signposting you to relevant support services, calling a family member or friend or calling emergency services.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I want to make a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact Scarlet or Norbert (lifeafterCOVID@manchester.ac.uk ).

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researcher in the first instance then please contact:

TheResearch Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: [research.complaints@manchester.ac.uk](mailto:research.complaints@manchester.ac.uk)  or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email [dataprotection@manchester.ac.uk](mailto:dataprotection@manchester.ac.uk) or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner’s Office](https://ico.org.uk/concerns) about complaints relating to your personal identifiable information Tel 0303 123 1113

**What do I do now?**

**Contact Scarlet or Norbert if you have any questions or want to take part.**

**Scarlet O/Norbert Minion**

**Email:lifeafterCOVID@manchester.ac.uk**

**Phone: 0161-275-1111**