Ethics Application

Research

Please be mindful that each application, submitted via the University's Ethical Review Manager (ERM), costs the University **£750** due to the number of people required to process, review and approve your application.

Please respect this fact and ensure that you carefully follow the guidance provided and help bubble text in order to complete your application appropriately (and choose the correct route of ethical review). Please **DO NOT** use the ERM system for 'test' submissions. Misuse of the ERM system is a waste of numerous resources which could otherwise be dedicated to research, teaching and social responsibility activities.

You are logged into the Ethical Review Manager (ERM), the system provided by Infonetica Ltd that will process the application on behalf of The University of Manchester. Your contact details will be stored by Infonetica Ltd and used by the University for the purpose of managing your application for ethics review. The University will use your details for that purpose only. The information will be retained, archived and deleted in line with the agreed retention policy. Your details will not be passed to any other third party organisations.

The University, in compliance with the Data Protection Act 2018 (DPA) and the UK General Data Protection Regulation (GDPR), has a **Data Protection Policy** and **Research Privacy Notice** and any information you provide on this form and associated documents will be protected in accordance with these policies. However, it will be assumed that you have not included any sensitive personal information and you should not, therefore, include a *curriculum vitae* or identifiable information about your racial or ethnic origin, political opinions, religious or similar beliefs, trade union membership, physical or mental health, sexual life, commission of offenses and/or criminal proceedings. Should you feel it essential to include such details in your application please contact the Research Governance, Ethics and Integrity team (research.ethics@manchester.ac.uk). Please note, applications submitted in the ERM system may be used for educational, auditing and monitoring purposes but the information contained will be protected and kept confidential in accordance with the policies as outlined above.

Please also note this system will send all correspondence related to your ethics application to your University of Manchester email account.

Please do not proceed unless you are content to comply with this.

A0. Required declarations

- ☑ I confirm that I have read the above information with regard to data protection and will comply with the requirements as described.
- ☑ I confirm that prior to completing this application I have reviewed the guidance information available on the research ethics website and if appropriate have contacted my ethics signatory for additional support

A1. Does your study meet the definition of 'research' using human participants or have you been advised to seek ethical approval for your study (either via the Ethics Decision Tool or other guidance)?

Please visit the help bubble (blue circle with the white letter 'i') to the right of this question for a link to the Ethics Decision tool and supplementary information on the types of projects which may or may not require ethical review.

- (•) Yes

You **must read** the information in the help bubble before answering this question. If you cannot answer yes **do not complete the rest of this form, log out of the ERM system** and if you have any queries contact your Ethics Signatory.

You should only be submitting this form if you can answer yes to this question.

A02 HRA Approval

A2. Does your study include a component which would require approval by the Health Research Authority (HRA)?

Please visit the Help Bubble in the upper right hand corner for more information.

Please choose the option which is most relevant for your study. If you have 2 components (i.e. one using healthy volunteers and one using NHS patients), please speak with a member of the FBMH Research Governance team who will advise on the most appropriate avenue for review.

- ( ) Yes: it includes a component that requires review by BOTH the HRA and the University Research Ethics Committee or a Division/School based Committee (e.g. it is being carried out in the NHS but is exempt from NHS REC review)
- ( ) Yes: it is a study involving patients BOTH in the UK as well as internationally and requires review by both the NHS REC and the University Research Ethics Committee (this is rare)
- (•) No: it only requires review by the University Research Ethics Committee (UREC) or a Division/School based Committee

A03 - 05 Decision Tree

A3. I confirm that this research project is being conducted by a:

- (•) Student
- ( ) Member of Staff
- ( ) Member of Eurolens Research, Optometry Staff

IMPORTANT: Your answer to **Question A4** will lead you to the correct application form for ethical review and it is important that you answer this question carefully**.**

Please ensure you read the guidance notes carefully **BEFORE** answering this question and for student projects, discuss the details with your supervisor.

The guidance notes can be found in the Help Bubble (small blue circle with the white letter 'i') to the right of Question A4.

Answering this question incorrectly will result in **SIGNIFICANT** delays to the review process and will result in you needing to **re-apply** for ethical review.

*A4. Please select how you will be applying for ethical review:

Please ensure you read the criteria as described in the help bubble carefully before deciding which route of ethical review to select.

****Division/School review is only available for the 10 Schools/Divisions/Departments listed in the help bubble to the right of this question. If your School/Division/Department is not listed you must apply for Proportionate or full UREC review****

- ○ Division/School Review
- ◉ Proportionate University Research Ethics Committee (UREC) Review
- ○ Full University Research Ethics Committee (UREC) Review

STOP!

Are you doing a **student** project?

If so, are you sure that your project could not be ethically reviewed by a **Division/School** panel instead of the UREC?

Incorrectly applying for UREC review rather than Division/School review can result in you needing to re-apply for ethical review and will result in significant delays. In addition, it wastes a considerable amount of UREC resources.

For details on whether your project qualifies for Division/School review please see the help bubble in Question A4.

A4.1 I am applying for Proportionate UREC Review and confirm one of the following:

- ☑ Data collection does NOT involve travel to or travel within an international setting that is on the list of countries/regions that the Foreign and Commonwealth Office advises against 'all but essential' travel to.
- ☐ My study is limited to an electronic questionnaire/survey that will be hosted on a University approved platform
- ☐ My study is limited to the analysis of secondary data
- ☐ My study involves patients both in the UK as well as internationally and requires review by both the NHS REC and the UREC (this is RARE)

Please take care when selecting your Division/School/Department/PSS Directorate/Cultural Institution from the drop-down list below.

Mistakes will result in your application being sent to the wrong ethics signatory for review.

Please note, the selection made below should reflect where you are based at the University.

A5 UREC Review (full or Proportionate): Please select which Division/School/Department/Centre/area of PSS/Cultural Institution you are based in:

Department of Computer Science

A5.1 Please confirm which of the following criteria are applicable to your project:

Please ensure you read through the options below and tick **all** that apply to your project. Further guidance is available in the help bubble to the right of this question.

****Denotes mandatory criteria** that must be met in order to qualify for Proportionate UREC review. If your study does not meet these mandatory criteria you will need to apply for full UREC review, where appropriate.

IMPORTANT NOTE: If your study involves the use of human tissue, please **ONLY** tick the box in relation to human tissue near the bottom. **DO NOT** tick any of the other criteria. You will however need to tick 'human tissue' in question C1.

IMPORTANT NOTE: If your study involves **ONLY** secondary data analysis (i.e. not involving another data collection method such as interviews), please **ONLY** tick the final box in relation to secondary data analysis. **DO NOT** tick any of the other criteria. You will however need to tick 'secondary data analysis' in question C1. If your study involves **BOTH** secondary data analysis and another data collection activity, please do not select the final box, but tick the ** criteria as appropriate.

If your research involves an activity falling within one of the conditional criteria beginning with "If" then it must meet the requirements of that criterion or criteria to be considered for Proportionate UREC Review.

Participants and Consent

- ☑ **Involves only participants who are non-vulnerable adults able to give informed consent or, if children/ young people are involved, they must be a) in an educational setting/accredited organisation, b) have the opportunity to assent (with parental/guardian opt-in consent also provided) and c) NOT be classed/viewed as specifically vulnerable.

Data Collection and Experimental Procedures

Please note: Studies involving EEGs **may be submitted** for Proportionate UREC review as they are **not classed** as physically invasive procedures.

- ☑ **Data collection does NOT involve a significantly coercive recruitment strategy, or a recruitment strategy that is likely to be experienced as coercive by participants, including where a power dynamic between the researcher/participants or the gatekeeper/participants would be present
- ☑ **Data collection does NOT involve activities that could be interpreted as or lead to the potential exploitation of participants
- ☑ **Does not involve physically invasive procedures (any test in which the skin of the participant is broken, an injection is admistered or an implement is inserted into any opening of the human body (e.g. eyes, ears, nose, mouth, lungs, stomach, rectum, vagina and urethra) or involves the taking of body samples such as blood, saliva, hair, urine, faeces, sputum, skin, nails, or taking biopsies of any form for any purpose, or any form of scanning such as Ultrasound scans, MRI or fMRI scanning) with the only exceptions being standard audiology techniques performed on healthy adult volunteers as outlined in the Help Bubble to the right of this question.
- ☑ **Does not involve activities that pose a significant risk of causing physical harm or more than mild discomfort.
- ☑ **Does not involve activities that pose a significant risk of causing psychological stress or anxiety.
- ☑ **Does not require participants to take part in activities that pose a significant risk of having an adverse effect on their personal well-being (e.g. physical and psychological health), social well-being (e.g. social standing, social connectedness) or economic well-being (e.g. employment, employability, professional standing).

Sensitivity of Topic or Data

- ☑ **Does not involve collecting or revealing data that enables individuals, groups or organisations to be identified in such a way that they could experience negative effects on their personal, social or economic well-being.
- ☑ **Does not require research participants to provide personal and sensitive information likely to lead to significant levels of distress (ie research must only involve topics that are either not contentious or sensitive at all, or where a reasonable person would agree the topic is of legitimate interest and may result in distress only in rare instances).
- ☐ If topics being researched are of a sensitive nature, they are not personal to the participants.
- ☑ If using video recording or other images captured by the researcher and/or research study participants, the researcher is able to guarantee controlled access to authorised viewing.

- [x] If researching professional practice, participants are in professional roles and the research is conducted in their work setting (It would also be acceptable to conduct these interviews via telephone or Zoom/Teams as long as the content of the interviews is focused on professional practice and non-sensitive topics. Please note that in this instance, participants will be responsible for ensuring appropriate privacy arrangements).
- [ ] If conducting observations, they will be on ordinary, non-sensitive behaviours.

Location of Data Collection

- [x] **Data collection does NOT involve travel to or travel within an international setting that is on the list of countries/regions that the Foreign and Commonwealth Office advises against 'all but essential' travel to.
- [x] If applicable, will be carried out within normal working hours or at a time convenient to participants.
- [ ] If research will involve going into the homes of participants and this is a student project, participants will be limited to family and friends..
- [ ] If research will involve going the homes of participants and this is a staff project, participants may include members of the general public providing a completed and signed risk assessment has been attached in support of this application
- [ ] If conducting observations they will be located in a public space or the clearly public areas of a building (e.g. the high street, the University campus, the entrance hall of a town hall).

Human Tissue Specific Criteria - **Please ensure you have used the ethics decision tool to verify if your project requires UREC approval**

Please note: if you are performing research using human tissue you MUST confirm the following condition.

- [ ] This study involves the use of human tissue and I will complete the additional questions in Section C5.

Secondary Data Analysis ONLY Specific Criteria

Please note: if you are ONLY performing research using secondary data you MUST confirm the following condition.

- [ ] This study ONLY involves the use of secondary data and I will complete the additional questions in Section C6.

NHS REC + UREC approval

Please note: if your study requires approval by both the NHS REC as well as the UREC, please tick this box ONLY and do not tick any of the other boxes above.

- [ ] This study involves patients both in the UK as well as internationally and requires review by the NHS REC as well as the UREC (this is RARE).

B02 Students

B2. Contact information for the individual completing this form:

Title	First Name	Surname
Ms	Carolina	Costa Lopes

Email: carolina.costalopes@postgrad.manchester.ac.uk

B2.1 Please confirm one of the following:

- (•) I am the student investigator of this project.
- ( ) I am the supervisor of this project.

B2.2 Please provide the full contact details of your primary supervisor:

This **MUST** be a University of Manchester member of staff with a UoM email address. Please note, the primary supervisor is also the data custodian for your research project. If you have more than one supervisor, please use the '**Add Another**' button below to add the contact details of your additional supervisor(s).

If when using the Search function you cannot locate your supervisor, please ensure they have logged into the ERM at least once. Once they have done this, their details will be stored for future use.

Title	First Name	Surname
Dr	Alex	Casson

Email: alex.casson@manchester.ac.uk

B2.2 Please provide the full contact details of your primary supervisor:

This **MUST** be a University of Manchester member of staff with a UoM email address. Please note, the primary supervisor is also the data custodian for your research project. If you have more than one supervisor, please use the '**Add Another**' button below to add the contact details of your additional supervisor(s).

If when using the Search function you cannot locate your supervisor, please ensure they have logged into the ERM at least once. Once they have done this, their details will be stored for future use.

Title	First Name	Surname
Dr	Janet	Deane

Email: janet.deane@manchester.ac.uk

B2.3 Are there any additional collaborators on this project?

Please note: Collaborators are defined as individuals who will assist in either the data collection or data analysis of the project and can be members of staff or students.
Please include any external collaborators from other institutions or organisations. They will **NOT** be involved in any of the electronic correspondence for this project.

- ○ Yes
- ◉ No

B2.12 Please confirm the degree being studied for by the student investigator:

- ○ Postgraduate Research (PGR) (e.g. PhD degree)
- ◉ Postgraduate Taught (PGT) (e.g. masters degree)
- ○ Undergraduate (UG)
- ○ Postgraduate Taught + Undergraduate (the study will be conducted by BOTH an UG and PGT student; note: this is rare)

B2.13 IMPORTANT: BEFORE CONTINUING:

Look on the left hand side of the screen for the '**share**' button. Push this button, enter the appropriate email address and be sure to tick all the relevant boxes in the pop up window.

- ☑ I confirm that I have pushed the share button on the left hand side of the screen and 'shared' this form with my supervisor.

C01: Compliance & Monitoring

Please note: Everyone is required to complete the compliance & monitoring questions below, whether you are completing a Proportionate University Research Ethics Committee (UREC), full UREC or Division/School template application.

IMPORTANT NOTE: If you will be travelling abroad for your research, and in particular to what is considered to be a risky or dangerous area of the world, you must ensure that you have completed the appropriate Division/School based **risk assessment**, had this **approved** by appropriate individuals within your Division/School and **checked** with the University's Insurance office **regarding travel insurance**. The ERM system **WILL NOT** inform the University's Insurance office of your travel plans automatically (unless you are performing clinical activity) and it is therefore the responsibility of all members of staff and supervisors to contact the Insurance office **prior** to obtaining ethical approval. Please note that specific areas of the world will require additional approvals and this should be taken into consideration when planning a timeline for seeking ethical approval.

If your study involves **ONLY** the use of secondary data, please tick the option from the list below. If your study involves the use of secondary data as well as another method, please **do not** tick this box but proceed with the rest of the Prop UREC form.

C1. Will your research involve any of the following:

Before answering this question please ensure you click on the help bubble to read the guidance information which includes definitions of each of the terms below. Tick all that apply.

- ☐ the use of invasive techniques on participants
- ☐ the use or collection of human tissue
- ☐ the physical testing of participants
- ☐ the use of psychological intervention (please DO NOT tick this option if you are only administering standard psychological tests/questionnaires)
- ☐ the ingestion or inhalation of any substance by participants
- ☐ the use of a medical device or a potential medical device
- ☐ the use of previously collected data ONLY (secondary data analysis)
- ☑ None of the above

OR

Important: if you select this box, please **DO NOT** select any other box above.

- ☐ patients both in the UK as well as internationally and requires approval by both the NHS REC as well as the UREC (this is RARE)

D01 - 02 General Project Information: Resubmission and titles

D1. Is this a re-submission of a project that has previously received an unfavourable ethical opinion?

Please note: this **does not** include applications where revisions have been requested.

- ○ Yes
- ◉ No

D2. Short title of your research project (200 character max)

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

D2.1 Formal title of your research project (if different to short title)

D03 Dates of Data Collection/DMP/Data Collection

D3. Will you be collecting data during the course of the research project?

Please note, data refers to any information being gathered about a person or organisation. This information can include specifics such as thoughts, beliefs or characteristics and can be in different formats such as written notes, questionnaires, observations, audio recordings, films, photographs, social media postings or bodily samples.

Please note, if you are ONLY conducting secondary data analysis then please select 'no'.

- (•) Yes
- ( ) No

D3.1 Do you plan to begin collecting data as soon as ethical approval is granted?

- (•) Yes
- ( ) No

D3.2 Please provide your proposed end date of data collection

01/09/2026

D3.4 Will the research involve any of the following activities at any stage (including identification of potential research participants)?

Tick all that apply

- [x] Storage of personal data on University computers
- [ ] Storage of personal data on non-University computers
- [x] Use of audio/visual recording devices
- [ ] Sharing of data with other organisations
- [ ] Exporting of data outside of the UK, EU or EEA
- [ ] Publication of data that might allow identification of individuals
- [ ] NONE OF THE ABOVE

Please note if you intend to publish the results of this research it is advised that you complete a data management plan using the DMP online system and attach it (to the additional documents question at the end of the application) in support of this application. If this is the case please write 'N/A' to all responses below as you will be asked to complete the same questions in your DMP.

D3.5 Please provide details of how you plan to store and protect the study data as stated in the question above:

N/A

D3.6 Please provide details of how data will be transferred from recording devices to more secure storage:

N/A

D3.7 What measures have been put in place to ensure confidentiality of personal data?

Give details of what encryption or other anonymisation procedures will be used and at what stage.

You **MUST** provide details for **EACH** type of data collected/generated (i.e. interview data, visual data, etc).

Although participants must be free to withdraw from the study at any point you must ensure they are made aware that once you have anonymised their data into the full data set, it will no longer be possible to identify their specific data and therefore will not be possible to withdraw **their data** from the study.

N/A

D3.8 Where will the analysis of the data from the study take place and by whom will it be undertaken?

Please provide the name(s) of the individual(s)

N/A

D3.9 Who will control and act as the custodian of the data?

For student research projects, this **must be the primary supervisor**. **Please ensure you provide a name for this individual.**

Dr Alexander Casson

D3.10 Will anyone outside the University have access to the data generated by the research?

- ○ Yes
- ◉ No

D3.12 Will the data be stored for use in future studies or will the researchers be retaining participant contact details?

- (•) Yes
- ( ) No

D3.13 Has this been addressed in the consent process (i.e. explicitly mentioned in the participant information sheet and consent form)?

- (•) Yes
- ( ) No

D3.14 For how many years will the personal or pseudonymised data (including signed records of consent) from the study be stored/archived?

5

D04 Data Protection Training

All staff and students at the University of Manchester are responsible for ensuring they are familiar with the data protection policies and processes and follow these when conducting their research projects. Under the Data Protection Act (2018) and UK General Data Protection Regulations (GDPR) the University is required to provide assurances and safeguards to all research participants that their data will be treated confidentially and will be protected as set out to the relevant data protection legislation. To support this, please complete the relevant question below to confirm that you have undertaken the required Information Security & Data Protection Training or discussed the University's requirements and expectations with your supervisor.

D4. Please tick **each statement** below to indicate that you **understand** and **will adhere to** data protection regulations and The University of Manchester's data protection policies.

For more information, please see the **University's Records Retention Schedule**, **Advice on the use of Personal Devices** and **SOP for Recording of Research Participants**.

- ☑ I will ensure that paper data (e.g. consent forms) are stored in a locked cabinet that only the research team has access to.
- ☑ I confirm that all electronic data will be stored on University servers such as my P drive or on the research drive of my supervisor or University approved cloud services e.g. Dropbox for Business.
- ☑ I will NOT use external hard drives, USB sticks or any other portable device to store personal identifiable data as they are subject to loss or theft.
- ☑ I confirm that I will use an encrypted device for the recording of audio, video or photographs. If this is my personal device, as no other option is available, it conforms to University expectations/requirements and cloud back-up has been disabled.
- ☑ I understand that if I need to use a portable device to record and transfer data, this device should be encrypted, the data transferred to a secure server as soon as possible and must be deleted from the portable device following the transfer. (If an encrypted device is not available you will need to make specific arrangements with respect to securing data as soon as possible and this must be detailed in your ethics application).
- ☐ I will NOT store data on cloud based services other than Dropbox for Business approved by the University.
- ☑ I will ensure that all data are anonymised/pseudonymised as soon as possible to protect the confidentiality of my participants.
- ☑ I will only collect the personal information that is required to answer my research question and as approved by the ethics committee.
- ☑ I understand that personal information should be deleted as soon as it is no longer required. If keeping the contact details of participants to contact them about future research or to share findings of my project, I will store these in a separate password protected file or database held on University servers or approved cloud services.
- ☑ I understand that all data should be stored in accordance with the University's Records Retention schedule and must be kept for the period as specified in my data management plan or approved ethics application.
- ☑ I understand that my supervisor MUST be listed as the data custodian for my project and I must ensure that I transfer custody of all paper and electronic data to them before I leave the University.
- ☑ I understand that I SHOULD use encrypted devices when analysing my study data if not accessing the data directly from my P drive or other secure University server.
- ☑ I understand that I MUST ensure that when I am transcribing or analysing data that it is done in a way in which other people are NOT able to see any personal data on my devices.
- ☑ I understand that if I wish to share study data with other researchers or retain the data for use in future studies that I MUST ensure this is explicitly mentioned in the participant information sheet and consent form.
- ☑ I understand that ONLY University of Manchester or study specific email addresses/phone numbers can be used by researchers for their research projects.

Project Specification: L1-L3

WARNING: You are now completing the ethical review form for the **Proportionate UREC Review**. If you are not applying for Proportionate UREC review, then please return to **Question A4** and **update your answer.**

It should **only be used** for **low risk** research projects **which adhere to the criteria in Question A5.1 (including those that require approval by both the NHS REC and UREC)**.

If you are conducting a **high risk** research project, you must submit go for **Full University Research Ethics Committee (UREC) review**.

Please press the '**Next**' button in the upper left hand corner of the screen to continue with the form and please note that the question numbers may not be sequential.

Ethical Considerations: L4

L4. Are participants from any of the following groups?

Tick all that apply

- ☐ Children under 16 years who are being researched outside of an educational setting or accredited organisation.
- ☐ Adults with learning difficulties who are being researched outside of a supportive environment
- ☐ Adults with dementia
- ☐ Adults or children in emergency situations
- ☐ Prisoners or criminals
- ☐ Young offenders
- ☐ Users of illegal drugs or illegal substances
- ☑ None of the above

Research Project Details: L14

L14. What is the principal research question, in lay terms?

Limit response to 750 characters. This **MUST** be in lay language and should not be a cut/paste of your theoretical or intellectual rationale.

People with chronic low back pain are instructed to do certain exercises at home to help them manage their condition. We are researching the design of a mobile phone application connected to small electromyography sensors that would be applied on the patients' backs whilst they do the exercises. We want to know what patients and physiotherapists want from the phone application. We also want feedback on the designs made for the application. We want to know how the patients would want to use the application and what features they care most about.

L15

L15. How have the quality and suitability of the research design and methods been assessed?

Tick all that apply

- ☐ Independent internal review (e.g. review by academic mentor/advisor, research centre/research group at the University of Manchester)
- ☐ External review (e.g. review by the funder of the research, methodological/technical expert, research centre/research group or commercial organisation not at the University of Manchester)
- ☑ In the case of a student research project reviewed by supervisor(s)
- ☐ Other

L16

L16. Please confirm the following:

- [x] I confirm the design and methods of the study are appropriate for the question(s) being asked and the researcher(s) has addressed potential threats to validity, accuracy and/or integrity.

You **MUST** tick the box above in order to submit this form.

L17

L17. What is the maximum number of participants you plan to recruit (including, if relevant, the potential for dropout)?

50

L17.3 If you will be using more than one group of participants, please explain why and how your total number will be broken down into specific groups:

This includes if you have experimental and control groups.

Group 1: People who have experienced back pain.
Group 2: Physiotherapists.

L18

L18. How was the number of participants decided upon?

Please select at least one option

- [ ] Statistical sampling. The sample size is large enough to provide adequate power for appropriate statistical tests concerning statistical significance, effect size and confidence intervals.
- [ ] Theoretical sampling. The number of participants is estimated to provide sufficient data such that further increases would likely yield no significant additional insights concerning the topic under investigation.
- [ ] Purposive sampling. The number of participants is based on access to the subject group most appropriate for answering the research question(s) under investigation (e.g. critical case sampling, key informant sampling or snowball sampling).
- [x] Convenience sampling. The number of participants is based on selection of the most accessible subject group, to control costs in terms of time, effort or other resources.

L18.1 Please confirm the following:

- [x] Convenience sampling is appropriate because the research is exploratory in nature and/or the conclusions to be drawn from the data will not be threatened by issues concerning selection bias, generalisability, sampling error, and/or statistical power.

Research Methods: L20

L20. Does the research involve any of the following data collection methods?

Tick all that apply

- ☐ Method validation
- ☑ Interviews
- ☑ Focus Groups
- ☐ Paper based surveys/questionnaires
- ☐ Electronic or online surveys/questionnaires
- ☐ Standard, copyrighted psychology questionnaires/tests
- ☐ Field observation (including participant observation)
- ☐ Child/infant behaviour observation
- ☐ Ethnography
- ☐ Visual methods (such as those used in Anthropology)
- ☐ Case study
- ☐ Social Network Analysis
- ☐ Diary methods
- ☐ Assessment (such as those used in Education research)
- ☐ Intervention
- ☑ Recordings (audio, video, photographs, etc)
- ☐ Use of pre-existing media (photographs, video, etc)
- ☐ Creative practice as research (such as drama or music pieces)
- ☐ Cognitive psychology/psychophysics (e.g. perception, attention, memory, language, emotion)
- ☐ Cognitive neuroscience (e.g. EEG, eye-tracking, pupillomery, or related measures)
- ☐ Clinical, social or personality psychology (e.g. hypothetical scenarios, role playing, group interactions, personality/state/trait scales)
- ☐ Other qualitative methods (e.g. discourse analysis, interaction analysis, conversation analysis)
- ☐ Other on-line or electronic methods (e.g. netography, on-line research, textual analysis of digital sources)
- ☐ Secondary data analysis
- ☐ Any other method not listed above

L20.1 Please attach either a copy of the data collection tools you plan to use (e.g., questionnaires) or a very brief protocol describing the procedure (stimuli, responses, conditions manipulated, etc.)

If performing a study with more than one data collection tool please ensure you include documents for each (i.e. interview topics guides, focus group schedules, questionnaires/surveys, etc)

IMPORTANT: If you are administering standard, **copyrighted** psychology questionnaires/tests to participants you **MUST** provide a description of the questionnaire/test to the Committee using the approved description form. Please ensure you use a separate form for each test and label each document with the name of the corresponding test before attaching to this question in the application form.

***Please upload all documents throughout the application in PDF format if at all possible**

Documents

Type	Document Name	File Name	Version Date	Version	Size
Additional docs	data_collection_tools	data_collection_tools.pdf	14/04/2022	1	217.8 KB

L20.2 Please briefly describe your methodology:

Please ensure your description is written according to the guidelines below:

- **Provide responses in bullet point format and limit responses to no more than 2 sentences per bullet point.**
- **One or more bullet points must explain the background of the project.**
- **One or more bullet points must explain how participants will be identified, approached and recruited.**
- **Describe exactly what will happen to participants, how many times and in what order.**
- **Provide responses which are as clear and concise as possible**

Background of the project:
- Low back pain is the world's leading cause of disability. Chronic low back patients are recommended to complete sets of exercises at home to manage their condition.
- The project includes the development of a mobile application that visualizes the input from EMG sensors that can be used for the recommended exercises.

There will be two groups of participants: people who have experienced low back pain before, and physiotherapists. The former will be recruited through the VOCAL group - https://www.wearevocal.org/. Dr Janet Deane has conducted PPIE sessions with members of the group before. The latter will be a group of physiotherapists from The Withington Community Hospital. I will speak to them during their weekly allocated hour of in-service.

Participants will join a group Teams meeting at an allocated time for roughly an hour. Once everyone is ready, a reminder that the session will be recorded will be given, and a reminder that they may turn their video camera off if they wish. Then the recording will be started.

The meetings will consist of three main sections:

1. A presentation on the background of the project and the aims and objectives of the research.

2. A series of designs will be shown to the participants, where they will be asked a series of questions (see list below for possible questions) about their thoughts and opinions on the designs seen. These designs will be presented both through simple screenshots/drawings on a PowerPoint presentation and through clickable prototypes using Figma by screen-sharing.

3. The group will then be encouraged to discuss any other thoughts or opinions that they would like to mention regarding the development of the application.

There will be two sessions for both groups. In the second session, the presentation will be a short reminder of the project and then new designs will be shown, developed based on the feedback from the initial session.

Researchers will be conducting these meetings online whilst located either on-campus in University buildings or at their respective homes. The sessions will always include Carolina Costa Lopes and Dr Janet Deane. In the case of the group of participants who have experienced low back pain, a representative from the VOCAL group will also be present.

L20.3 Please provide additional information below regarding recordings:

Please describe the content of the recordings and how they will be recorded/stored.

The meeting recordings will be saved and stored on OneDrive automatically. The automatic transcription provided by Microsoft Teams will also be saved and stored with the recording. The transcriptions will be checked and corrected by Carolina Costa Lopes. Any personal information will be replaced by a unique ID. The transcript will be checked against the recording to ensure correctness, and then the recording will be deleted within 1 month.

L20.4 Please confirm the following:

☑ I confirm that I have read, understood and agree to adhere to the guidelines and processes as outlined in the Recording of Participants in Research Projects standard operating procedures.

L21

L21. What do you consider to be the main ethical issues raised by the methodology and how will you address them?

Please provide details in the box below and structure your answers into a bulleted list.

The ethical risk is that we are collecting signals from the participant, and under GDPR they must be aware of what we are collecting and our intended purposes for this data. We will address this through our informed consent procedure. All data collection will be made anonymous as soon as the transcriptions for the second session have been completed and checked.

Consent: L22

L22. Will the researcher(s) obtain direct informed consent/assent to take part in the research from all participating individuals?

- (•) Yes
- ( ) Not required as this project will access social media data available to the general public or other routinely available online content for which informed consent is not required.

L23

L23. How will the consent be obtained or verified?

Please note, this section refers to the information being given to adults (or parents only).

*Tick **all** that apply*

- [x] Written consent (please use the University template)
- [ ] Verbally (please explain recording method in the box below)
- [ ] Implied (with the return/submission of a completed questionnaire/survey)

L23.2 Please declare the following:

- The researcher(s) will provide an information sheet to all persons invited to take part that explains in concise and clearly understandable terms:
  1. who is conducting the research
  2. why it is being conducted (including the true purpose of the research)
  3. why they have been asked to take part
  4. what it requires of them (including the amount of time they will be required to commit and what they will have to do)
  5. what will happen to the data they provide
  6. whether and how their anonymity and confidentiality will be maintained
  7. that their participation is voluntary and they are free to withdraw at any time without detriment (where possible)
- The researcher(s) will ensure that participants either sign/mark a consent form or that oral consent is recorded or witnessed, to indicate that they have received sufficient information about the research and are happy to take part.
- All information sheet(s) and consent form(s)/script(s) to be used are attached below.

- [x] I confirm all of the above declarations.

The declaration above **MUST** be ticked in order to submit this form.

L23.3 Please attach a copy of your UK GDPR compliant consent form(s)/script(s):

WARNING: Your application will be returned to you and incur substantial delays unless you use the new UK GDPR compliant templates. Please see the help bubble attached to this question for additional guidance.

For secondary data analysis studies only, please provide proof that the analysis you wish to perform falls within the original consent of data subjects.

This **must** be attached in order to submit your form.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Consent Form	consent_form	consent_form.pdf	14/04/2022	1	112.8 KB

L23.4 Please attach a copy of your UK GDPR compliant participant information sheet(s)/script/summary of information page:

WARNING: Your application will be returned to you and incur substantial delays unless you use the new UK GDPR compliant templates. Please see the help bubble attached to this question for additional guidance.

For secondary data analysis studies only, please upload a copy of the permission letter from the data controller or external organisation in support of the project.

This **must** be attached in order to submit your form.

Documents

Type	Document Name	File Name	Version Date	Version	Size
Participant Information Sheet	information_sheet	information_sheet.pdf	14/04/2022	1	166.8 KB

L24-L25

L24. Will you be including participants who are under the age of 16?

- ○ Yes
- ◉ No

L26-L27

L27. Will the researchers give participants at least 24 hours to decide whether or not to take part in the research?

- ◉ Yes
- ○ No

L29

L29. Could participants be considered to have a particularly dependent relationship with the researcher(s) (e.g. students taught or examined by the researcher(s), clients of the researcher(s)).

- ○ Yes
- ◉ No

L30-L31

L30. What are the inclusion criteria for participants?

- ☑ Participants will be included only if they have experiences and/or characteristics relevant to the research question(s) being investigated.

You **MUST** tick the box above in order to submit this form.

L31. What are the exclusion criteria for participants?

- ☑ Participants will be excluded only when they do not have experiences or characteristics relevant to the research question(s) being investigated.

You **MUST** tick the box above in order to submit this form.

L32

L32. How will participants be approached and recruited?

Tick the method below which you will be using for your study. If using more than one method, please tick the appropriate box(es).

- ☑ The researcher(s) will approach participants directly and will:
    1. provide sufficient information to enable informed consent
    2. not pursue non-responders beyond two reminders, and
    3. maintain the anonymity and confidentiality of responders and non-responders

- ☑ The researcher(s) will approach participants indirectly via a third party and the third party will ensure any and all information:
    1. is not coercive,
    2. is limited to information that prospective participants need to determine their eligibility and interest,
    3. does not state or imply a favourable outcome or other benefit beyond what is outlined in the participant information sheet and does not emphasise payments/inducements, using means such as large or bold type, and
    4. contains information that is accurate, honest and socially responsible regarding who is conducting the research, its purpose, risks/benefits, requirements of taking part, contact details for further information

- ☐ Participants will be recruited using an advertisement or equivalent communication (e.g. posters, flyers, bulk email/distribution list, social media invitations/announcements/pages) and the researcher(s) will ensure that any and all information:
    1. provide sufficient information to enable informed consent,
    2. not pursue non-responders beyond two reminders, and
    3. maintain the anonymity and confidentiality of responders and non-responders

- ☐ Not applicable as this is a secondary data analysis of existing data/samples

L32.1 Please attach a copy of any introductory letters or emails that will be sent to gatekeepers or used to recruit participants:

L33

L33. Will participants receive payment or other incentives for taking part in the research?

- (•) No
- ( ) Yes, but the payments and/or incentives provided will not be sufficiently coercive to over-ride freely given consent, taking into account the financial status of the participants targeted. Specifically, the sums involved will only cover reasonable out of pocket expenses (e.g. travel expenses), reasonable recompense for time given to take part in the study, Psychology credits at standard rate for this type of research and/or will be in the form of a prize draw.

Risks to Researchers: L34

L34. Where will the data collection take place?

Please choose the location of where the researcher will be when collecting the data.

***Tick all* that apply.**

- [x] This study involves online surveys/questionnaires/experiments that are distributed either globally or to a specific location
- [x] In a University building on campus.
- [ ] In the researcher's residence/accommodation
- [ ] Off-campus in a public space (e.g. a high street or cafe) in the UK that poses no significant risk to the safety and well-being of participants and researchers
- [ ] Off-campus in a public space (e.g. a high street or cafe) in a safe international setting which poses no significant risk to the safety and well-being of participants and researchers.
- [ ] Off campus at a private building or institutional setting (e.g. the premises of a work organisation, participant's place of work or private residence) in the UK that poses no significant risk to the safety and well-being of participants and researchers.
- [ ] Off-campus at a private building or institutional setting (e.g. the premises of a work organisation, participant's place of work or private residence) in a safe international setting which poses no significant risk to the safety and well-being of participants and researchers.
- [ ] SALC Linguistics/English Language Students ONLY: My project will be primary or practice research conducted in a public space or building within normal working hours, or in a domestic environment familiar to the researcher, within normal working hours or at a time convenient to participants.

L34.1 You MUST agree to the following condition:

- [x] The researcher(s) has reviewed the Division/School's risk assessment for office environments.

L34.4 Please specify the location:

Example: Kro Bar, Oxford Road, Manchester

***Do not** include home addresses. If collecting data in your personal residence, please simply put 'personal residence, Manchester, UK'*

ONLINE - University of Manchester, Manchester, UK.

L35

L35. Will any of the researchers be required to collect data alone in an off-campus setting?

Please note this does not include gathering survey results or social media data from a computer in your own residence/accommodation.

- ○ Yes
- ◉ No

L39

L39. How will the results of research be made available to research participants and communities from which they are drawn?

Tick all that apply

- ☐ Written feedback to research participants
- ☑ Presentation to participants or relevant community groups
- ☐ Other (e.g. video/website)
- ☐ Results will not be made available

Research Sponsorship: L40

L40. Are you in receipt of any funding for your study (either internal or external)?

- ○ Yes
- ◉ No

Supporting Documents: L42

Please use this section to attach any additional documentation that you have not attached previously in this form. If you do not need to attach any additional supporting documentation, please tick the box at the bottom of the page.

The supporting documents that you may have already been required to attach are:

- Interview guide
- Focus group topic guide
- Questionnaire(s)
- Statistical review
- Advertisements/e-mails/recruitment text
- Social media recruitment text
- Consent/assent form(s)
- Participant information sheet(s)
- Letters from gatekeepers/letters of permission

Examples of documentation that you may wish to attach include, but are not limited to:

- Translated documents
- Verification of translated documents
- Distress protocol/debrief sheet
- Lone worker policy/procedure
- Confidentiality agreements
- Ethical approval from partnering institutions
- Local insurance arrangements
- Completed risk assessment forms

L42. Additional supporting documentation

☐ I confirm that all required supporting documentation for this project has been appended.

L43. In order for your application to proceed to review, please confirm the following:

- To the best of my knowledge the information that I have provided here is accurate and I understand that any deliberate attempts to withhold necessary information or mislead the Proportionate UREC will result in my project being given an unfavourable decision.
- I understand that while I have completed this form, the Proportionate UREC may escalate my application for Full University Research Ethics Committee (UREC) review if my research is deemed to be high risk.

☐ I confirm both of the above declarations.

You **MUST** tick the box above in order to submit this form.

Required Signatures

Final Declarations

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I agree to abide by the ethical principles underlying the Policy on the Ethical Involvement of Human Participants in Research and the University's Code of Good Research Conduct.
3. If the research is approved I agree to adhere to the terms of the full application as approved and any conditions set out by the review body in giving approval.
4. I agree to notify the review body of any amendments to the terms of the approved application (both minor and major), and to seek a favourable opinion from that review body via the formal process before implementing the amendment.
5. I agree to submit annual progress reports setting out the progress of the research as well as end of study reports, as required by the review body for all UREC proposals.
6. I understand that research records/data may be subject to inspection by the review body for audit purposes. In addition, I understand that research records/data for those studies that use human tissue, medical devices or pharmaceutical products may be subject to inspection by regulatory authorities for audit purposes.
7. I understand that the information contained in this application, any supporting documentation and all correspondence with the review body or its operational managers relating to the application
   - Will be held by the University until at least 5 years after the end of the study or at least 10 years for those studies involving medical data.
   - May be disclosed to the operational managers of the review body in order to check that the application has been processed correctly or to investigate any complaint
   - May be seen by auditors appointed to undertake accreditation of the University (where applicable)
   - Will be subject to the provisions of the Freedom of Information Act and may be disclosed in response to request made under the Act except where statutory exemptions apply
   - May be sent by email to members of the review body
8. I understand that information relating to this research, including the contact details on this application, will be held by Infonetica Ltd, and that this will be managed according to the principles established in the Data Protection Act 2018.
9. I confirm that I have not included any sensitive personal information including a curriculum vitae or identifiable information about my racial or ethnic origin, political opinions, religious or similar beliefs, trade union membership, physical or mental health, sexual life, commission of offenses and/or criminal proceedings.

IMPORTANT: Please ensure you request the signatures of the PI or supervisor (if required).

The system now features an updated submission function which will automatically queue your application for submission after all required signatures are obtained.

If you do not receive a confirmation email within 1 hour of signing the form that the application has successfully submitted, please perform the following:

1. Open the application and double check the form status as it should be listed as submitted, resubmitted or sent to. If the status is one of these, please email your Ethics Signatory or School Administrator to double check that they have received your application.

2. If the form status is listed as 'changes requested', 'not submitted' or 'returned' then please double check:

   a. That an appropriate signature has been obtained in Section S (it should say for example: Mr Smith has signed on 5/7/2019 at 13.15pm)

   b. That no additional blank signature boxes are listed in Section S

   c. That the application is not pending a mandatory update (listed in a red bar at the top of the screen)

   d. If you have performed all of these checks and the application has still not automatically submitted, please email research.ethics@manchester.ac.uk and provide your project reference number, title and a screenshot confirming these criteria and a member of the team will be able to assist you.

WARNING: Once you have signed the form, it will be **locked** and if you wish to make further changes you must **'unlock'** the form, which will break any signatures already obtained.

For staff projects, if you are NOT the PI, you must obtain their signature (using the request button below).

For student projects, if you are NOT the supervisor, you must obtain their signature (using the request button below).

For student projects, if you ARE the supervisor please ensure you sign the form.

Signature of the Primary Supervisor

To sign this form please look on the left hand side of your screen for an action button called Sign that has a picture of a pencil on it. Please push this button and this button only to sign the form.

Please note that if you are the student requesting your supervisor's signature that by pressing this request button you are confirming that the application is complete, accurate to the best of your knowledge and ready to be signed off by your supervisor for further processing by relevant Division/School/UREC colleagues.