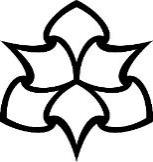
C:\Users\55123899\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Outlook\BWUOQDWT\MMU Logo 2 lines Range left Outlined CS6 (002).jpg

Study Acronym/Short Title

Full study title

Protocol v0.0, DD MMM YYYY

This is a 2-in-1 document that serves as both template and guide. All text in blue represents instructions and should be removed as the document is completed. All items in red in the document footer have to be filled in. **Please fill out the form using black font colour.**

This template is uncontrolled after download so you should always access it from our webpage at <https://www2.mmu.ac.uk/research/staff/ethics-and-governance/ethics/> to make sure you have its latest version. Please avoid using this template if it was sourced from a third party, the version handed to you risks being out of date.

|  |  |  |
| --- | --- | --- |
| **Protocol authorised by:**  Students will ask their lead supervisor to review and authorise their protocol before submitting their ethics application.  For staff applicants, the protocol is signed and authorised by the project’s Principal Investigator. | | |
| Full name in print  Role | Date | Signature |
|  |  |  |

|  |  |
| --- | --- |
| **Project Team** | |
| Principal Investigator | (In the case of student projects, the student is considered to be the PI.)  full name, role, faculty, department |
| Co-investigators | (Usually applies to staff projects delivered by a team. Please delete this row if it does not apply to your project.)  full name, role in project, faculty, department |
| Supervisory Team | (Only applies to student projects. Please delete this row if it does not apply to your project.)  Director of Studies full name, faculty, department  Supervisor(s) full name, faculty, department (and institution, if external) |
| Study Team | (Please list all other researchers or project admin staff that are not listed above as PI/Co-I. If not relevant for your project, please delete row.)  full name, role, faculty, department |

For general queries, supply of study documentation, and collection of data, please contact:

Name:

Project role:

Address:

Tel:

E-mail:

Fax:

Web address:

Problems relating to this study should be referred, in the first instance, to the Principal Investigator.

**Funder**

(Please provide the identity of your research funder here. Please note that tuition fees are not considered research funding. Therefore, if you are a student, your project would not normally be classified as funded and you should indicate so.)

Contents

[1 BACKGROUND 4](#_Toc15380718)

[2 RESEARCH QUESTION(S) AND OBJECTIVES 4](#_Toc15380719)

[3 RESEARCH DESIGN 4](#_Toc15380720)

[4 SETTING 5](#_Toc15380721)

[5 PARTICIPANTS 5](#_Toc15380722)

[5.1 Inclusion Criteria 6](#_Toc15380723)

[5.2 Exclusion Criteria 6](#_Toc15380724)

[6 STUDY PROCEDURES 6](#_Toc15380725)

[6.1 Participant Recruitment 6](#_Toc15380726)

[6.2 Consent 6](#_Toc15380727)

[6.3 Withdrawal Criteria 7](#_Toc15380728)

[7 INCIDENTS 7](#_Toc15380729)

[8 DATA ANALYSIS AND HANDLING 8](#_Toc15380730)

[8.1 Sample Size 8](#_Toc15380731)

[8.2 Data Collection 8](#_Toc15380732)

[8.3 Data Handling 8](#_Toc15380733)

[8.4 Access to Data 9](#_Toc15380734)

[8.5 Record Keeping 9](#_Toc15380735)

[9 REGULATORY ISSUES 9](#_Toc15380736)

[9.1 Peer Review 9](#_Toc15380737)

[9.2 Ethics Approval 9](#_Toc15380738)

[9.3 Insurance 10](#_Toc15380739)

[9.4 Health and Safety 10](#_Toc15380740)

[9.5 Conflicting Interests or Competing Roles 10](#_Toc15380741)

[9.6 Monitoring, Audit & Inspections 10](#_Toc15380742)

[9.7 Protocol Compliance and Amendments 10](#_Toc15380743)

[9.8 Data Protection and Confidentiality 10](#_Toc15380744)

[10 DISSEMINATION POLICY 11](#_Toc15380745)

[11 PROJECT TIMELINE 12](#_Toc15380746)

[12 REFERENCES 12](#_Toc15380747)

# BACKGROUND

*[Please read the instructions in blue then remove them and replace with your text in black font].*

Your background section will ideally cover up to one page (two at the very most). Please keep in mind that it is not acceptable for you to copy your entire literature review here. The purpose of this section is to introduce the reader to the subject, to show that the research you propose has not already been done by someone else, and to show that the research will contribute to the body of knowledge on the topic.

Therefore, in this section you will offer: general information about the topic you have chosen to study, a summary of what is already known about the issue, a summary of the research gap / problem you have identified, and a statement about why it is important that the research gap / problem is addressed. Citations may be used, but please limit yourself to a small number of the more important ones.

The section should be written so it is easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Please include an explanation of any specialist terms and concepts that you introduce.

# RESEARCH QUESTION(S) AND OBJECTIVES

*[Please read the instructions in blue then remove them and replace with your text in black font].*

You will present here your research question(s) for the proposed project. Your research question(s) may or may not be further broken down into a small number of specific objectives. You will also briefly explain how the research question(s) will help address the research gap.

# RESEARCH DESIGN

*[Please read the instructions in blue then remove them and replace with your text in black font].*

Please provide here a summary of your research design, showing the following:

* The chosen methodology and methods, as well as a short statement showing why these are the appropriate ones for answering the research question(s);
* A brief account of the primary and secondary sources you will draw upon;
* A summary of the analytic strategy to be employed and the analytic techniques included in it;
* A description of the expected outcomes/outputs of the research and the measure(s) by which you will assess whether the desired outcomes/outputs have been successfully achieved.

Please keep in mind that this section is meant to provide a succinct overview of your research design and that more in-depth descriptions must be included in the appropriate sections below.

# SETTING

[Please read the instructions in blue then remove them and replace with your text in black font].

Please describe here where your study takes place. Some research projects will be fully undertaken on Manchester Metropolitan University premises. Other projects might take place entirely on location somewhere else. Yet other projects might have a mixed approach: data collection might take place at one site while data analysis might be done at another. Please account for your project as appropriate. When listing locations and sites, please indicate clearly:

* if the project has only one site or if various stages of the project will be undertaken in different locations;
* if applicable, the eligibility criteria for selecting locations or sites;
* if any of the locations or sites are situated abroad; if yes, please specify where and any issues arising from this;
* if any special permissions or clearances are needed for accessing the locations/sites.

# PARTICIPANTS

[Please read the instructions in blue then remove them and replace with your text in black font].

**If your study does not use human participants, please insert here a statement to this effect and delete subsections 5.1 and 5.2 and the entirety of section 6. Do not forget to update the contents page after you delete sections/subsections.**

If your study uses participants, please insert here a statement about the total number of participants that you are targeting. If applicable to your study, please also indicate number of participants per each stage of the project or per each type of data collection (e.g. xy participants for interviews and qz participants for physical test).

## Inclusion Criteria

Please give full details including ages, gender etc. You should clearly state all of the eligibility criteria that you will be using.

## Exclusion Criteria

Please explain clearly what criteria will lead to the exclusion of certain potential participants.

# STUDY PROCEDURES

## Participant Recruitment

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe here two stages of the recruitment process: identification and approach. Therefore, you will describe:

* who will identify the potential participants;
* what resources will be used to identify the potential participants;
* if you need to access any identifiable personal information for this, how will you gain legal access to it;
* if you are using any publicity: posters, leaflets, adverts or websites, social media;
* how will potential participants indicate their interest in your project;
* how you will approach them and give them the details of your project (PIS and consent form, other means?);
* how long you will allow participants to decide to take part in the project.

## Consent

[Please read the instructions in blue then remove them and replace with your text in black font].

You should describe:

* discussion between the potential participant and his/her legally acceptable representative and researcher, based on written material (PIS and consent form);
* the opportunity for potential participants to ask questions;
* assessment of capacity. For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. Capacity is usually assumed and should not be outright questioned unless the researcher notices signs leading to suspicion that the participant might not be capable to:
  + understand the purpose and nature of the research;
  + understand what the research involves, its benefits (or lack of benefits), risks and burdens;
  + understand the alternatives to taking part;
  + retain the information long enough to make an effective decision;
  + make a free choice;
  + make this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity);
* where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected.

Where the participant population is likely to include a significant proportion of participants who cannot read or write, require translators or have cognitive impairment, appropriate alternative methods for supporting the informed consent process should be employed. This may include allowing a witness to sign on a participant’s behalf (in the case of problems with reading or writing), or allowing someone to date the form on behalf of the participant, or providing Participant Information Sheets in other languages or in a format easily understood by the participant population (in the case of minors or cognitive impairment).

You must produce the following document when relevant:

* For adults and young people (16-17 years of age) who have capability and capacity to legally consent: PIS and Consent form;
* For children under 16 years of age: PIS and Assent form for the child, one set for each age group that you recruit; also, PIS and Consent form for their legal guardian;
* For Adults who do not have legal power to consent for themselves: PIS and Assent form for vulnerable participant; also PIS and Consent form for legal representative.

## Withdrawal Criteria

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe what you will do in the following situations:

* if the participant wishes to withdraw;
* if there is any case in which you will automatically withdraw the participant.

You will create a withdrawal form that you will use to indicate in your records when a participant has been withdrawn.

# INCIDENTS

[Please read the instructions in blue then remove them and replace with your text in black font].

During the course of research, sometimes situations might occur that lead to unwanted effects on the participants: distress, accidents, complaints etc. Please describe here if any such incidents are possible in your research and what you will do to help the participant (if applicable) if they occur. Please note that complaints are always possible, regardless of the type of research you conduct.

Please also describe how you will report such incidents and how you will keep a record of them.

# DATA ANALYSIS AND HANDLING

[Please read the instructions in blue then remove them and replace with your text in black font].

Please describe here what is considered data in your project. This can be: paper based-material, electronic data, biological samples, etc.

## Sample Size

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe here how you have decided the sample size of your study (based on literature recommendations, based on statistical calculations, etc.).

## Data Collection

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe here how you collect your data: method and software (if any) used. You will also describe what data is collected. For personal data and sensitive personal data you will list all the identification categories you collect (e.g.: names, ages, location, gender, sexual orientation, political affiliation etc.).

## Data Handling

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe:

* how you process the data (software, entry methods);
* if you use transcription/ translation/ coding done by a third party, please provide evidence of a service contract being put in place to safeguard GDPR requirements;
* describe how data will be stored and backed up securely, including any data storage requirements (lockable drawers, secure computers, secure servers);
* if data will be transferred, describe the method of transfer to be used, the security arrangements in place to ensure the security of the data during transfer where data are, and the legal contract put in place to ensure this;
* whether data will be transferred outside of the EU (note that explicit consent from participants and a Modal Clause Agreement with the destination is required if their personal data is to be transferred outside of the EU)
* arrangements to anonymise or pseudo-anonymise the data (if, when, and how this will be done; who will do it)document and detail if there is a disaster recovery plan.
* state who is responsible for data entry and quality
* state who is responsible for data analysis

## Access to Data

[Please read the instructions in blue then remove them and replace with your text in black font].

Besides the researcher, access will be granted to authorised representatives from the University to permit study-related monitoring, audits and inspections. Please indicate this and also describe all other individuals who will be granted access to the data.

## Record Keeping

[Please read the instructions in blue then remove them and replace with your text in black font].

Please describe here for how long you will keep the data set and the research records. Please make sure to indicate how long you will store them and if archiving is necessary at the end of the store period. If archiving is necessary, please describe your arrangements for this.

# REGULATORY ISSUES

## Peer Review

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe what peer review has been done for your project (if any). Please note, review by Principal Investigator, Supervisor, Ethics Reviewers or any other member of the project team do not count as peer review.

## Ethics Approval

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe the ethical approval obtained for the research and the procedure for obtaining amendments and extensions for it.

## Insurance

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe what insurance arrangements apply to this research.

## Health and Safety

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe here any significant health and safety risk and how you will mitigate it. A risk assessment form might be need to be provided along with your application.

## Conflicting Interests or Competing Roles

[Please read the instructions in blue then remove them and replace with your text in black font].

Identify and disclose any competing interests that might influence study design, conduct, or reporting. Also identify any competing roles that might influence your behaviour or that of your participants (e.g. you are recruiting your own students as participants). Please explain how you will mitigate these circumstances.

## Monitoring, Audit & Inspections

[Please read the instructions in blue then remove them and replace with your text in black font].

You will describe the research records you will keep and how your will prepare yourself for the eventuality of an audit.

## Protocol Compliance and Amendments

[Please read the instructions in blue then remove them and replace with your text in black font].

Protocol deviations, non-compliance, or breaches are departures from the approved protocol. No protocol deviation is allowed without an approved amendment to the ethical approval. Please acknowledge this and explain how you will go about obtaining one if necessary.

## Data Protection and Confidentiality

[Please read the instructions in blue then remove them and replace with your text in black font. Do not forget, the information here also has to match what you declared in section 8.3.]

This will explain in detail all that you will do to be compliant with GDPR and the UK Data Protection Act 2018. This will include:

* Who is the data controller.
* Who is the data custodian.
* Who has access to personal data during the project and after the project’s end.
* If any personal data is shared in any way with a third party. A third party is anyone besides the researcher, the authorised research team members and the authorised Data Controller representatives. A ‘third party’ will include the following: your employer outside of the University, a Supervisor you might have at another University, research collaborators from other institutions, a transcriber you hire, a data coder you hire etc. If yes, describe the legal contracts that you will put in place for this transfer.
* How you will securely handle the personal data at all times. In general, this involves:
  + the creation of coded, depersonalised data where the participant’s identifying information is replaced by an unrelated sequence of characters
  + secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media
  + limiting access to the minimum number of individuals necessary for quality control, audit, and analysis
* How you will determine if you have the legal right to share/transfer data to other parties and how the confidentiality of data will be preserved when the data are transmitted to other parties
* Who is responsible for the data destruction and what technical requirements will be followed (consult the ISDS website for more tech guidance).
* In the case of a data breach, who is responsible for informing the Data Protection Officer. Keep in mind that, when acting as a Data Controller, the University has the legal duty to report any data breaches to the Information Commissioner’s Office within 72 hours. Therefore, the plans you make here must make this possible.

# DISSEMINATION POLICY

[Please read the instructions in blue then remove them and replace with your text in black font.]

The protocol should describe:

* Who owns the data arising from the study;
* What are the authorship agreements for final report and other publications;
* Where the final project report can be accessed;
* Where else are you going to publish results;
* Whether any funding or supporting body needs to be acknowledged within the publications and whether they have review and publication rights of the data from the study;
* Whether there are any plans to notify the participants of the outcome of the study, either by provision of the publication, or via a specifically designed newsletter etc;
* Whether the anonymised dataset will be made publicly available in Open Access; and if so, describe where, the timeframe and any other conditions for access.

# PROJECT TIMELINE

[Please read the instructions in blue then remove them and replace with your text in black font].

Please design your project timeline using week/month numbers, not actual calendar dates.

# REFERENCES

🟋end of project protocol🟋

[Please read the instructions in blue then remove them and replace with your text in black font].

Do not forget! Depending on what activities you have declared in your protocol, here is a list of the additional documentation that you might need to create for your application:

* Participant withdrawal form;
* Contract for services;
* Data/Modal Clause Agreement;
* Risk Assessment.