Guidance: Research Ethics Application

This document is intended to support you to complete the research ethics application form. If you are unsure of how to answer any questions seek guidance from your supervisor, PGR Co-ordinator, or Research Office, as appropriate.

Should you still be unsure, we recommend answering in a manner that ensures review takes place so that the panel may support you in conducting high-quality, ethically robust research.

1. Title of Research Project

Generally speaking, titles should reflect the subject of the research. Where more than one ethics application is required to cover the research of a specific project, please use the title plus subtitle or other form of identification. When submitting multiple protocols for review, ensure that the titles are different.

2. Researcher Information

The researcher is the person who assumes responsibility for the conduct of the research. In the case of student research, the student will be listed as the researcher with supervisor as a named co-researcher

3. Rationale

This section should be a clear and concise outline of your research. Researchers are encouraged to use references in the rationale in order to give the reviewers an understanding of why the research is being proposed and what research has already been done in this area. It should be assumed that the Research Ethics Panel is not familiar with the discipline, but is knowledgeable in research. In general, lengthy literature reviews are not appropriate. Researchers should therefore avoid the use of technical jargon as much as possible. An explanatory paragraph giving an overview of the project would be very helpful.

4. Initial Review Checklist

1. You should answer YES to this question if your research involves participants identified from, or because of their past or present use of, the NHS and/or Social Care Services.

Such research will likely require review by an NHS Research Ethics Committee (REC). If you are unsure whether your research requires NHS REC review please consult the NHS Health Research Authority, NHS REC review decision tool and seek guidance from the appropriate R&D office

It is the policy of the University Research Ethics Panel to avoid duplication of ethics review. Researchers should forward a copy of the forms and outcomes of review by other panels or committees to ethicspanel@marjon.ac.uk for record keeping. **In all cases it is the responsibility of the researcher to determine what means of approval are required for their projects and to obtain approval prior to starting the project.**

2. You should answer YES to this question if your research involves intrusive procedures with adults who lack capacity to consent for themselves or health-related research involving prisoners.

Such research will likely require review by an NHS Research Ethics Committee (REC). If you are unsure whether your research requires NHS REC review please consult the NHS Health Research Authority, NHS REC review decision tool and seek guidance from the appropriate R&D office

It is the policy of the University Research Ethics Panel to avoid duplication of ethics review. Researchers should forward a copy of the forms and outcomes of review by other panels or committees to ethicspanel@marjon.ac.uk for record keeping. **In all cases it is the responsibility of the researcher to determine what means of approval are required for their projects and to obtain approval prior to starting the project.**

3. You should answer YES to this question if your research will be reviewed by another research ethics panel such as a University or NHS REC.

It is the policy of the University Research Ethics Panel to avoid duplication of ethics review. Researchers should forward a copy of the forms and outcomes of review by other panels or committees to ethicspanel@marjon.ac.uk for record keeping. **In all cases it is the responsibility of the researcher to determine what means of approval are required for their projects and to obtain approval prior to starting the project.**

4. You should answer YES to this question if your research involves any non-human animals, non-human animal cellular material, tissue, organs, and/or bodily fluids.

5. You should answer YES to this question if your research has been contracted by an external body – such as a school or local council - to evaluate a service or initiative they provide.

If you answered YES to ANY question in the initial review checklist please contact ethicspanel@marjon.ac.uk before proceeding with the rest of the ethics application form or your research.

Potential Issues Checklist

1. You should answer YES to this question if your research involves human participants or the collection of personal data, as defined by the GDPR. Generally speaking, personal data is data relating to a living individual who is, or can be, identified directly from the data or from the data in conjunction with other information that is in, or is likely to come into, the possession of the researchers.

2. You should answer YES to this question if your research involves your own students/clients/athletes

3. You should answer YES to this question if your research involves participants who are in potentially vulnerable situations, especially in dependent or unequal relationships.

You should also answer YES to this question if the ability of potential participants to understand your research project and any potential consequences of their decision to participate, or not participate, is compromised. Decision-making capacity may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought. Determining decision-making capacity requires the researcher to ascertain whether at a particular point in time a participant (or prospective participant) understands the nature of a particular research project, and the risks, consequences, and potential benefits associated with it.

If your research follows well-established protocols for commonly occurring situations, such as research with healthy children in schools, then you may answer NO to this question.

4. You should answer YES to this question if your research will require the permission of a gatekeeper for initial or continued access to participants. This includes research involving gatekeepers such as adult professionals, or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, and research where participants are in a dependent relationship with the gatekeeper such as employees recruited through their workplace, athletes recruited through their coaches, or students recruited through their teachers.

5. You should answer YES to this question if your research will collect data from records from which people might be identified from that data directly or in conjunction with other information that is in, or is likely to come into, the possession of the researchers.

More specifically, this includes record data which relate to a living or recently deceased individual who can be identified from those data or from those data and other

information which is collected in the research, data given in confidence, or data agreed to be kept confidential not in the public domain including information on business, income, health, medical details, and political opinion, and/or data on a person's race, ethnic origin, political opinion, religious or similar beliefs, trade union membership, physical or mental health or condition, sexual life, commission or alleged commission of an offence, proceedings for an offence (alleged to have been) committed, disposal of such proceedings or the sentence of any court in such proceedings.

6. You should answer YES to this question if your research involves access to data collected initially for administrative, record-keeping, or other non-research related purposes. This includes, for example, academic or medical records.

7. You should answer YES to this question if your research deceives, purposely misleads, and/or misinforms the participants about the nature of the research.

8. You should answer YES to this question if your research addresses potentially sensitive topics including, for example, participants' sexual behaviour, illegal or political behaviour, experiences of violence, abuse or exploitation, mental health, their personal or family lives, or their gender or ethnic status.

You should answer YES to this question if your research involves participants chosen for inclusion in research because of the public role they hold, or because they represent views of their general position (i.e., elite interviews)

You should answer YES to this question if your research addresses terrorism or extremist views and/or behaviours.

9. You should answer YES to this question if your research involves, either in whole or in part, participants or representatives of community groups and organisations leading, undertaking or working alongside researchers in research design and/or data collection and/or data analysis

10. You should answer YES to this question if your research employs visual or vocal methods where participants or other individuals may be identifiable in the material used, generated, or distributed.

You should answer NO to this question if using audio recording of interviews for the purposes of transcription is the ONLY audio or vocal method

11. You should answer YES to this question if your research involves ingestion, consumption, administration, or injection of any drug, placebo, or other substance, including food, vitamins, or supplements.

You should answer YES to this question if your research involves the introduction of instruments or other objects into the body or body cavities.

12. You should answer YES to this question if your research involves blood or tissue samples from participants.

You should answer NO to this question if your research uses Capillary Blood Sampling as the ONLY method of taking blood samples from participants and follows the School of Sport, Health and Wellbeing Standard Operating Procedures Manual.

13. You should answer YES to this question if it is likely that participants will experience pain or discomfort in the research including through vigorous or maximal exercise testing.

You should answer NO if pain or discomfort implied by participation in the research is no greater than those encountered by participants in aspects of their everyday life that relate to the research.

14. You should answer YES to this question if it is likely that participants will experience some form of psychological stress, anxiety, or cause harm or negative consequences beyond those encountered in normal life.

You should answer NO if pain or discomfort implied by participation in the research is no greater than those encountered by participants in aspects of their everyday life that relate to the research.

15. You should answer YES to this question if your research requires participants to undergo repeated testing and/or make significant time commitments as part of their involvement in the research.

16. You should answer YES to this question if your research involves the remote acquisition of data from or about human participants using the internet and its associated technologies.

You should answer NO to this question if your research uses e-mail, social media, and/or instant messaging services for advertising your study ONLY and NOT to collect data

17. You should answer YES to this question if participants are offered compensation for their time or effort as cash or in kind. Examples of the latter include gift cards/gift certificates, gifts (toys, books), or class marks.

You should answer NO to this question if participants are offered reimbursement for reasonable out of pocket expenses such as parking, transport, food/refreshments, or childcare for example.

18. You should answer YES to this question if your research uses any external organisation to recruit participants.

19. You should answer YES to this question if the research presents risks to your physical, social, and/or emotional/psychological wellbeing.

You should answer YES to this question if the research presents legal or reputational risks for the researchers or University.

20. You should answer YES to this question if the research involves data collection outside of the UK, and/or researchers outside of the UK, and/or sharing of data in an international context where data handling may not be subject to the UK Data Protection Act.

21. You should answer YES to this question if the research involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

You should answer YES to this question if the research involves the sharing of data in an international context where data handling may not be subject to the UK Data Protection Act.

You should answer YES to this question if data was obtained for purposes other than the proposed research. This includes reanalysing data collected as part of previously conducted research.

22. You should answer YES to this question if the research is funded by the University or an external funding agent or body

If you answered NO to ALL these questions, please complete the declaration

If you answered YES to ANY question, please complete the Research Project Further Information

Research Project Further Information

1. Project Start and End Dates

a. The start date should refer to the beginning of formal recruitment processes, or, where there is no formal process, the commencement of the informed consent process and data collection.

Researchers are not to engage in data collection or recruitment until they have received a favourable ethical opinion from the Panel.

b. The estimated date where involvement of human participants or data has completed

c. The estimated date when data analysis has been completed in order to answer the original research question(s) at which time a study completion report should be submitted.

2. Methods

a. Specify all locations where the research - including recruitment and/or data collection - will be conducted. If the research is taking place within an institution or organisation, including schools, which requires formal consent be sought prior to the research being conducted, please attach evidence such consent has been received.

b. Describe all the methods to be used in the study to collect data. When presenting a complex proposal, tables, figures and timelines are helpful.

c. Describe all the methods and techniques to be used in the analysis of data.

Please append all tests, questionnaires, and tools, including standard instruments. Interview guides and focus group questions should also be appended. For semi-structured and unstructured interviews, please submit a document that gives a general sense of the type of questions you plan to ask. It is understandable that some interview questions may change once the research begins.

3. Research Participants

a. This section should include all the relevant details about the study participants. List the inclusion and exclusion criteria.

If your research involves existing data - as well as or instead of – participants, explain how the data will be collected/extracted, what it will include, and how you

will gain access to the data. If appropriate, state and justify sample size.

b. If YES, please specify whether your research is collecting:

- **Directly identifying information:** information that identifies a specific individual through direct identifiers (e.g., name, National Insurance number);
- **Indirectly identifying information:** information that can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, unique personal characteristic, or job role);
- **Anonymous information:** information that never had identifiers associated with it (e.g., anonymous surveys).

Please then explain how you will protect the identity of participants.

Ethical concerns regarding privacy decrease as it becomes more difficult (or impossible) to associate information with a particular individual. Concerns also vary with the sensitivity of the information and the extent to which access, use, or disclosure may harm an individual or group. Strategies for safeguarding entrusted information include:

- **Anonymisation of data:** data is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low;
- **De-identification of data**: 'link-coded' data with names and other identifiers removed, but which is linked to a separate file held by, or accessible to, the researcher which enables individual research participants to be identified (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary)

c. If YES, please explain the approval of data transfer and submit supporting documentation in as an appendix.

d. If YES, please specify the nature of the relationship and how any power

differentials will be addressed.

e. If YES, please specify ownership and property rights of the researchers, any sponsors, and those of participants as related to commercial products.

Please provide supporting documentation in the application appendices.

4. Consent Process

Informed consent is an on-going process that starts with the researcher's first contact with the individual and continues through study completion/participant withdrawal, and beyond. Any verbal exchange about the study, the written informed consent form and any other written documentation given to participants should provide adequate information for the participant to make an informed decision about their participation. Traditionally written consent is considered standard research practice. However, the Research Ethics Panel understand that many disciplines and cultures do not accept written consent as appropriate. It is the quality of the consent process, not the format that is most important.

a. This section should include a full description of how you will obtain free and informed consent from participants and how this will be recorded, for example, please explain who will approach whom, where the approach will take place, and what documents will be provided to participants.

Please append any documents that will be used in the consent process.

b. Any conditions on withdrawal of data if the participant chooses to withdraw from the study should be clarified. This should differentiate between participants withdrawing from data collection processes and withdrawing data that has been collected.

It is not appropriate to state 'participants may withdraw at any time', anonymous or anonymized data cannot be withdrawn, it is almost impossible to withdraw data from

a focus group discussion, and it may be impractical to withdraw data after analysis has taken place. Withdrawal dates, especially of data, must be provided.

5. Data Management

Management of research data is subject to a range of policies and laws.

It is the responsibility of the researcher to ensure that they comply with all relevant policies and laws related to their research.

a. Please confirm whether participants' personal data will be collected. Personal data is defined
by –insert GPDR link here -

b. The storage of electronic data on the University's secure network drives is considered best practice and authentication can be managed by user privileges to a project's storage and management environment.

For research based at Plymouth Marjon University that involves co-investigators from other institutions the researcher should organise for their co-investigators to have access to a secure folder on the network from Computing Services.

If you answer NO, please explain where data will be stored, how data will be protected, how this meets legal requirements, and how this will be communicated to participants.

c. Only the research team should have access to participants' personal data.

If you answer NO, please specify who, beyond the research team, will have access to participants' personal data, explain why this access is necessary, how this meets legal requirements, and how this will be communicated to participants.

d. If de-identifying, sometimes called pseudo-anonymising, data, 'link-coded' data (with directly or indirectly identifiers removed) which is linked to a separate file that enables individual research participants to be identified (e.g., the principal investigator retains a list that links the participants' code names with their actual name so data can be re-linked if necessary), then the data and identifying codes must be stored separately to help protect participant identity.

If you answer NO, please specify why separate storage is not possible, how this meets legal requirements, and how this will be communicated to participants.

e. Normally, data should not be shared with third parties or transferred to others via third parties.

If you answer NO, please specify which third parties data will be transferred to or via, how this meets legal requirements, and how this will be communicated to participants.

Any data transfer or sharing practices should be explained. **Please append any transfer/sharing agreement documents that will be used in the consent process.**

If you are processing personal data as part of a collaborative research project you need to determine which institution is the data controller. If the other institution is processing data for a purpose determined by you and they have no role in determining the purpose or methods of processing then Plymouth Marjon University will be the data controller and the other institution will be the data processor. You will be responsible for ensuring the other institutions process the data in accordance with the Data Protection Act (1998) and as data controller the Plymouth Marjon University will be liable if they do not. You will need a Data Processor contract in place.

If the institutions are jointly processing personal data under a jointly agreed purpose and methodology they will most likely be joint data controllers.

If you are collaborating with other institutions in collecting personal data but you are then using the data for different purposes, your relationship may be one of data controllers in common.

In the case of both joint controllership and controllership in common you will need a data Controller agreement or appropriate clauses for a consortium agreement including processes for handling Subject Access Requests.

f. Each research project is unique and judgement is required to determine how long data should be kept. **There is no standardised period for data retention.** Researchers must determine the retention requirements for their research records and data on a project by project basis taking account of issues including:

- Legal and regulatory framework for particular types of research;
- Terms and conditions imposed by external research sponsors/funders/potential publishers;
- Commercial, political, or ethical sensitivity of particular types of research or any research for particular external sponsors.

The data retention period and strategy should be communicated clearly to participants

If you answer NO, please specify how long data will be retained for, how this meets legal requirements, and how this will be communicated to participants.

g. Data should be disposed of securely ensuring that personal data cannot be accessed by unauthorised persons. As a basic standard:

- data held in paper form should be disposed of by shredding;
- data held in digital form should, wherever possible, be destroyed by multiple over- writing. The 'delete' function and emptying the recycle bin will not usually erase data permanently;
- data held in non-rewriteable digital media, such as cd-roms, dvds and Blu-Ray discs, should be disposed of by destruction of the physical media (e.g., shredding).

Care should be taken to examine and erase data from all digital equipment,

including voice recorders, laptops, cameras etc.

If you answer NO, please specify how data will be disposed of, how this meets legal requirements, and how this will be communicated to participants.

i. Using the prompts relevant to the questions you have answered NO to, please explain the data management process.

6. Risk Evaluation

The risk matrix should be understood as guide to help researchers consider risk factors and participant vulnerability.

There is no standardised protocol for risk evaluation.

a. To evaluate participant vulnerability consider:

1. Any pre-existing vulnerabilities associated with proposed participant groups;
2. Any pre-existing physiological or health conditions;
3. Any pre-existing cognitive or emotional factors, developmental stage, socio-economic or legal status, and/or;
4. Any power-differentials between researchers and participants.

To evaluate the risk(s) of your research consider the probability and magnitude of harms participants may experience as a result of participating in the research, these include:

1. Physical risks (e.g., relating to physiological or health issues such as clinical diagnoses or side effects, and injuries);
2. Psychological or emotional risks (e.g., stress or anxiety during data collection);
3. Socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of duty to report intent

to cause serious harm, subpoena, or breach of confidentiality).

b. Justify the risk level indicated in the risk matrix with reference to the probability that it will occur and seriousness of the harm.

Minimal risk in research is where the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

c. Justify the participant vulnerability indicated in the risk matrix

Full Review Information

1. Risks Management

a. Please specify all potential risks associated with the research.

b. Please explain how you will manage the risks listed above.

Scholarly review is required for all 'higher risk' research (i.e., orange in the risk matrix). Scholarly review can take many forms, these include, for example:

- Student research should be reviewed by thesis committee, or supervisor and at least one other expert in the research area *external* to the project;
- By colleagues within the researcher's department or within the Plymouth Marjon Unviversity more broadly not associated with the research project;
- External, expert colleagues at the invitation of the researcher;
- Competitive funding grants (e.g., Wellcome Trust, ESRC etc.) will entail some form of scholarly review and awarding of such funding is considered to satisfy scholarly review requirements. However, sometimes funders approve large

grants that include multiple research protocols. Please outline whether the scholarly review was done for this specific protocol or whether the review was part of a larger grant. Project-based research funding does not constitute scholarly merit.

Regardless of the process of the review the comments of the reviewer should be included in order to outline the scholarly merit of the proposed research. The Research Ethics Panel maintains the authority to review the science or scholarship - which may include seeking external guidance above and beyond that provided in the application - for any of the applications it is assigned.

2. Experience of investigators with this type of research

a. Please outline the training and experience of the individuals involved in the research to evidence the research team's experiences and/or ability to conduct the research.

If the research involves data collection techniques for which formal training and/or certification is required (e.g., phlebotomy) then the protocol should confirm that researchers are appropriately qualified to complete the research.

For student research, the degree of supervision by the faculty supervisor should be included.

b. If the project involves community members or research associates, their training should be outlined with special attention to privacy and confidentiality in research.

3. Possible benefits

Please specify any benefits to participants as a result of their participation in the research.

Compensation or reimbursement is not a benefit.

Please specify if there is no benefit to the participant.

Please explain potential benefits to the community, society, and/or the scientific or scholarly community.

4. Compensation

Please specify any compensation provided to participants.

Please justify the amount of compensation to be offered to participants with particular reference to participant vulnerability.

Please specify what level of compensation participations will receive should they withdraw from data collection or withdraw their data. Whenever possible, participants who withdraw should receive prorated compensation.

Declaration

All signatures are required before a protocol will be accepted for review. E-signatures and scanned signatures are accepted, however, the protocol should be submitted as a single (pdf/word) document.

For student research where the project will serve as the thesis or degree-fulfilling requirement, the student shall sign as investigator and the supervisor should sign the application as supervisor having reviewed the project and submission.

For undergraduate research a countersignature, in addition to the supervisor's signature, is required as part of internal faculty review processes.