RESEARCH ETHICS POLICY

This document establishes the principles and practices for research ethics at Plymouth Marjon University.

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1.0 Introduction

1.1 Plymouth Marjon University is committed to enhancing the contribution research can make to our understanding of the world around us and improving practice. Research is essential for generating new knowledge as well as achieving efficient and effective services. However, research often involves risk. It is important that any risks are minimised and do not compromise the dignity, rights, safety and well-being of the people who take part. Therefore, it is important that research is conducted with the highest ethical standards and aligns with Marjon's values. This policy sets out the values and principles guiding Marjon with regards to research of all kinds, in all disciplines.

1.2 The Research Ethics Policy draws on national and international ethical guidelines and aligns with the Concordat for Research Integrity (2019). The Concordat seeks to provide a national framework for good research conduct and its governance. The Concordat applies to research of all kinds, in all disciplines. UKRI expect funded research organisations to implement the Concordat. Marjon has adopted the Concordat and the five commitments contained within it, namely:

1. Upholding the highest standards of rigour and integrity in all aspects of research
2. Ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards
3. Supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers
4. Using transparent, timely, robust and fair processes to deal with allegations of research misconduct should they arise
5. Working together to strengthen the integrity of research and to review progress regularly and openly

1.3 Implementation of the Research Ethics Policy is coordinated by the Research Ethics Panel, which is a sub-committee of, and reports to, the Research and Knowledge Exchange Committee. Ultimate oversight is the responsibility of Senate. Implementation of the Ethics Policy in relation to research activity is the responsibility of researchers.

1.4 The Research Ethics Policy acknowledges that research activity may be conducted with reference to ethical guidelines from professional bodies relevant to the researcher's discipline and/or profession. The Research Ethics Policy recognises research ethics guidelines published by professional bodies. Researchers are encouraged to engage with ethical guidelines from relevant professional bodies in the design and conduct of their research, but note in research where the University undertakes the responsibilities of research sponsorship the University Research Ethics Policy takes precedence should any unavoidable conflicts arise.

2.0 Scope and Aims

2.1 The aim of the Ethics Policy is to ensure good governance and good practice in research ethics within the University. The following objectives are considered integral to the achievement of this aim:

2.1.1 To ensure that all proposed research projects involving human participants and/or their personal data and/or potential material ethical issues are subject to independent ethical scrutiny by more than one person;
2.1.2 To provide staff with the opportunity to undertake training in the identification and evaluation of ethical considerations that pertain to research;
2.1.3 To provide staff, through the research ethics application process, with an opportunity to participate in the ethical scrutiny of research proposals, thereby increasing familiarity with and confidence in research ethics across the institution;
2.1.4 To ensure that researchers (see paragraph 2.3) are supported in developing their capacity to identify and think through ethical issues that may arise during their own research.

2.2 The values, principles, requirements and standards set out in this document apply to research activity. We adopt the definition of the Research Excellence Framework, as described in Assessment framework and guidance on submissions (REF2021 Guidance on Submissions):

> 'research' is defined as, 'a process of investigation leading to new insights, effectively shared... It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction'.

The Ethics Policy provides for provision of ethical opinions of research projects as defined above. Broadly speaking, research includes original investigation leading to the creation or gaining of new knowledge and understanding. This document does not apply to collection of data for the purposes of:

2.2.1 Personal reflective practice
2.2.2 Internal audits
2.2.3 Quality assurance procedures
2.2.4 Service evaluations

These activities are not defined as research and do not need ethics review. This is not a comment on the relative importance of any of these activities, nor does it mean such work does not contain ethical issues requiring consideration.

2.3 Following the UK Research Integrity Office (UKRIO) Code of practice for research (2009), 'researchers' are defined as any people who conduct research, including but not limited to: as an employee; as an independent contractor or consultant; as a research student; as a visiting or emeritus member of staff; or as a member of staff on a joint clinical or honorary contract.

More specifically, a researcher at Marjon includes:

1. Any Marjon staff, postgraduate or undergraduate student or associate researcher who is undertaking research. Marjon staff registered for higher degrees at another Higher

Education institution should follow the research ethics guidance and review procedures of the institution at which they are registered.

2. Any individual who is not a member of the Marjon, as defined above, but is undertaking research using the Marjon's premises and facilities, and/or under the name of the Marjon.

3.0 Context and Values

3.1 All research carried out by Marjon researchers should be conducted in a manner consistent with our values. All projects, prior to their initiation, must be reviewed in light of these values.

Plymouth Marjon University's core values are;

Humanity: An active regard for the welfare of participants as well as the welfare of researchers and reviewers.

Ambition: Empowering people, holding to the highest standards of conduct, and commitment to creating a society that treats people fairly and equitably.

Curiosity: Stimulating debate and discussion to develop questions, establish new insights and encourage innovation.

Independence: Recognising the intrinsic value of research, researchers, and reviewers by respecting, and protecting, autonomy.

These values are the basis for Marjon's research ethics principles listed below. Research ethics principles are the considerations discussed and deliberated on through the review of research protocols.

- Protection from harm
- Privacy and confidentiality
- Free and informed consent
- Fairness and equity in research participation
- Openness, honesty, and integrity
- Social and scientific Value

3.2 Humanity: requires an active regard for the welfare of others. Humanity means that researchers and reviewers must protect the welfare of participants as well as the welfare of researchers and reviewers. Through the review process, researchers and reviewers must attempt to minimize the risks associated with answering any given research question. This process involves *both* ensuring participants are not exposed to any unnecessary risks *and* achieving the most favourable balance of risks and potential benefits in a research proposal.

Aligned with our value of Independence, participants (and authorised third parties) must be provided with enough information, in an easily understandable format, for them to be able to judge any risks and potential benefits of participation to make a final judgment about the acceptability of this balance.

Our value of humanity requires specific consideration of protection from harm, and privacy and confidentiality in the review process.

3.2.1 Protection from harm

Researchers and reviewers must minimise the risk of physical, social or psychological harm arising to any person or organisation as a result of research (including participants, researchers, and reviewers whether directly or indirectly involved) and minimise the risk of harm to the environment. All research stakeholders, including the University, share responsibility for the physical and psychological wellbeing of researchers and participants.

The evaluation of research risk is undertaken in relation to participant vulnerability and research risk. Through the review process, researchers must describe foreseeable risks and explain mitigation procedures.

The ethical review process is conducted in proportion to the potential risks of the research. Full Review at the Research Ethics Panel meeting is the default review process for all research. However, delegated review process may be used when the research is determined to be at or below the threshold of 'minimal risk'. To evaluate risk for proposed research, researchers and reviewers must consider participant vulnerability and research risk.

Participant vulnerability is evaluated in relation to any pre-existing vulnerabilities associated with proposed participant groups as well as the vulnerability of any individual potential participant at the time they are approached to participate. This can include pre-existing physiological or health conditions, cognitive or emotional factors, socio-economic or legal status, and power differentials.

Research risk is evaluated in relation to the probability and magnitude of harm participants may experience as a result of the proposed methods to be used and types of data to be collected. This can include physiological or health issues such as potential diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of the researcher's duty to report intent to cause serious harm, subpoena, or breach of confidentiality). Minimal risk in research is where the probability and magnitude of possible harms entailed in the research are no greater than those encountered by participants and/or researchers in those aspects of their everyday life that relate to the research.

In line with the values of ambition and curiosity, researchers shall assess the potential risks of their research to determine whether delegated review is appropriate. The delegated review process, conducted by a subcommittee of the Research Ethics Panel for staff and PGR research, and programme teams for undergraduate and taught masters research, may be used when the research is determined by to be at or below the threshold of 'minimal risk' and involve participants who are not considered to be vulnerable. Where reviewers disagree with the risk evaluation of researchers Full Review by the Research Ethics Panel is the default review process.

3.2.2 Privacy and Confidentiality

Researchers, reviewers, the Research Ethics Panel, and the University share the responsibility for protecting participant confidentiality. Researchers must safeguard information entrusted to them and in all situations collect the minimum identifiable information that is necessary to

answer the research question. The Research Ethics Panel and the University must support researchers in maintaining promises of confidentiality.

Researchers shall maintain their promise of confidentiality to participants within the extent permitted by ethical principles and law. Through the review process, researchers and reviewers should consider whether the proposed research is likely to put researchers in positions where they may experience tension between the ethical duty of participant confidentiality and the legal obligation of disclosure of confidential participant information or attempts to compel disclosure of confidential participant information to third parties. For research addressing topics or working with participants where tension between the ethical duty of confidentiality and disclosure to third parties is foreseeable (for example, research involving participants at risk of abuse, studies of criminal behaviour, or research about reportable communicable diseases), researchers must where possible, practicable and appropriate, design their research to avoid or mitigate such risks. Insofar as it does not undermine or obviate the disclosure, researchers must apprise the participants or their guardians or responsible others of their intentions and reasons for disclosure. Researchers' conduct in such situations should be assessed on a case-by-case basis and guided by consultation with colleagues, any relevant professional body, the Research Ethics Panel, legal counsel and persons knowledgeable about applicable laws and regulations in the relevant jurisdictions as appropriate.

Information provided to participants prior to consent should outline the research project's procedures to protect confidentiality including who will have access to the data when informed consent is obtained. Information obtained about a participant during the course of an investigation must be treated as confidential unless otherwise agreed upon in advance. In instances where participants wish to be identified for their contributions to the research and therefore waive anonymity any such waiving of anonymity requires researchers obtain consent of these participants and negotiate agreements with them that specify how they may be identified or recognised for their contribution.

Ethical concerns regarding confidentiality and 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. Researchers and reviewers must consider what kind of data is being collected. This can be defined as:

- **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).

Strategies for safeguarding entrusted information include:

- **Collecting anonymous information:** data is 'born anonymous' in that it never contains, or links to, identifying information.

- **Use of anonymisation keys:** data is stored with names and other identifiers removed. Each participant is given an identifying code that is attached to their data. A key, linking codes with names, is stored in a separate, password protected or encrypted file, stored in a separate location from the main data. Once data analysis is complete, the key is destroyed.

When reporting the results of a study, this should be done in such a way that the identity of individuals cannot be determined.

The collection, storage, use and disclosure of personal data must comply with the Data Protection Act (2018) or any statutory amendment or regulation.

3.3 Independence: recognises the intrinsic value of researchers, research participants, and research topics, and the respect and consideration they are due. Independence incorporates dual moral obligations to respect autonomy of those involved in research and to protect those with developing, impaired or diminished autonomy.

Autonomy includes the ability to deliberate about a decision and to act based on that deliberation. Respecting independence and autonomy means giving due deference to a person's judgment and supporting choices to be made without interference. Equally, independence means those with impaired or diminished autonomy must be given the opportunity to participate in research that may be of benefit to themselves or others.

Our value of independence requires specific consideration of informed consent in the review process.

3.3.1 Informed Consent

When a participant has the ability to understand the research requirements and to act on that understanding voluntarily, the decision to participate is an expression of independence. Research can begin only after participants, or their authorised third parties, have provided their consent. Exceptions to this general ethical requirement are outlined below.

In line with our value of humanity, participants consent is the clearest demonstration that their participation is based on consideration of the risks and potential benefits of the research project. Evidence of consent shall be recorded by the researcher.

An important mechanism for respecting participants' independence in research is the requirement to seek their 1. voluntary, 2. fully informed, and 3. ongoing consent.

3.1.1.1 Voluntary Consent

The voluntariness of consent is important because it respects human dignity and means that individuals have chosen to participate in research according to their own values, preferences and wishes.

The approach to recruitment is an important element in assuring voluntariness. When and where participants are approached, who recruits them, and length of time between invitation and recording consent are important elements in assuring (or undermining)

voluntariness. To consider the voluntariness of consent reviewers and researchers must be cognisant of situations where pre-existing relationships, undue influence, coercion or the offer of incentives may undermine the voluntariness of a participant's consent to participate in research.

Aligned with our values of curiosity, where researchers seek knowledge that critiques or challenges the policies and practices of institutions, governments, interest groups or corporations, the fact that the organisation under study may not endorse the research project must not prevent reviewers reaching a favourable ethical opinion of the research where there is compelling public interest in this research.

Researchers may not need to seek the organisation's permission to conduct their research. However, in the review process researchers and reviewers should be aware that the organisations under study may have requirements for allowing access to their sites and to participants, which should be respected. Nevertheless, reviewers should not view proposed research unfavourably because the research will be unpopular or looked upon unfavourably by an organisation.

While organisational consent may not be required, the researcher must inform any individual who is approached to participate in research about their organisation of the possible consequences of participation, including: if permission of the organisation has been obtained or if it has not been forthcoming; any foreseeable risks that may be posed by their participation, including those that might influence their relationship with the organisation; and the views of the organisation regarding the research, if these are known.

Researchers using auto/biographical and autoethnographic methodologies must seek consent from individuals who may be identifiable either directly or through their relationship with the researcher or other research participants.

3.1.1.2 Fully Informed Consent

Fully informed consent focuses on the quality of the process that supports potential participants to understand the information being conveyed to them by researchers. Through the review process, researchers and reviewers must consider how best to convey that information to facilitate understanding.

For consent to be fully informed participants (or authorised third parties) must be provided with enough information, in an easily understandable format, as well as sufficient time, opportunity, and support to understand the information provided, ask any questions they may have, and give due consideration of any risks and potential benefits of participation to make a final judgment about the acceptability of this balance to them. The time required for this initial phase of the consent process will depend on various factors including the magnitude and probability of harms, complexity of the information conveyed, and the setting where the information is given.

Aligned with our value of ambition, researchers and reviewers must give due consideration to the decision-making capacity of potential participants. Furthermore,

those who lack the capacity to decide on their own behalf must neither be unfairly excluded from the potential benefits of research participation, nor may their lack of decision-making capacity be used to inappropriately include them in research. Through the review process, researchers and reviewers must be aware of competing values and seek to find a balance between them for the benefit of prospective participants who lack decision-making capacity

Assessment of decision-making capacity must adhere to the core principles of the Mental Capacity Act (2005):

- A person must be assumed to have capacity unless established otherwise
- Individuals should be helped to make their own decisions as far as practicable
- A person is not to be treated as unable to make a decision merely because they make an unwise decision
- All decisions and actions must be in the best interests of the person lacking capacity
- All decisions and actions must be the least restrictive of the person's rights and freedom of action.

Decision-making capacity is determined by the ability to understand material information, evaluate any risks and potential benefits of participation, make a final judgment about the acceptability of this balance to them, and communicate a choice. A person lacks capacity when they are unable to make or communicate a decision about a particular matter because of an impairment of, or a disturbance in, the mind or the brain, which may be the result of a variety of conditions. Decision-making capacity is also related to age. However, rather than an age-based approach to consent, our value of independence requires an approach based on decision-making capacity if it does not conflict with any laws or professional body requirements governing research participation.

If participants do not possess sufficient decision-making capacity, they must be engaged in the research discussion at the level of their capacity to understand. Through the review process, researchers and reviewers must ensure participants are supported through the consent process to agree to or to decline participation in the study. In all instances, researchers are required to determine and adhere to all applicable legal and regulatory requirements with respect to decision-making capacity and consent. Authorised third parties who are asked to make a consent decision on behalf of a prospective participant must also be aware of their responsibilities.

Aligned with our value of curiosity, researchers and reviewers must give consideration to research that can be carried out only if the participants do not know the true purpose of the research in advance. Research employing deception may include giving participants incomplete or false information about themselves, events, social conditions and/or the purpose of the research. Blinding in experimental studies is not considered deception, however, participants must be fully informed of the blinding process and have reasons for blinding explained.

If researchers determine deception is indispensable for research rigour, through the review process researchers must demonstrate that: no alternative to deception is available; the research has significant social value; and no information has been withheld that, if divulged, would result in refusal to participate.

Through the review process, researchers and reviewers must determine how participants will be informed (or "debriefed") of the deception upon completion of the research. Such debriefing must explain reasons for the deception and provide participants the option to remove their data and/or human biological materials unless this is impossible or inappropriate. When considering any exception to debriefing, reviewers must consider the level of potential harm to the participant debriefing may cause and the impact of the debriefing on the feasibility of the research. When seeking any exception to debriefing requirements, researchers must demonstrate debriefing is impossible or inappropriate due to undue hardship or onerousness that jeopardises the conduct of the research. It does not refer to mere inconvenience.

3.1.1.3 Ongoing Consent

Ongoing consent is important because consent begins with initial contact and recruitment and continues beyond the end of participants' involvement in the research project.

If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials. The consent process should set out any circumstances that do not allow withdrawal of data or human biological materials once collected. In some research projects, the withdrawal of data or human biological materials may not be possible (e.g., when personal information has been anonymised and added to a data pool). Researchers must provide a rationale for using collection methods that do not permit subsequent withdrawal of data or human biological materials. Where the terms of the research do not allow for withdrawal of their data or human biological materials, the identity of the participants shall be protected at all times during the project and after its completion. Participants shall also be informed that it is impracticable, if not impossible, to withdraw results once they have been published or otherwise disseminated.

Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research. Ongoing consent requires researchers provide participants and reviewers with all information relevant to participants' decision-making in the research. The researcher has an ongoing ethical obligation to inform participants of any changes to the research project that may affect them. Such changes must be documented through the amendment process. Through the amendment process, the ethical implications of any changes that may be germane to participants decision to continue research participation or may be relevant to the circumstances of participants must be evaluated. Any changes are likely to require changes to the disclosed risks or potential benefits of the research. This gives participants the opportunity to reconsider the basis for their consent in light of the new information.

3.4 Ambition: refers to our commitment to empowering people, holding to the highest standards of conduct, and the obligation to create a society that treats people fairly and equitably. Researchers must ensure their research treats all people with equal respect and concern, and distributes the benefits and burdens of research participation so that no part of the population is unduly burdened by the harms, or denied the benefits of the knowledge generated from, research.

Our value of ambition requires specific consideration of fairness and equity, and openness, honesty and integrity in the review process

3.4.1 Fairness and Equity

Fairness and equity do not mean treating people the same. Differences in treatment or distribution are justified when failures to take differences into account may result in the creation or reinforcement of inequities. People or groups whose circumstances cause them to be vulnerable or marginalised may need to be afforded special attention in order to be treated justly in research.

Recruitment, methodology, and inclusion and exclusion criteria are all important components of fair and equitable research. In cases of under-representation of groups that results in, or perpetuates, inequities and disparities, fairness and equity may require special efforts to include members of those populations in research. This relates particularly to groups who have, at times, been treated unfairly and inequitably in research. Aligned with our value of humanity, inclusion and exclusion criteria should not be based upon potentially discriminatory criteria such as race, ethnicity, economic status, age or sex, without sound and clearly explained ethical or scientific justification. Through the review process, researchers and reviewers must determine the ethical and or scientific justification of exclusion criteria. Increased difficulty or inconvenience of recruiting participant groups is no basis for exclusion criteria, unless such difficulty creates undue hardship or onerousness that jeopardises the conduct of the research. It does not refer to mere inconvenience redressing historically unfair and/or inequitable treatment of population groups in research is basis for exclusion criteria only when such treatment can be demonstrated within the specific field of research proposed by researchers.

An important threat to our value of ambition is imbalances of power between researcher and participant through pre-existing relationships or dual roles of researcher and, for example, teacher, lecturer, clinician, module or programme leader, line or senior manager, student, or colleague. Reflective practice is integral to professional development and should not be restricted unless the researcher's reflective practice impinges upon others.

Once research moves beyond what would be considered standard reflective practice, measures need to be introduced to minimise the influence of the dual roles and the impact of perceived or actual conflicts of interest. If the activity or exercise to be examined can be integrated into regular professional activities, is of value to study, and does not exclude specific students, clients, or colleagues, then the researcher can proceed without introducing measures to separate their dual roles. If the subject of the research is self-reflection on practice, there is no need for consent. However, if any materials produced by the students, clients, or colleagues are to be collected and analysed, their consent is required. The consent process must state explicitly that the decision whether to participate will not prejudice the relationship between potential

participants, the researcher, and institution, that no advantage will be gained by agreeing to participate and no penalty will result by not agreeing to participate.

3.4.2 Openness, honesty and integrity:

Researchers should be open and honest about the purpose and content of their research at all times and conduct the research in such a way as to ensure the professional integrity of its design, the generation and analysis of data, and the publication of results. More specifically: researchers should, in all aspects of their research:

- Demonstrate honesty, integrity and professionalism. Researchers must be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to experimental design, generating and analysing data, publishing results and acknowledging the direct and indirect contributions of colleagues, collaborators and others and other research related matters.
- Observe all legal and ethical requirements laid down by the University or other properly appointed bodies as are involved in their field of research.
- Make efforts necessary to ensure they are familiar with 'best practice' (e.g. in relation to matters of research policy, finance or safety) relevant to their area of research.
- Avoid, or if unavoidable declare, conflicts of interest, whether actual or perceived.
- Take steps to ensure the safety of those involved in their research.
- Provide opportunities for research participants and stakeholders to access research findings.
- Observe fairness and equity, including ensuring that all work presented as their own complies with protocols for acknowledging the contribution of others and acknowledges all source material.

3.5 Curiosity refers to our commitment to research that generates answers to important research questions. Poorly designed research is unethical because it wastes resources, wastes participants' time and exposes them to risk for no purpose. Through the review process reviewers must ensure that the research poses answerable questions, whether the research methods are appropriate for answering the question, and whether the study is designed with accepted principles, clear methods, and reliable practices. Reviewers must make these judgements based on the disciplinary and methodological traditions, paradigmatic assumptions, and markers of research rigour and quality of the proposed research, not their own disciplinary and methodological preferences. Although curiosity is a fundamental impetus for undertaking research, researchers and reviewers have an obligation to ensure research is carried out in ways that are consistent with our values of independence, ambition, and humanity.

Our value of curiosity requires special consideration of social value and research rigour.

3.5.1 Social Value

Social value refers to the importance of the information that a study is designed to produce. Social value of research cannot be quantified, but reflects the quality of the information the research will produce so that it offers the means of creating knowledge not otherwise obtainable. The social value of research can be realised through its contribution to knowledge

and understanding, or through direct contribution to the creation of interventions, policies, or practices that address practical problems. The importance of such information can vary depending on the prevalence or significance of the practical application, the novelty of the approach, and other considerations. As such, well-designed studies may still lack social value. Through the review process reviewers must ensure that the proposed study has sufficient social value to justify its associated risks and burdens, especially in studies that lack prospects of potential direct benefit to participants.

3.5.2 Research Rigour

Research rigour refers to the ability of a study to produce new knowledge and meet the stated objectives of the research. Research rigour cannot legitimate subjecting participants or stakeholders to mistreatment or injustice. For the review process researchers are required to communicate the research aims and the expected standards of rigour consistent with their disciplinary and methodological norms and standards. While these norms and standards may differ across studies, the requirement of research rigour applies to all research, regardless of its discipline, methodology, funding source, or potential risks. Researchers are required to adhere to the agreed research protocol.

Reviewers are required to support researchers to undertake research that upholds high standards of rigour to maintain the integrity of research and its ability to meet its stated aims. To support reviewers, specialist referees may be asked to provide advice on any aspect of an application relevant to the formation of an ethical opinion and which lies beyond the expertise of the reviewers. Referees may be specialists in research ethics, specific disciplines, topics, or methodologies, or representatives of communities relevant to the research. In all cases, researchers must be provided with the referee's advice in full. Advice of a referee should be sought by either:

1. The Research Ethics Panel Chair or Secretary, who may contact the referee seeking written advice prior to a review. A copy of the advice received should be made available to reviewers and researchers.
2. The referee may be invited to attend a meeting in person for discussion of the application concerned. The attendance of the referee and the substance of their advice at the meeting should be recorded.
3. Reviewers may decide to seek written advice following a meeting.

4.0 Review Process

4.1 Independent scrutiny of research proposals is provided by reviewers. Reviewers can be based in the School and the University's Research Ethics Panel where applicable. A description of these procedures is available on the Research Ethics webpage.

All research proposals determined to be 'higher risk' through the application must be reviewed at a full meeting of the Research Ethics Panel. Research proposals determined to be 'lower risk' through the application may be reviewed by delegates.

4.2 All researchers should note that:

4.2.1 It is University policy that a favourable ethical opinion is required for all research. Researchers who proceed to undertake research without such an opinion will not be able to rely on the support of the University and may be subjected to disciplinary action.

4.2.2 The issue of a favourable ethical opinion does not connote an expert assessment of the research or of the possible risks involved, nor does it detract in any way from the ultimate responsibility of researchers for all research undertaken by them, and its effects on participants.

4.2.3 A favourable ethical opinion is granted solely for the research activity described and for the time period specified by the researcher in their application. If the research is amended (for example in terms of its aims, methods, participants, or timeframe) during the progress of the project, the researcher should ensure that ethical issues are reconsidered using the appropriate procedures, and the appropriate documentation completed and submitted for review.

4.2.4 Where there is uncertainty over any aspect of a proposed research project, researchers may choose to request that the proposal be discussed with the Research Ethics Panel even where this is not a formal requirement

4.2.5 When research projects require the scrutiny of another body (e.g. applications going through another UK University or national-level Ethics such as the UK's Integrated Research Application System/IRAS), the Research Ethics Panel should be made aware of the research and the outcome of the review process. The Panel will not normally review such projects, but reserves the right to comment on the project and have these comments noted.

4.3 Applications for ethics review should be made in accordance with a process set out in standard operating procedures and in written guidance available on the Research Ethics webpage. Only complete applications will be accepted for review, notwithstanding other discussions as mentioned in 4.2.4 above.

4.4 The review process is proportionate to the scale, complexity, and risk of the proposed research. Research proposals determined to be 'lower risk' through the application process do not warrant consideration at a full meeting of the Research Ethics Panel. They should be identified on receipt in accordance with standard operating procedures so that ethics review may be delegated.

4.5 Reviewers must be assured about the planned ethical conduct and anticipated risks and benefits of any proposed research. However, reviewers and the Panel are not responsible for the conduct of researchers, especially where research is not carried out as agreed. This responsibility rests with the researcher who, as named in the application, takes primary responsibility for the design, conduct and reporting of the research. In doing so, the researcher is responsible for ensuring the research is carried out as agreed as part of the scientific and ethical conduct of the research.

4.6 The review process must be competent, timely and authoritative. The membership of the Panel, as well as the operational and administrative support reviewers receive, must be arranged to maximise the quality, rigour and promptness of review and the efficiency of decision-making processes.

4.7 Reviewers must be independent and impartial. Their opinion must be free, and must be seen to be free, from conflicts of interest. This includes freedom from pressures of: line-management or supervisory relationships; coercion; strategic concerns or institutional directives; market forces or funding arrangements; and agency-, discipline- or topic-related bias.

4.8 Full-Panel Meetings

4.8.1 All research proposals determined to be 'higher risk' through the application must be reviewed at a full meeting of the Panel.

4.8.2 A study representative(s), normally the researcher, co-researchers, and/or supervisor, shall be invited to the full-panel meeting to discuss their application.

4.8.3 Research Ethics Panel members do not sit on the Panel in any representative capacity and need to be able to discuss freely the applications submitted to them. For this reason, full panel meetings should be held in private, deliberations kept confidential by those in attendance, and members should be encouraged to raise any matters of concern.

4.8.4 The Chair is responsible for the conduct of Panel business. Where the Chair is unavailable, the meeting should normally be chaired by the Vice-Chair. The Chair, or Vice-Chair as appropriate, are responsible for ensuring that the Panel reaches clearly agreed decisions on all matters.

4.8.5 The meeting should reach decisions by consensus wherever possible. Where a consensus is not achievable a formal vote should be taken by a counting of hands. The decision of the Panel should be determined by a simple majority of those members present and entitled to vote. A record should be kept of the number of votes, including abstentions, in the minutes. Where the vote is tied, the Chair may give a casting vote, but should first consider any other options to arrive at a more consensual decision.

4.8.6 External observers may be invited to attend Panel meetings, subject to written invitation setting out the terms under which observer status is permitted, the signature of a confidentiality agreement, and the agreement of members at the meeting to be attended. If any observer is present they must adhere to the same confidentiality standards as members. External observers should have no vested interest in any applications being considered at the meeting. The Chair should inform any study representative who attends the meeting of the presence of an external observer. The attending study representative should be given the opportunity to object to the presence of an observer.

4.8.7 Initial opinions of the Panel must be communicated to researchers within 10 working days of the meeting.

4.9 Delegated Reviews

4.9.1 Research proposals determined to be 'lower risk' through the application may be reviewed by delegates. For all Marjon staff and PGR researchers at least two members of the Research Ethics Panel will conduct the delegated review. For taught-programme researchers at least two members of staff will conduct the delegated review.

4.9.2 For taught-programme delegated reviews at least one reviewer must be completely independent of the proposed research, although they may be part of the programme team.

4.9.3 Applications for delegated review can be deemed unsuitable for delegated review by any single reviewer. The application is then transferred to the next full Panel meeting. Reviewers

must inform the Research Ethics Panel why the application is not suitable for delegated review. The Research Ethics Panel must inform researchers of the transfer and associated timelines.

4.9.4 Delegated reviews should reach decisions by consensus wherever possible. Where a consensus is not achievable the Research Ethics Panel must be informed and an additional reviewer from the Panel membership will be delegated to conduct the review. The review outcome is then determined by a simple majority of reviewers. Where disagreement persists, the application will be transferred to the next full Panel meeting. The Research Ethics Panel must inform researchers of the transfer and associated timelines.

4.9.5 Initial opinions of reviewers (including transfer to full review) must be communicated to researchers within 20 working days of submission deadlines as listed on the Research Ethics webpage

4.10 Favourable Opinion

4.10.1 Reviewers give a favourable opinion when they are sure the ethical issues presented by the proposed research will be effectively managed by researchers.

4.10.1 Reviewers must not give a favourable opinion where they know the research will break the law. However, it is not the role of reviewers to offer a legal opinion on research proposals, although they may advise researchers that legal advice might be helpful to them. Researchers remain responsible for making sure the research is conducted in accordance with the requirements of law, relevant regulators and guidance.

4.11 Favourable Opinion Subject to Minor Amendments

4.11.1 Reviewers give a favourable opinion subject to minor amendments when specific and limited additions or amendments to the application or supporting documentations are required. When giving a favourable opinion subject to minor amendments reviewers must specify the amendments that must be made prior to the start of the study. These should be clearly set out in the decision letter.

4.11.2 The amendments must be made for a favourable opinion to be reached. Until specified amendments are made the study does not have a favourable opinion and should not start. It is the responsibility of the researcher to ensure that the specified amendments are made and communicated to reviewers.

4.11.3 Reviewers may delegate the responsibility for determining whether the amendments have been made to the Chair or a named reviewer.

4.12 Major Amendments

4.12.1 Reviewers give a decision of major amendments when an application requires further information, clarification, consideration, or additional documentation from the researchers and the changes concerned may require further ethical consideration before the reviewers are asked to give favourable opinion of the research.

4.12.2 Applications requiring major amendments will receive clear explanation of ethical issues that require attention before a favourable opinion can be reached. Reviewers should only

include advice or suggestions where, if the researcher opts not to implement them, a favourable opinion will not be possible.

4.12.3 Resubmission of applications that have received a decision requiring major amendments must be reviewed by all at least two reviewers, or the Research Ethics Panel as appropriate.

4.13 Unfavourable Opinion

4.13.1 Reviewers give an unfavourable opinion when, in the opinion of the reviewers, the research as presented in the application would be ethically indefensible. Researchers must be informed of the reasons for this opinion.

4.14 No Opinion

4.14.1 Reviewers may provide no opinion when an application is incomplete, where there is uncertainty regarding additional review procedures (for example, by other external bodies), and/or the application is of such poor quality that it is not possible for an informed opinion of the research to be formed.

5.0 Communication and Monitoring

5.1 The Research Ethics Policy, Standard Operating Procedures, Panel members, named contacts for research integrity and whistle-blowers, proformas and guidance documentation are publicly available on the University website on the Research Ethics page.

5.2 The minutes of a full panel meeting should be prepared by the secretary to the meeting. The minutes should be stored for at least 20 years and contain a record of the following for each study:

1. The members, referees and observers present for the review.
2. Any material interests declared, and the decision of the Panel on the participation of the member.
3. The submission of written comments by members or referees.
4. A summary of the main ethical issues considered.
5. The decision of the Panel on the application including any conditions to be met prior to the start of the study, or the predominant reasons for an unfavourable opinion or no opinion.
6. The outcome of any vote taken and/or any formal dissent from the opinion of the Panel by a named member.

5.3 The minutes of a delegated review should be prepared by reviewers. The minutes should contain a record of the following for each study:

1. Names of reviewers.
2. Any material interests declared and any written comments by members or referees.
3. The decision of the reviewers on the application (unless deemed unsuitable for delegated review, see paragraph 4.9.3) including any conditions to be met prior to the start of the study, or the predominant reasons for an unfavourable opinion or no opinion.
4. The outcome of any vote taken and/or any formal dissent by reviewers (see paragraph 4.9.4

5.4 The minutes should be submitted to the following full panel meeting for ratification as a true record. Any necessary revisions should be incorporated in the final version of the minutes.

5.5 Subject to the provisions of the Freedom of Information Act, the minutes should be treated as confidential and not routinely disclosed to researchers, stakeholders, or colleagues.

5.6 Auditing of research projects granted a favourable ethical opinion: The process of auditing research projects that have received a favourable ethical opinion within the University has two aims:

1. To monitor compliance with the Research Ethics Policy and Code of Conduct and any project-specific requirements of ethical approval, thereby meeting external expectations relating to research governance such as those defined by the Concordat to Support Research Integrity.
2. To provide opportunity for the identification and sharing of good practice and the improvement of institutional systems and processes, in accordance with the underlying ethos of the Research Ethics Panel, i.e. to support staff in the good conduct of research.

5.7 The process for auditing research projects is as follows:

5.7.1 At the first Research Ethics Panel meeting of the new academic year, a subset (to be determined by the Research Ethics Panel) of research projects granted a favourable opinion in the previous 24 months (i.e. projects completed or on-going during the current academic session) shall be identified for audit.

5.7.2 Prior to the audit of a selected project, a set of criteria (as determined by the Research Ethics Panel) shall guide the examination of selected research projects during the audit. These criteria include whether the researcher(s) carried out their study in accordance with described protocol and how complaints, if any, were handled. The record of ethical approval (including any conditions or recommendations) shall be used to identify the aspects of the project for which evidence is to be required during the audit.

5.7.3 The lead researcher of projects selected for audit shall be asked to provide the required evidence. With regard to any recommendations made by the Research Ethics Panel, the researcher(s) shall be asked to provide evidence of adoption.

5.7.4 The evidence shall be reviewed by appointed members of the Research Ethics Panel

5.7.5 The Research Ethics Panel shall provide a written audit report to be included in the Research Ethics Panel annual report. The audit report is to be presented to the Research and Knowledge Exchange Committee.

5.8 In the event of an ethical issue that carries potential negative impact on the University's reputation, the named contacts for research integrity and whistleblowing must be notified.

5.9 The Research Ethics Panel will report annually to the Research and Knowledge Exchange Committee and make recommendations regarding any amendments or revisions to the Ethics Policy and/or Terms of Reference and/or Standard Operating Procedures deemed necessary. The Research Ethics Panel annual report will normally include:

5.9.1 Summary of applications and decisions received by the Panel

5.9.2 Summary of Panel membership and any procedural or training developments

5.9.3 Audit reports and confirmation of data destruction

5.9.4 Good practice and issues arising

5.10 The annual report shall be provided to the Board of Governors, in accordance with the Concordat to Support Research Integrity.

6.0 Research Ethics and the PREVENT policy

6.1 This Ethics policy is intended to cover the full scope of research activity, included in which might be research on issues that may be considered "sensitive" or that have a potentially adverse impact on the researcher or participant. With specific regard to the PREVENT guidance this includes security-sensitive research material that can be interpreted as engaging the Terrorism Act.

6.2 Researchers dealing with such material should indicate in the Ethics Checklist material which might be linked, or interpreted as linked, to terrorism or matters that the PREVENT policy is concerned with. In addition, they must register and log their work with the Deputy Vice-Chancellors Office.

6.3 The secure storage, and access to, such material are important considerations. The University will isolate research material that may fall within the scope of the PREVENT Policy, while ensuring that it is made available to the researcher so that research is not impeded.

6.3.1 Researchers will utilize a secure data store to hold all relevant sensitive materials. Secure storage must be identified under the advice of IT Services and after the project has been logged with the Research Ethics Panel Administrator via the appropriate forms.

6.3.2 Placing of materials in the store identifies them as being for research purposes and stops any further circulation of the material. The store may contain documents that are electronic in origin or those scanned from notes or paper copies.

6.3.3 Researchers using the material will not transmit electronically (or otherwise) any data or research materials to any third party. All planned research related use of the material should be carefully considered and clearly documented within the relevant logging forms in advance of use.

6.3.4 Special permission rights will need to be applied for by the researcher in order to be granted access to the materials for a limited time period (renewable upon application).

7.0 Research Ethics and the Human Tissues Act

7.1 The Human Tissue Act (2004) provides the regulatory framework for the acquisition, use, storage and disposal of human tissue for research. An establishment must hold an appropriate license for the activity.

Plymouth Marjon University does not hold a license.

7.2 Relevant material, defined by the Act as ‘material, other than gametes, which consists of or includes human cells’ must not be stored for the purposes of research.

7.3 Relevant material may be held only for the following temporarily, for the shortest possible period of time, for the following purposes only:

7.3.1 As incidental to transportation to a facility with a license

7.3.2 Whilst being processed with the intention to extract subcellular components that are not relevant material (i.e. rendering the tissue acellular).

7.3 In all cases relevant material must be held for the shortest possible time as explained in the HTA Code of Practice and Standards E: Research

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