



The Research Ethics Handbook

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GLOSSARY

Ethics application form - supporting documents

Assent Form - AF

Consent Form - CF

Data Management Plan - DMP

Overseas Risk Assessment form - ORA

Participant Information Sheet - PIS

Privacy Notice – PN

Risk Assessment form - RA

Legislation

Data Protection Act, 2018 - DPA

Disclosure and Barring Service – DBS

Human Tissue Act 2004 – HTA

Mental Capacity Act 2005 – MCA

The Equality Act 2010 - EA

UK General Data Protection Regulation, 2018 - GDPR

Institutes

Institute for Connected Communities – ICC

Rix Centre - RIX

Sustainability Research Institute - SRI

Schools

Arts and Creative Industries – ACI

Architecture, Computing and Engineering – ACE

Education and Communities – Educom



Health, Sport and Bioscience - HSB

Psychology – PSY

Royal Docks School of Business and Law - RDSBL

UEL departments

Communications Office (CO)

Data Protection Office – DPO

Ethics and Integrity Sub-Committee - EISC

Health, Safety and Wellbeing - HSW

Human Resources – HR

Insurance Office – IO

Information Security - IS

Library, Archives and Learning Services – LALS

Office for Compliance, Governance and Legal Services – OCGLS

Office for Postgraduates, Research and Engagement - OPRE

Research Ethics Office – REO

UEL staff

Director of Impact and Innovation – DII

Director of Institute/Service – DI/S

Introduction

The Research Ethics handbook¹ is a practical guide for understanding the principles of research ethics and completing applications for ethical approval. The handbook should be read in conjunction with the University's [Code of Practice for Research](#), [Code of Practice for Research Ethics](#) and the [Staff and Student Misconduct in Research Procedure](#). The Codes of Practices define the University's expected standards for research projects to be conducted in accordance with appropriate ethical, legal and professional frameworks, obligations and standards. Researchers should also consult and abide by the principles, practices and standards of statutory, regulatory and professional bodies for their discipline.

Research ethics can be considered as the principles that govern the responsible conduct of researchers engaged in research activity. Researchers must respect the dignity, rights, safety, well-being, and values of individuals, groups and communities. Additionally, where possible, the risk of harm to participants should be removed or mitigated. The hoped for benefits of the research project should not outweigh possible harm to participants. Researchers should be aware that the principles of high ethical standards applies to every discipline within the University.

Drawing on the UK funding bodies' definition of research used in the Research Excellence Framework, as described in 'Assessment framework and guidance on submissions' (Hefce, Hefcw, SFC, DEL, 2011):

'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': [Updated FINAL-the-concordat-to-support-research-integrity.pdf \(universitiesuk.ac.uk\)](#)

[The Concordat to Support Research Integrity, 2019](#) states that research projects should be conducted to the highest standards of rigour and integrity. Researchers have a duty to consider how the work that they undertake affects society and the wider research community.

[The European Code of Conduct for Research Integrity, 2023](#), states that the principles of research integrity are:

¹ The handbook is based on the guidance produced by the [UK Research Integrity Office](#), [UK Research and Innovation](#), the [Association for Research Managers and Administrators](#) and [The Concordat to Support Research Integrity, 2019](#)

- **Reliability** - in ensuring the quality of research, reflected in the design, methodology, analysis, and use of resources.
- **Honesty** – in developing, undertaking, reviewing, reporting, and communicating research in a transparent, fair, full and unbiased way.
- **Respect** - for colleagues, research participants, research subjects, society, ecosystems, cultural heritage, and the environment.
- **Accountability** - for the research from idea to publication, for its management and organisation, for training, supervision, and mentoring, and for its wider societal impacts.

The core principles and values of conducting high quality research should be understood and upheld by all researchers. Striving for research excellence and engaging with the practical, ethical and intellectual challenges inherent in research, are essential to support a culture of research integrity and good research practice, amongst the research community and its stakeholders.

The [Research Ethics Office](#) (REO) is part of the University's Office for Postgraduates, Research and Engagement (OPRE) team and has oversight of the University's adherence to research ethics frameworks with research projects. The Ethics and Integrity Sub-Committee (EISC) is the University's main ethics committee, responsible for upholding the highest standards of rigour and integrity across all disciplines, including that within taught programmes, whilst prioritising and protecting the interests and well-being of participants, and those affected by the proposed research project.

1. Why is ethical approval necessary?

The primary purpose of obtaining ethical approval is to ensure that research projects conducted under the auspices of the University are subject to rigorous ethical oversight and approval. All research projects should meet UK legislation, ethical and regulatory requirements, and the University's standards and expectations of its researchers.

1.1 It is a mandatory requirement of the University to obtain ethical approval from one of UEL's ethics committees, for research projects² that involve data gathering from interaction with:

- human participants;
- human material;
- human data, personal or sensitive;
- pre-existing data collected from humans without their knowledge of inclusion of the information in a research project;
- non-human animal, or projects which
 - cause environmental issues over and above normal day to day activities, or
 - present a risk to the reputation of the University.

1.2 [The Concordat to Support Research Integrity, 2019](#), states that 'Research misconduct is characterised as behaviours or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld'. To comply with the Concordat, the University has clear policies and procedures in place and provides training on research integrity and ethics, to underline the importance of conducting high quality research and prevent research misconduct. See Section 30 'Misconduct in Research'.

1.3 To safeguard the participant and researcher from harm arising from the research project, the application for ethical approval is reviewed by an ethics committee constituted by the University's Academic Board, who have responsibility for establishing, monitoring and periodically reviewing the procedures for the examination of proposals for research.

1.4 The University has a central Ethics and Integrity Sub-Committee (EISC), School Ethics Committees (SECs) and Collaborative Partner Ethics Committees (CRECs). The ethics committee will ensure that an appropriate

² Including consultancy projects that provide advice and work to a client (commercial or non-commercial) without the creation of new knowledge. Consultancy may be carried out either by academic staff or staff members, who are not on academic contracts, such as senior University managers or administrative/support staff.

Contract research are projects with an agreement to meet the specific research needs of external partners. The partners could be commercial or non-commercial organisations including charities.

method for seeking informed consent from potential participants for the research project is employed. A participant's contribution to the project should be clearly explained allowing the participant to ask questions. Additionally, participants must be informed that their involvement in the research project is voluntary, and they can remove themselves from the project at any time.

- 1.5 Obtaining ethical approval ensures that the research project is subject to appropriate consideration of ethical issues, as ethics committees assist researchers in identifying and clarifying any ethical concerns before the research project commences.
- 1.6 The ethics committees ensure that appropriate structures and arrangements are in place to manage collaborative research projects, before the project commences. Partnerships formed for research projects should have formal agreements/contracts established with all researchers, having a clear understanding of their roles and responsibilities, the expected standards and behaviours for good research conduct and the process to make any amendments to the project or the agreement.
- 1.7 Obtaining ethical approval is necessary to provide appropriate indemnity cover for the research project and to protect the University and the researcher from public liability claims for negligence or harm caused to participants.
- 1.8 As a condition of researchers receiving monies or resources for their projects, some funders of research stipulate that ethical approval for the research project must be obtained.

2. Ethics by Design

At the planning stage of a research project, researchers should consider the ethical implications of the project. This consideration can be described as 'ethics by design'. The purpose of ethics by design is to minimise issues occurring as the project progresses, by identifying and addressing ethical concerns from the outset of the planning stages.

2.1 The following list may assist with developing a research project; however, this list is not exhaustive:

2.1.1 Aims and methodology

- Have a clear plan or proposal in place. Where appropriate, be clear as to whether the proposed project replicates prior work, and/or duplicates existing work and/or has an element of originality.
- To be aware of and adhere to the policies and procedures relating to good practice in research produced by the University and regulatory and professional bodies.
- If applicable, identify the proposed benefit of the project to society.

2.1.2 Resources

- Ensure that adequate resources are in place, e.g., equipment, space, availability of premises, recruitment of the research team and an appropriate sample size of potential participants.
- Discuss the project with the relevant stakeholders, e.g., funders, sponsors or arrange a peer review of the project. Discussions with the appropriate ethics committees, internal and/or external, may assist with anticipating any issues with the project, and addressing potential problems before the project is underway.
- Be mindful that as the research project progresses, the aims and objectives, methodology, recruitment or data collection may change, or issues may occur which require an assessment of any ethical concerns that have arisen.

2.1.3 Collaborators and permissions

- Have an awareness of collaborator's policies that govern research projects e.g., misconduct in research, data management and conflict of interest policies. Additionally, to be aware of funder's processes and procedures and conditions of grant funding. See Section 25 'Collaborative research partnership'.

- Secure any agreements, permissions, or contracts, if appropriate. Researchers can seek an agreement of a favourable opinion or approval from an organisation to contribute to the project. However, data collection or in-depth conversations should not commence, until ethical approval is obtained from the appropriate research ethics committee. See Section 6 'Gatekeeper permission request'.
- It can take time to obtain permissions/agreements from gatekeeper organisations or ethical approval from a collaborative partner(s), so sufficient time should be planned to apply for ethical approval.
- Ensure that appropriate arrangements will be in place for insurance and indemnity before the research project commences. If the research project is funded the researcher should contact the relevant funding body for guidance. For research projects sponsored by UEL, the researcher should contact the University's [Insurance Office](#) for guidance.
- A Material Transfer Agreement (MTA) is a legal contract that regulates the transfer of materials between the owner or authorised licensee; the 'Provider' and the 'Recipient' of the material. Material can also include the transfer of data which is relevant to the material. The MTA will specify the terms of the transfer of the material, any restrictions or special conditions, approved use of the material, effective date, access to the results of the research where the material is used, intellectual property rights, confidentiality and limitation of liability clauses.
- If the research project requires an MTA the researcher should contact the University's [Office for Compliance, Governance and Legal Services](#) (OCGLS) who will compose the MTA in accordance with the terms and conditions of the transfer. A MTA questionnaire should be submitted with the researcher's request for an MTA. See Annexe 12 'Material Transfer Agreement questionnaire'.

2.1.4 Participants

- Establish the location of data collection and format e.g., in-person interaction or remote data gathering from individuals/focus groups. Make sure that data collection is conducted in a safe location.
- Calculate the timescale for data collection and the time commitment required from participants for the project. The participant should be given sufficient time to decide whether they wish to be part of the research project. Participants should also be permitted to ask questions and seek clarification if there are any aspects of the research project which are unclear. It may be necessary to provide information

about the project using different formats such as pictures, a short presentation or simplified documents with appropriate wording and language used.

- Determine whether participants will be remunerated for their contribution to the research project. The [BPS Code of Human Research Ethics](#) states that there are alternatives to monetary recompense such as gift vouchers, small gifts or 'certificates of participation'. Certificates, books or stickers may be appropriate for children, whilst offering food or drink should be avoided, as it may have health and safety issues. The use of prize draws should be carefully considered as they can be perceived as coercive, and collecting a participant's personal data to be entered into the draw may be an unnecessary risk to the security of the data.
- A consideration of whether informed consent from participants will be obtained in written form, electronically or verbally. The method used to obtain consent should be appropriate for the nature of the research project. For research projects with pre-existing data researchers should check that the data had the necessary permissions in place and the data can be shared with a third party. For internet-mediated data collection, such as using social media; Facebook, 'X' (formerly Twitter) or Instagram, data mining being part of forums or groups, measures should be taken to protect the identity of individuals. See Section 20 'Internet-mediated research projects'.
- Decide whether participants will be permitted to withdraw their research data from the research project. Participants can withdraw themselves from the research project at any time, without disadvantage or an obligation to give a reason. However, researchers can stipulate the point up to which participants can withdraw their data. This is normally up to the point of analysis, after which the data may be anonymised. With self-completion questionnaires or surveys, it may not be possible for participants to withdraw the form once submitted. This should be clearly stated on the Participant Information Sheet and Consent Form. See Appendices – 'Ethics and Integrity Sub-Committee (EISC) template recruitment documents'.
- Determine whether the project is covert research, will involve the use of deception or will withhold information from participants. The [BPS Code of Human Research Ethics](#) states that 'Deception or covert collection of data should only take place where it is essential to achieve the research results required, where there are no alternatives, where the research objective has strong scientific merit and where there is an appropriate risk management and harm alleviation strategy'. Using deception in the research project must be fully justified. Participants must receive a full debriefing as soon as practically possible following their involvement in the project. Researchers should consider the

scientific value to the project of using deception or covert practices to obtain research data.

2.1.5 Data

- The University has comprehensive data management processes and procedures in place. Researchers should ensure that their projects comply with all applicable laws and statutes concerning research. This includes compliance with the University's data protection regulations. Any breaches of the [Data Protection Act](#), (DPA) 2018 must be reported to UEL's [Data Protection Office](#) as soon as possible. See Section 10 'Data protection and data management'.
- For research projects conducted overseas; in addition to compliance with UK legislation and ethical frameworks, a consideration of relevant regulations and the local laws of the country or countries and local authorities who may be contacted for advice e.g., non-governmental organisations, should be considered.
- An outline of how participants' confidentiality will be maintained. Researchers are placed in a position of trust and the information that participants provide should be kept confidential, unless a disclosure of harmful behaviour is made. Participants must be made aware that if they declare that they will harm themselves or someone else, the researcher has a duty to report the disclosure to the appropriate authority. See Appendices – 'Ethics and Integrity Sub-Committee (EISC) template recruitment documents'. If a translator is required for the research project, a confidentiality agreement should be drafted to arrange a contract between the researcher and the third party. See Annex 9 'Guidelines for a Confidentiality agreement'.
- Be clear about the anonymisation/pseudonymisation procedure for the research data to protect the identity of participants.
- Complete a Data Management Plan (DMP) determining how data will be handled from the beginning to the end of the project, including metadata creation, analysis, access, storage, sharing, preservation and destruction of the data. DMPs are administered by the University's [Library, Archives and Learning Services department](#).
- Determine the ownership of any intellectual property created from the research project at the earliest opportunity.
- Consider the dissemination of the outputs for the conclusion of the project. This can include publication of a thesis, journal articles, book chapters, pre-prints, reports or a conference presentation.

2.1.6 Equity and fairness of participation

- Determine the eligibility criteria, identification, sampling, and initial approach to potential participants.
- Ensure that the recruitment of participants is inclusive and equitable. Researchers should be familiar with the protected characteristics under [The Equality Act, 2010](#), special category data under the [UK General Data Protection Regulation](#), (GDPR) 2018 and where appropriate, the agreed list of ethnic groups³ for the country where the research is taking place. The language and terminology used in the application form should be inclusive and not discriminatory. The exclusion criteria for the project should be clearly defined and justifiable.
- Consider the additional needs that individuals with any of the following conditions may require; however, this list is not exhaustive:
 - Physical disabilities.
 - Mental health conditions, e.g., depression, anxiety, bipolar disorder.
 - Specific Learning Differences (SpLDs) e.g., dyslexia, dyspraxia.
 - Autism Spectrum Conditions.
 - Sensory conditions, such as vision and hearing impairments.
- Identify a working practice for projects involving vulnerable person(s) and over-researched groups, such as children, refugees, or those who are socio-economically disadvantaged.
- The [United Nations Convention on the Rights of the Child](#) (UNCRC) states that “For the purposes of the present Convention, a child means every human being below the age of eighteen years unless under the law applicable to the child, majority is attained earlier.” The [NSPCC](#) provides a definition of a ‘child’ in the UK. [UK Research and Innovation](#), provides guidance on conducting research with children and young people. Permission from a parent or legal guardian should be sought to conduct research projects with those under 18 years of age. Children and young people can ‘assent’ to a research project in addition to ‘consent’ being given by a parent or legal guardian. See Section 7 ‘Participant Information Sheet and Consent Form’.
- A consideration of power dynamics, if the research project will involve individuals and/or groups known to the researcher or there is the potential for the researcher to exert influence or pressure or coerce a person(s) to participate in the project. See point 7.4.

³ In England and Wales, the agreed list of ethnic groups which can be used is determined by the groups included in the Census: [List of ethnic groups - GOV.UK \(ethnicity-facts-figures.service.gov.uk\)](#)

- Agreements regarding authorship should be determined and documented at the outset of the research project. Only those who have made a substantial contribution to the research project should be listed as an author. These agreements may need to be reviewed as the project progresses.

2.1.7 Health and Safety and risk management

- Be mindful of the health, safety and well-being of all stakeholders involved in the project. Research projects should be initiated and continued only when the researcher has adequately assessed and identified any risks inherent with the project, implemented the appropriate mitigatory steps, and/or additional safeguards, and the researcher is confident that the anticipated benefits justify any residual risks involved.
- Comply with all legislation regarding working with children, young people and vulnerable person(s), groups or communities, and appropriate safeguarding measures and procedures should be in place before the research project commences.
- The NSPCC states that ‘Safeguarding is the action that is taken to promote the welfare of children and protect them from harm’. Research projects that involve children should be carefully managed, so that the activity does not have a detrimental effect on the child, the child is protected and safe from harm and the child’s views and feelings are listened to and treated respectfully.
- The University’s [Safeguarding Policy and Procedure](#) states that ‘UEL is committed to providing a safe environment for children and young people under 18 and adults at risk who may be present on campus or engaged in University activities’. UEL’s legal safeguarding duties applies to ‘adults at risk’.⁴ Researchers should be aware of their responsibilities and duty of care to protect those groups who are at risk.
- Research projects involving children, adults at risk and vulnerable persons may require a Disclosure and Barring Service certificate. For research projects conducted overseas, an equivalent credential or appropriate permissions must be sought and obtained before the project commences.

⁴ ‘An adult at risk is someone aged 18 years or over who is, or may be, in need of community care services by reason of mental or other disability, age or illness; and who is or may be unable to take care of him or herself, or unable to protect him or herself against significant harm or exploitation’.

- For research projects that may cause emotional distress, consider whether a 'Debrief Sheet' is required, which provides the contact details of organisations or agencies who can provide support for participants following their contribution to the research project. See Annexe 8 'Guidelines for a Debrief Sheet'.
 - Be aware of the process for reporting adverse events/reactions occurring in the research project and incidental findings. See Section 13 'Outcome of the review of an ethics application form'.
 - Consideration of the damage to the natural environment, over and above that of normal daily activity, or harm, or ruin of cultural objects, artefacts, sites of historical importance or human remains.
 - A conflict of interest can arise where there are personal or institutional interests including, but not limited to financial matters, that can inappropriately affect research. Researchers should inform relevant parties if there is a possible or real conflict of interest at the earliest opportunity.
 - Where applicable, a consideration of negative publicity or reputational risk to the University. If the project has the potential to cause reputational harm UEL's [Office for Compliance, Governance and Legal Services](#) should be contacted for guidance.
- 2.2 As part of 'Ethics by Design' consult Annexe 17 'Security risk checklist' which lists the topics that can affect the security of the research project and should be considered at the planning stage of the project.

3. Ethical approval

Researchers must respect the autonomous nature of human participants in research and the protection of their rights, dignity, values and well-being. The safety of participants and researchers must be a primary concern for those planning or preparing to conduct a research project, to ensure that the risk of harm is avoided or minimised. Therefore, obtaining ethical approval should not be the final consideration when planning a study.

- 3.1 The Ethics and Integrity Sub-Committee (EISC) ethics application form is an electronic document⁵ hosted on '[Ethics Monitor](#)' which is an online platform on the University's server 'ResearchUEL'. All applications for ethical approval from EISC are submitted electronically and hosted and administered by Ethics Monitor.
- 3.2 Before commencing the ethics application form, researchers should familiarise themselves with the University's [Code of Practice for Research](#), [Code of Practice for Research Ethics](#) and [Staff and Student Misconduct in Research Procedure](#) on the Research Ethics and Integrity [webpage](#) and the UEL [Safeguarding policy](#).
- 3.3 Research projects may involve and are not limited to, questionnaires/surveys, interviews, focus groups, observations, physical activities, physiological measurements, interventions and internet-mediated data collection. Projects of this type will require ethical approval. In some cases, an analysis of secondary data may require ethical approval which is not limited to the following: if the data is of a sensitive nature, where participants may be identifiable or vulnerable, in cases where participants may not have been aware that the data would be used in a research project, analysis of anonymised data sets, data mining and using data collected for a previous project.
- 3.4 See Annexe 15 for a comprehensive guide of the information that is required for EISC to complete a thorough review of the application form for ethical approval.

⁵ The process for applying for ethical approval specified is for ethics applications from academics, staff members, MPhil/PhD, Professional Doctorates (excluding those from the School of Psychology), Master's by Research students and interns, submitting to the University's Ethics and Integrity Sub-Committee (EISC). School Ethics Committees (SECs) and Collaborative Partner Research Ethics Committees (CRECs) review applications for ethical approval from undergraduate and taught master's students. Professional Doctorate students from the School of Psychology have a separate process for applying for ethical approval.

4. Applying for ethical approval

At the start of the Ethics and Integrity Sub-Committee (EISC) ethics application form, information is required regarding the aims, objectives and methodology for the project, an outline of the research journey from the beginning through to dissemination and publication of the findings. The ethics application form is intuitive, and researchers should select the option that applies to their research project at the beginning of the form. The relevant sections will be displayed as the researcher progresses through the ethics application form.

4.1 There are five ethics application forms on Ethics Monitor:

- A generic ethics application – including research, consultancy and contract projects.
- A practice research project ethics application form.
- An HRA-NHS ethics application form.
- An amendment to an existing research project application form.
- An amendment to an application approved outside of ResearchUEL application form.

4.1.1 **The generic ethics application** - is the main ethics application form for obtaining ethical approval. This application form should be used for projects including research, consultancy and contract projects.

4.1.2 **Practice research application**⁶ – the application form is for projects where practice is the significant method conveyed in a research output, e.g., creative arts projects. Additionally, the form is for participants who are deemed co-researchers and may be involved in planning the project, analysing the research data and disseminating the findings.

4.1.3 **HRA-NHS Ethics Application** – the application form should be used for projects that involve the NHS and researchers are required to submit an ethics application form to the [Health Research Authority](#) (HRA). Applications for projects with the NHS are submitted through the [Integrated Research Application System](#) (IRAS).

4.1.4 **Amendment to an existing research project** – the application form is for amendments to existing research projects.

4.1.5 **Amendment to an existing application approved outside of ResearchUEL** – the application form is for amendments to existing research projects, which were approved using an alternative system to Ethics Monitor.

⁶ For further guidance see 'What is Practice Research' (2021, page 1) by James Bulley and Özden Şahin: <https://doi.org/10.23636/1347>

5. Research projects

Research projects involving human participants are required to have ethical approval and part of the ethical approval process includes the consideration of the risk of harm to those participating in the study.

- 5.1 Whilst preparatory activity for the project is permitted, such as that specified in Section 2 'Ethics by Design,' data collection should not take place from potential participants until written approval has been received from the appropriate research ethics committee. Where an academic, staff member or student is found to have breached this expectation, the matter will be reviewed under the University's [Staff and Student Misconduct in Research procedure](#) and, in some cases, this may lead to disciplinary proceedings. See Section 30 'Misconduct in Research'.
- 5.2 Researchers should be aware, that ethical approval is not the same as approval to conduct the research. Ethical approval to conduct research projects can be given and withdrawn at any point by the Dean of the School or the Ethics and Integrity Sub-Committee (EISC). The Dean of the School and/or EISC will consider several factors, including the information that was specified in the ethics application form and adherence to this, health and safety implications, any resources that were required and, if necessary, obtain the advice of senior management.
- 5.3 Research projects involving security-sensitive data, including material on extremism, radicalisation, or terrorism, must be managed carefully and stored on the University's central server only. The research data must not be transmitted electronically to any third parties, and any paper documents must be scanned and uploaded to the central server.
- 5.4 Security-sensitive research data can be defined as information that must be protected against unwarranted disclosure. Researchers must follow the guidance on the '[Oversight of Security-Sensitive Research Material in UK Universities](#)' from Universities UK, and declare to EISC if they will be doing any of the following:
 - Accessing websites, viewing, streaming, downloading or transferring material linked to terrorism or radicalisation or material which would be considered extremist.
 - Conducting research that requires security clearances.
 - Conducting research commissioned by the military.
 - Conducting research commissioned under an EU security call.
- 5.5 The collection, recording, possession, viewing, streaming on the internet, downloading and distribution of security-sensitive material '...of a kind likely to be useful to a person committing or preparing an act of terrorism,' may be

interpreted as committing an offence under the provisions of Section 58 of the [Terrorism Act 2000](#), as amended by sections 3 and 7 of the [Counter-Terrorism and Border Security Act 2019](#), if the material is not used purely for academic research purposes. Should the research project include material that could be considered extremist or involve statements, records or documents relating to terrorist actions, researchers should contact the [Office for Compliance, Governance and Legal Services](#) (OCGLS) for guidance. The University has a [proforma](#) on the collection and storage of security-sensitive material that all researchers conducting research projects of this nature must complete⁷.

- 5.6 All co-researchers for the research project should be listed on the ethics application form. All UEL co-researchers will have access to the ethics application form in [Ethics Monitor](#) and will be able to make amendments to the form. The application form is available to print in PDF format only. It is not possible to share the ethics application form with researchers outside of UEL, as Ethics Monitor is an internal platform.

⁷ See UEL's [Code of Practice for Research](#) for further guidance.

6. Gatekeeper permission request

A gatekeeper is a person or organisation who grants the researcher permission to use their premises and/or provide access to potential participants for the research project. The gatekeeper may also actively assist with recruiting participants, this may include distributing advertisements or providing information about the project. Whilst the researcher can seek the gatekeeper's permission to support or contribute to the proposed research project, data collection should not commence until ethical approval is granted. See Annexe 7 'Guidelines for a Gatekeeper permission request'.

- 6.1 Provisional ethical approval can be granted to researchers should a stakeholder require evidence of the Ethics and Integrity Sub-Committee's (EISC) ethical approval, before agreeing to contribute to the research project. EISC will issue the researcher with a full approval letter upon receipt of all necessary permissions provided.
- 6.2 If the research involves external organisations or institutions who are collaborators in the project, ethical approval or permission letters from the parties must be submitted. If the permission letter is not available to the researcher at the time of submitting the EISC ethics application form, researchers should complete and submit the ethics application to begin the process of obtaining ethical approval. Once the permission letter is received by the researcher, reviewed and accepted by EISC, ethical approval can be granted.
- 6.3 If a researcher is working with several organisations or institutions and does not have gatekeeper permission from all groups involved, the project can still be granted ethical approval and commence with the parties that have provided permission. An amendment form will be required to add additional organisations to the project once gatekeeper permission is received from each association and submitted to EISC. See Section 15 'Amendment to an existing research project'.
- 6.4 If permission is required for a data set to be used in the research project, the researcher should submit confirmation to EISC that approval to use the material has been granted by the appropriate person and/or authority.
- 6.5 Copies of recruitment posters and/or the text to advertise research projects e.g., via email or on social media, should be submitted to EISC. If the researcher seeks to recruit UEL staff and/or students, permission should be sought from the Dean of the School, Director of Impact and Innovation (DII) or Director of the Institute/Service (DI/S). A copy of the approval should be included with the ethics application form.

7. Participant Information Sheet and Consent Form

A Participant Information Sheet (PIS) and a Consent Form (CF) can be described as 'recruitment documents'. The purpose of a PIS is to provide potential participants with the necessary information that they will need to make an informed decision as to whether they would like to participate in the research project. The University's official logo should be included on all public facing documents and checked for spelling and grammatical errors.

A CF is required to obtain the participant's consent to take part in the research project. Participants should select the clauses and statements that they agree to and provide written or verbal agreement to participate in the project. Both the PIS and CF should be given to the participant simultaneously. There are guidance notes at the beginning of the PIS and CF templates to assist researchers with completing the documents. The guidance notes should be removed for the final version of the PIS and CF, which should be submitted to the Ethics and Integrity Sub-Committee (EISC). See Annex 1 and 2 'Template Participant Information Sheet and Consent Form'.

- 7.1 Potential participants should be fully informed about a research project and have the capacity to consent to participate in the project. Researchers should ensure that participants understand the nature of the research and explain their contribution to the project. Participants must be given the opportunity to ask questions. A participant's involvement in a project is voluntary and participants can withdraw themselves from the project at any time, without giving a reason. This should be a simple process, without causing the participant any discomfort or awkwardness to withdraw their consent from participating in the project.
- 7.2 Participants should be given sufficient time to decide whether they would like to contribute to the research project. As a guide, participants should be permitted a minimum of 24 hours to consent; however, this timeframe may not be practical for some research projects, for example, if the research involves audience participation.
- 7.3 The recruitment of participants must be inclusive and equitable. The language and terminology used in the PIS and CF should be inclusive and all documents should be accessible. The exclusion criteria for the project should be clearly defined and justifiable. See point 2.1.6.
- 7.4 Care should be taken with potential participants who are in a dependent or unequal relationship with the researcher, to minimise direct or indirect coercion or undue pressure, from those who have influence or authority over the individual. This can be deemed 'pressure to participate,' which may affect the person's decision to contribute to the research project. It should be clear that the individual will not suffer any detrimental effects to their educational

experience, qualification or treatment and services, in declining to participate or to remain in the project. Researchers should also be aware of the potential for the power dynamic of the relationship to bias the findings of the data and measures put in place to prevent predetermined conclusions.

- 7.5 When obtaining consent from participants to contribute to a research project, researchers should be mindful of local customs or cultural sensitivities, for example, some communities dislike signing consent forms and, as such, verbal consent may be appropriate.
- 7.6 It may not be feasible to obtain consent for research projects taking place in public settings. Researchers should exercise discretion and diplomacy when collecting information and, if appropriate, consent should be obtained from a gatekeeper in the setting. If filming or photography will take place in a public space this should be made clear. A sign can be displayed to inform the public that they are being observed.
- 7.7 Auto-ethnographic research involves the researcher using their own life experiences as data for the project. This may mean that individuals and events in the researcher's life are identifiable. Where possible, if people who have engaged with the researcher will be identifiable, informed consent should be obtained from the person to permit the researcher to use the material. The identity of individuals should be protected, and any recognisable places or events may need to be replaced or changed to prevent identification.
- 7.8 The PIS and CF should be written in lay language, without technical terms, and be concise and age appropriate. The PIS is normally two sides of A4 paper, excluding the Privacy Notice. The University approved PIS and CF templates should be used for the project, as the documents have mandatory statements that must be included. Potential participants should be informed about the University's research integrity, data protection and disclaimer statements, and the contact details for the Ethics, Integrity and Compliance Manager must be included. See Appendices – 'Ethics and Integrity Sub-Committee (EISC) template recruitment documents'.
- 7.9 Similarly, on the PIS and CF there are salient points that participants need to be aware of e.g., the aim of the project, the participant's contribution, if there are any risks associated with the research, how the participant's data will be managed and kept confidential, and the participant's right to withdraw themselves from the project. This information must be included on the PIS and CF. See Annexe 1 and 2 'Template Participant Information Sheet and Consent Form'.
- 7.10 Researchers should not use their personal mobile phone number for the research project. Researchers should include a UEL office telephone number, if applicable, or calls can be made using Microsoft Teams. Researchers can purchase a SIM card to be used in a mobile phone specifically for the project,

however any personal data on the phone should be deleted once the research project is complete. Schools and Institutes may be able to reimburse researchers for the cost of the SIM card.

- 7.11 A Consent Form for those under the age of 18 is called an 'Assent Form' (AF). Whilst permission from a parent or legal guardian must be sought for a child or young person to contribute to a research project, best practice is that those who are under 18 should be given the opportunity to 'assent' to be part of the project. Children aged 5 years old or over can indicate assent in various ways, as requesting a signature may not be appropriate. Children should be permitted to use stamps, stickers, drawings or selecting an image or icon to give their permission to participate in the research.
- 7.12 The ethics application form in [Ethics Monitor](#), on the online platform 'ResearchUEL' will automatically produce a PIS and CF for participants. Ethics Monitor will replicate the information entered into the ethics application form, on to a PIS and CF template for the researcher to amend and format the documents to suit. See point 3.1. As such, this may mean that not all of the information transferred from the application form is relevant or necessary for the recruitment documents. If researchers do not wish to use the PIS and CF generated by the ethics application form, the University approved templates are available on the '[Guides](#)' section of Ethics Monitor and on the Research Ethics and Integrity [webpage](#). See Annexe 1 and 2 'Template Participant Information Sheet and Consent Form'.
- 7.13 Where the research project involves different groups of participants, or various methods of data collection, a separate PIS is required for each group of participants involved in each activity in the project. For example, if parents, employees and managers will complete questionnaires or be involved in interviews or focus groups etc., a separate PIS is required for each group of participants. A separate PIS will also be required for each method of data collection used. Researchers should clearly label their PIS, identifying each group of participants and research instrument used, for ease of review of the information by EISC.
- 7.14 Additionally a CF or AF, for those under the age of 18, for each group of participants is required. The CF and/or AF will have a list of criteria to seek consent from participants for their agreement to contribute to the project. Participants are free to choose which conditions they consent to on the CF and/or AF.
- 7.15 For research projects involving children or young people, a bespoke version of the PIS and AF can be devised by the researcher, which may include pictures, drawings, illustrations, photos and simplified language, to inform children and young people about the project. See Annexe 5 'Example Child/Young Person Participant Information Sheet and Assent Form'.
- 7.16 The participant's confidentiality should be protected, unless a disclosure of

harm is made that indicates that the person or someone else is at serious risk of harm, or professional misconduct is witnessed. It should be made clear to the participant, before data collection commences, that disclosures of harm will be reported to the relevant authority. The limits to confidentiality must be included on the PIS and CF. See Annexe 1 and 2 'Template Participant Information Sheet and Consent Form'.

- 7.17 Researchers should inform those involved in the project of the name of the person who they can contact should they have any concerns about the conduct of a research project. This is normally the Ethics, Integrity and Compliance Manager. The contact details of other appropriate person(s) or organisations should also be included on the PIS.
- 7.18 Participants may be recompensed for their contribution to the research project in the form of gift cards/vouchers, prize draws or paid expenses. If researchers wish to remunerate participants with a monetary reward this should be discussed with the relevant School or Institute. The amount of the recompense should be in proportion with the participant's involvement in the project and specified on the PIS.

8. Supporting documents

The ethics application form on [Ethics Monitor](#) should be submitted alongside copies of any supporting documentation, which will be given to participants, including children and young people, for review by the Ethics and Integrity Sub-Committee (EISC). Templates for the relevant documents can be found under the '[Guides](#)' section on Ethics Monitor or on the Research Ethics and Integrity [webpage](#).

Supporting documents should not be emailed to the Research Ethics Office (REO). Ethics Monitor does not permit the REO to upload documents to the system on behalf of the researcher.

8.1 There are a range of supporting documents which should be included with the ethics application form, where applicable:

- Interview questions or an indicative topic guide.
- Questionnaire or survey.
- Gatekeeper permission letter(s).
- Collaborator(s) ethics approval letter(s).
- Confirmation of funding letter(s).
- Risk assessment form(s).
- Poster, advert or text for recruiting participants.
- A Data Management Plan (DMP).
- A Debrief Sheet.
- A blank Confidentiality agreement.
- A Model Release form.
- A Privacy Notice⁸

8.2 For research projects that involve interviews, a list of interview questions or an indicative topic guide should be provided for participants. If the researcher is conducting semi-structured interviews, it may not be appropriate to provide a list of interview questions to EISC. In this case, an indicative topic guide can be presented to EISC, outlining the topics that participants will be asked to discuss.

8.3 If participants will be asked to complete a questionnaire or survey, a list of the questions must be uploaded for review by EISC. The University supports Microsoft Forms only. Platforms such as Google Forms and SurveyMonkey, should not be used for data collection. Should researchers wish to use an alternative platform to Microsoft Teams they should consult UEL's [Data Protection Office](#) and/or [IT Services](#) for approval.

⁸ The Privacy Notice template is a mandatory document attached to the Participant Information Sheet and Consent Form templates.

- 8.4 Researchers should inform participants if they will be using survey platforms that are based outside of the UK and obtain the participant's consent for their personal data to be stored and processed in line with the platform's terms and conditions. Researchers should consult the University's [Data Protection pages](#) to ensure that they comply with the University's policies.
- 8.5 Questionnaires or surveys must provide a brief description of the research project and specify:
- How long the form will take to complete e.g., 10 minutes.
 - Whether the questions included are sensitive.
 - Whether the data is anonymous.
 - Whether the form can be withdrawn.
 - Whether data from non-completed forms will be used.
 - Whether submission of the form indicates consent to participate in the research project.
 - The data will be managed in accordance with the [Data Protection Act, \(DPA\) 2018](#) and the [UK General Data Protection Regulation, \(GDPR\) 2018](#).
- 8.6 The text of a gatekeeper permission letter should be provided with the ethics application form if the researcher requires permission to use the premises or obtain assistance from a third party to help with the administration of the project. See Annexe 7 'Guidelines for a Gatekeeper permission request'. Copies of any agreements for the researcher to receive support for the research project from the gatekeeper must be submitted to EISC.
- 8.7 Researchers may need to provide EISC with verification of ethical approval from external researchers and organisations working on collaborative research projects. Alternatively, the researcher should provide confirmation from an appropriate senior person in the external institution or organisation, stating that ethical approval/permission is not required for the external collaborator.
- 8.8 Researchers should provide the contracts or agreements confirming funding for research projects that are financed by grants or sponsorships. In this instance, funding does not include payments made by the Student Loan company.
- 8.9 A [research risk assessment form](#) is required for research projects that will take place outside of the University's premises. If the research project will be conducted online, a risk assessment form is still required. See Section 9 'Risk assessment form'.
- 8.10 If the research project may cause emotional distress a Debrief Sheet may be required. As specified in Section 2 'Ethics by Design,' the Debrief Sheet

should list the contact details of organisations or agencies who can provide support for participants, following their contribution to the research project. See Annexe 8 'Guidelines for a Debrief Sheet'.

- 8.11 Posters, adverts or text for recruitment letters or emails to be used for recruiting participants or seeking gatekeeper permission should be submitted to EISC to review the content of the documents. Researchers who wish to advertise their research projects to the UEL community, including displaying posters on UEL campuses and advertising on UEL's communication platforms, should complete the [Design and Digital Request](#) application form and adhere to the guidelines given.
- 8.12 The University's [Library, Archives and Learning Services](#) (LALS) department are responsible for administered the production of a Data Management Plan (DMP). The DMP specifies who will have responsibility for the research data and '...outlines how data will be handled throughout the project, including creation, organisation, storage, and sharing of the data': [Research Data Management](#). A submission of a DMP demonstrates to EISC that the researcher has considered the lifecycle of the research project and is managing the data in accordance with good research practice. The DMP must be signed by a member of the LALS team and submitted with the ethics application form. Applications submitted without a signed DMP will not be reviewed by EISC.
- 8.13 If a transcriber or translator is required for the project, a blank copy of the Confidentiality agreement between the researcher and the third party should be provided for EISC to review. See Annexe 9 'Guidelines for a Confidentiality agreement'.
- 8.14 Researchers have a responsibility to inform participants how their data will be collected, used, and managed. A Privacy Notice specifies the seven data protection principles of GDPR, which govern the management of personal data and an individual's information rights. The wording of the Privacy Notice should not be altered, and the document should be given to potential participants together with the Participant Information Sheet and Consent Form. See Annexe 3 'Privacy Notice'.

9. Risk assessment form and security related risk

- 9.1 A research risk assessment form is required for all projects that take place outside of the University's premises. The risk assessment forms can be found under 'Guides' on [Ethics Monitor](#) or on the Research Ethics and Integrity [webpage](#).
- 9.2 Projects that involve human participants, which are conducted remotely, i.e., not in-person, for example interviews taking place on Microsoft Teams, require completion of a [research risk assessment form](#). Remote data collection should still consider risks such as disclosures of harmful behaviour, data protection, management and storage, conflicts of interest, reputational risk to the participant or the University, as well as the possibility of psychological distress or witnessing unlawful activity. Additionally, if the project is of a sensitive nature, even though the data may be anonymised, or the project includes data collected for a previous study, a research risk assessment form is necessary.
- 9.3 The risk assessment should be signed by the Dean or Director of Impact and Innovation (DII) for the School, or the Director of the Institute/Service (DI/S) and submitted with the ethics application form. Ethical approval will not be granted if the risk assessment form is omitted or unsigned.
- 9.4 In addition to the research risk assessment form, an [overseas risk assessment form](#) must be completed if the project will take place outside of the UK and requires physical travel. The Dean of the School or the DI/S should sign the overseas risk assessment form.
- 9.5 If the researcher intends to travel to a country that is in conflict or is politically unstable, an overseas risk assessment form should be submitted to the University's [Insurance Office](#). A senior member of the University's Executive Board (UEB) will counter-sign the overseas risk assessment form on behalf of the Insurance Office. The overseas risk assessment form should be submitted together with the ethics application form and the research risk assessment form. Both signed risk assessment forms are required before ethical approval for the project can be granted.
- 9.6 Annexe 15 – 'Security risk checklist' details a list of topics that can affect the security of a research project. The checklist should be read in conjunction with Section 2 'Ethics by Design' to assess and address all potential security risks associated with the research project, specify the action that should be taken to mitigate any risks and outline the researcher's responsibilities.

10. Data protection and data management

- 10.1 The University defines data protection as ‘...the fair and proper use of information about people’: UEL Data Protection [webpage](#). The Principal Investigator (PI) for the project is responsible for the security of all data collected and participants must be fully informed as to how their personal data will be processed, stored and shared.
- 10.2 The University’s lawful basis for processing personal data is ‘public task’. Article 6(1) of UK GDPR [UK General Data Protection Regulation](#), 2018, which states that ‘processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller’. UEL is the data controller and where personal data is being processed for research, this is considered under [Article 89 of GDPR](#) which contains the following provisions for processing data for research purposes:
- Archiving purposes in the public interest;
 - Scientific or historical research purposes; and
 - Statistical purposes.
- 10.3 ‘The provisions recognise the importance of scientific and historical research and technological development to society. They ensure that data protection requirements enable technological innovation and the advancement of knowledge’: [ICO Information Commissioner’s Office](#) (ICO). This means that under Article 89 of GDPR researchers can refuse a request to remove a participant’s personal data from a research project (right to deletion) see Annex 3 ‘Privacy Notice,’ if removal of the personal data is ‘...likely to render impossible or seriously impair the achievement of the specific purposes...’ of the research. As such, reliance on Article 89 is beneficial for longitudinal studies where it would have a detrimental effect on the research project should participants request to withdraw their data. Therefore, the University does not rely on a participant’s consent as the legal basis to process personal data for research purposes. However, in line with ethical best practice, and so that the University complies with the common law duty of confidentiality, it is normal practice for researchers to obtain the person’s consent to participate in the research project and for the researcher to process the individual’s personal data.
- 10.4 Researchers may need to consult UEL departments such as the University’s [Data Protection Office](#) and [Insurance Office](#) for guidance about their projects. Research projects involving children, vulnerable individuals or groups may require [Disclosure and Barring Service](#) (DBS) clearance. Whilst the Ethics and Integrity Sub-Committee (EISC) does not require a copy of the DBS certificate to be uploaded with the ethics application form, researchers are required to enter their DBS certificate number and confirm that the certificate

is valid for the duration of the research project. Academic and staff members should contact the University's [Human Resources](#) (HR) department and student researchers should contact the University's [Hub](#) or Applicant Checks team for advice on obtaining DBS clearance: applicantchecks@uel.ac.uk. Some projects may require evidence of the University's professional indemnity or public liability insurance. The documents can be obtained from the [Insurance Office](#) or the [Research Ethics Office](#) (REO).

- 10.5 Research projects that involve sharing data with third parties may require completion of a data sharing agreement. It must be clear to all stakeholders the type of data that will be shared and its purpose, who will have access to the data and the duration of the data sharing agreement. Under the [Data Protection Act](#), (DPA) 2018 the University is the data controller for all personal data processed by the organisation, this includes participant's personal data which is collected by researchers. Guidance can be found on the University's Data Protection pages. If there is a significant risk to the personal data of research participants, it may be necessary to complete an additional data protection impact assessment before submitting a proposal to the Ethics and Integrity Sub-Committee (EISC).
- 10.6 The University's Data Protection Office states that 'A [personal data breach](#) means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data. This includes breaches that are the result of both accidental and deliberate causes. It also means that a breach is more than just about losing personal data'. Examples of data breaches are access to the data by an unauthorised third party, computing devices containing personal data being lost or stolen, deliberate or accidental action (or inaction) by an organisation that puts personal data at risk or sending personal data to an incorrect recipient. It is important that any data breaches are reported to the Data Protection Office immediately.
- 10.7 Research data must be stored on the University's server. Researchers should follow the University's data management, storage and information security policies. Researchers can use a UEL managed device or their personal devices; however, the research data must be stored on the University's servers and Microsoft OneDrive is recommended for recording data.
- 10.8 Consumer cloud storage services, for example, Dropbox and Google Docs, do not meet the requirements of many of the University's data protection policies and should not be used for storing research data. The data on consumer cloud storage services is often stored outside of the UK and subject to different privacy and data protection laws. Research data should be encrypted and transferred inside of the UK. If the data will be kept in or outside of the European Economic Area (EEA), this should be made clear on the ethics application form and on the Participant Information Sheet, informing participants of where their contribution to the research project will be stored. Researchers should ensure that the data is managed in accordance with the

DPA and GDPR. See the University's Data Protection [policies](#).

- 10.9 External researchers who are collaborating with UEL investigators can store research data on a secure server at their external institution; however, UEL researchers should be assured that the research data will be collected and managed in accordance with the DPA and GDPR. Research participants must be informed about the method of data collection and storage of their contribution to the project and their personal data. If the project is funded, researchers should also comply with the funders' data related policy statements and codes of practice.
- 10.10 If data will be shared between institutions or organisations a data sharing agreement should be in place before transferring data or material. The researcher will need specify the third party will be using the data, how long the data will be shared for and who will have access to the data. See the Data Protection [webpage](#) for guidance.
- 10.11 Sensitive research data should be transferred to Microsoft OneDrive as soon as practically possible, particularly when conducting research projects overseas where countries may be subject to data protection laws, which conflict with UK regulations. As such, researchers should avoid retaining hard copies of data or keeping sensitive data stored on electronic devices.
- 10.12 For internet-mediated research projects, if websites, forums or groups are not open access, researchers may require permission from the website/forum manager or administrator to use the data for research purposes. Information that is available publicly may still require permission and ethical approval from EISC. Information that is in the public domain should always be treated with respect and, where possible, consent is obtained if the information will be used as data for research projects. See Section 20 'Internet-mediated research projects'.
- 10.13 Data gathered utilising Facebook, X (formerly Twitter) or other online sources, may be subject to copyright. Researchers should check the copyright policy of the company to avoid infringement. The terms and conditions or guidelines of the organisation must be consulted before using the platform for data collection.
- 10.14 Participants' identities are normally anonymised in research findings to protect the privacy of individuals. The [UK Data Service](#) states that:
- 'A person's identity can be disclosed from:
- Direct identifiers such as names, postcode information or pictures.
 - Indirect identifiers which, when linked with other available information, could identify someone, for example information on workplace, occupation, salary or age'.

- 10.15 Researchers should be clear about the anonymisation procedures to be employed to protect the identity of participants. The process of anonymising data requires direct identifiers to be changed, such as being removed, substituted, distorted, generalised or aggregated. When anonymising data, care should be taken not to disclose the personal details of participants, whilst maintaining the integrity of the data. In some projects, participants may wish to be named in the research findings for example, professional artists, creative directors, people in public office or war veterans. Should participants wish to be named in the research project consent must be obtained from the person.
- 10.16 The DPA states that personal data should not be kept for longer than necessary. Researchers should be aware that audio and video recordings are deemed personal data. Consent from participants must be sought for their contribution to the research project, using this mode of data collection. Both the audio and video recordings should be retained in accordance with the DPA and GDPR.
- 10.17 Participants should be informed as to how researchers will disseminate their research findings. Publications can be in the form of a thesis, report, peer reviewed journal, conference paper, social media or a presentation, It should be made clear that the output of the project will be stored in the University's open access data repository, in accordance with the UEL [Data Management policy](#) and [Open Access policy](#). Guidance is also provided on the UEL [repository](#).
- 10.18 Outputs should be made freely available, unless there are legal restrictions which prevent this. Researchers are requested to deposit all outputs as soon as possible after acceptance for publication, or promptly after creation for other types of output. Researchers must also adhere to any conditions set by funders or other bodies regarding the publication of their research, and its findings in open access repositories, within a set period.
- 10.19 Any concerns or queries about data protection and research data should be addressed by the University's [Data Protection Office](#) before the project commences. Any breaches of data protection, security of research material or loss of confidential data must be reported to the Data Protection Office immediately.

11. Submission of an ethics application form

At the end of the ethics application form on [Ethics Monitor](#), there is a checklist for researchers to complete and confirm that they have complied with each of the statements. Researchers should confirm that all sections of the application form have been completed, prior to submission of the form. Researchers can print the ethics application form, if required. The ethics application form is in PDF format only.

Postgraduate Research Students (PGRs)

11.1 The process for submission of an ethics application form for Postgraduate Research Students (PGRs) is described below and in the flowchart in Annex 11 'Submission of an ethics application form PGR'.

- The ethics application form is submitted automatically through [Ethics Monitor](#).
- The ethics application form will be directed to the supervisor to review and e-authorise for submission to the School's Director of Impact and Innovation (DII) or the Director of the Institute/Service (DI/S).
- The supervisor should review the ethics application form and, if necessary, request changes from the student.
- The ethics application form will be returned electronically to the student through Ethics Monitor.
- If the ethics application form is returned, the student should address all of the points raised and re-submit the ethics application form to the supervisor.
- Once the supervisor is satisfied with the changes requested, the supervisor will e-authorise the ethics application form to be sent electronically to the DII/DI/S.
- The DII/DI/S will review the ethics application form and, if necessary, request changes from the student.
- The ethics application form will be returned electronically to the student through Ethics Monitor.
- If the ethics application form is returned, the student should address all of the points raised and re-submit the ethics application form to the DII/DI/S.
- Once the DII/DI/S is satisfied with the changes requested, the DII/DI/S will e-authorise the ethics application form for submission to the Ethics and Integrity Sub-Committee (EISC).
- If information is missing from the ethics application form the [Research Ethics Office](#) (REO) will return the ethics application form to the student.
- The student should address all of the points raised and re-submit the ethics application form to the REO. Once the REO is satisfied with the

changes requested, the ethics application form will be forwarded to EISC for review.

- 11.2 For the avoidance of doubt, the supervisor is listed as the Principal Investigator (PI) for postgraduate research student projects.

Academic and staff members

- 11.3 The process for the submission of the application form for academic or staff members is described below and in the flowchart in Annexe 12 'Submission of an ethics application form academic and staff members'.

- The ethics application form is submitted automatically through Ethics Monitor.
- The ethics application form will be directed to the line manager (LM) / DII / DI/S to review and e-authorise for submission to EISC.
- The LM / DII / DI/S should review the application form and, if necessary, request changes from the researcher.
- The ethics application form will be returned electronically to the researcher.
- If the application form is returned, the researcher should address all of the points raised and re-submit the application form to the LM / DII / DI/S.
- Once the LM / DII / DI/S is satisfied with the changes requested, the LM / DII / DI/S will e-authorise the application form for submission to EISC.
- If information is missing from the ethics application form the [Research Ethics Office](#) (REO) will return the ethics application form to the researcher.
- The researcher should address all of the points raised and re-submit the ethics application form to the REO. Once the REO is satisfied with the changes requested, the ethics application form will be forwarded to EISC for review.

- 11.4 The deadline for submission of an ethics application form is two weeks before the EISC meeting date. Committee meeting dates and deadline submission dates can be found on the Research Ethics and Integrity [webpage](#).

- 11.5 Researchers should allow enough time to obtain the supervisor's, line manager, DII or DI/S authorisation of the ethics application form. To avoid delays, researchers should inform those mentioned above that they have applied for ethical approval and require their e-authorisation. EISC does not accept late applications for ethical approval.

- 11.6 At any time during the process of submission of the ethics application form, should there be any queries researchers should contact their supervisor, line manager, DII, DI/S or the REO for guidance.

12. Ethics and Integrity Sub-Committee (EISC)

The Ethics and Integrity Sub-Committee (EISC) considers applications for ethical approval from academic and staff members, Postgraduate Research Students (PGRs), including MPhil/PhD, Professional Doctorates, Master's by Research students and research interns. Independent contractors and consultants, visiting or emeritus staff, staff on joint clinical or honorary contracts, anyone conducting research using the University's facilities, or on the University's premises, may require ethical approval from EISC.

- 12.1 EISC has specific responsibility for institutional oversight of matters relating to the ethics and governance for research projects that involve human participation, human material, human data, personal or sensitive, pre-existing data collected from humans without their knowledge of inclusion of the information in a research project non-human animal and cultural objects.
- 12.2 EISC consists of members from the different disciplines within the University, external members from within internal departments and members from outside of the University i.e., lay members. The membership of the committee includes a breadth of knowledge and experience of research activities and research ethics.
- 12.3 EISC holds monthly committee meetings throughout the year (except for August). The deadline and committee meetings dates are available at the start of each academic year and can be found on the Research Ethics and Integrity [webpage](#). As the committee meetings are held monthly researchers do not have to wait an extended period of time to submit their ethics application form. As such, EISC does not have a process for reviewing ethics application forms outside of a scheduled committee meeting. Researchers are encouraged to plan their research projects in good time, taking in to account the guidance in Section 2 'Ethics by Design'.
- 12.4 Each ethics application form is allocated to a minimum of two committee members to review the application prior to the committee meeting. Committee members review each ethics application form that they have been assigned and prepare for a discussion about the application form at the committee meeting.
- 12.5 At the EISC meeting, each committee member gives a summary of the project(s) that they have reviewed, raise ethical concerns, if any, or request clarification of points or ambiguity. The project is then discussed by the committee and an outcome for the project is agreed. The researcher will receive an email notification from 'ResearchUEL' which is an automated 'Do not reply' mailbox. The notification will advise the researcher that the outcome of the review of the project can be accessed in Ethics Monitor. The decision made for the project may be one of the following:
 - Approved

- Not approved - minor amendments required
- Not approved – major amendments required
- Declined

12.5.1 **Approved:** – the research project has been approved by EISC and ethical approval granted.

12.5.2 **Not approved: minor amendments required** – EISC requires the researcher to address or provide clarification of any points of concern or ambiguity. The project may also receive minor amendments if documents are missing, for example a gatekeeper permission letter or interview questions are omitted. The researcher will receive a comprehensive decision letter from the committee advising of the points that need to be addressed.

12.5.3 **Not approved: major amendments required** – EISC requires major revisions to the project. This may be because there are significant ethical concerns that have been identified by EISC, which have not been considered by the researcher, for example, risks to participants' welfare have not been addressed. The researcher will receive a comprehensive decision letter from the committee advising them of the points that need to be addressed.

12.5.4 **Declined:** – EISC has deemed the project ethically flawed and potentially damaging. The researcher will receive a comprehensive decision letter from the committee, informing the researcher as to why their application has been declined and the next steps that should be followed.

13. Outcome of the review of an ethics application form

Researchers will receive the decision letter for their application for ethical approval within 15 working days of the committee meeting, and the decision letter will clearly state the points that need to be addressed. The Ethics and Integrity Sub-Committee (EISC) advises researchers to discuss the outcome of the application for ethical approval with their supervisors, line managers, Director of Impact and Innovation (DII) or Director of Institute/Service (DI/S), if necessary. The [Research Ethics Office](#) (REO) can also provide guidance if researchers are unsure of how to address the points made by EISC.

- 13.1 If EISC required 'minor or major amendments' to the research project, researchers can re-submit the application form to the committee through Ethics Monitor, within 6 months of the same academic year that the ethics application was submitted. If the research project was 'declined' the researcher will need to submit a new application for ethical approval. The new application form can be submitted at the researchers' discretion; however, researchers should be mindful of the deadline and committee meeting dates when completing a new ethics application form. See the Research Ethics and Integrity [webpage](#) for details.
- 13.2 Researchers are not required to request authorisation a second time from their supervisor, Director of Impact and Innovation (DII), Director of Services DI/S or line manager to resubmit the amendments to the ethics application form. When the researcher resubmits the ethics application form through Ethics Monitor, the application form is sent directly to EISC.
- 13.3 should address all points and amendments requested by EISC and resubmit the ethics application form through Ethics Monitor. Researchers are not required to obtain authorisation again from those mentioned in 11.1 and 11.3. If the amendments are incomplete or points that the committee has raised have not been addressed, the application form will be returned to the researcher. The research project must not commence until ethical approval has been granted by EISC. Researchers who conduct research projects without ethical approval may be subject to disciplinary procedures. See Section 30 'Misconduct in Research'.
- 13.4 Researchers can check the status of their application by logging on to [Ethics Monitor](#) and reviewing the 'timeline' in their account. Once amendments have been completed satisfactorily the researcher will receive an ethics approval letter from EISC. Researchers must conduct their projects in accordance with the University's policies, supporting documents, the conditions of ethical approval specified in the approval letter, [the Data Protection Act](#), (DPA) 2018, [UK General Data Protection Regulation](#), (GDPR) 2018, legal, regulatory and ethical requirements and, where applicable, local laws.

- 13.5 Academics, staff members and Postgraduate Research Students (PGRs) are granted ethical approval for four years, and undergraduate and taught master's projects receive ethical approval for two years. Student researchers should inform their supervisors that they have received ethical approval and provide a copy of the ethics approval letter, if requested. It is the responsibility of all researchers to retain the ethical approval letter for their records. Following the commencement of the research project, should researchers wish to make any changes to the project, an application form for an amendment to the ethical approval granted must be completed and submitted to EISC. See Section 15 'Amendment to an existing research project'.
- 13.6 Any adverse events/reactions or incidents that occur in connection with the research project should be reported following the University's procedure for [Reporting an Adverse/Serious Adverse Event/Reaction](#). The event should be assessed for causality, seriousness and expectedness. If appropriate, the Principal Investigators (PI) for the project or delegate may contact the participant to discuss the event. In all instances the REO should be informed, and the researcher should follow UEL's regulations.
- 13.7 Researchers should be aware that EISC will periodically audit a sample of approved applications for ethical approval, to ensure that the research projects are conducted in compliance with the consent given by the appropriate ethics committee, and to the highest standards of rigour and integrity. The audit process may also require a progress report on a sample of research projects. Researchers should respond to any requests for information regarding a project which has received ethical approval.

14. Research Ethics Review Appeal procedure

Researchers may appeal a decision made by the Ethics and Integrity Sub-Committee (EISC) regarding their application for ethical approval.

- 14.1 A request for an appeals submitted by Postgraduate Research Students (PGRs) must be authorised by both the supervisor, Director of Impact and Innovation (DII) for the School or the Director of the Institute/Service (DI/S).
- 14.2 The Dean, DII or DI/S should authorise the request for an appeal from academics and staff members.
- 14.3 The appeal request should be submitted to the [Research Ethics Office](#) (REO) within 10 working days of receiving EISC's decision for the project. The [Research Ethics Review Appeal procedure](#) does not apply to undergraduate or taught postgraduate students or Collaborative Partner Research Ethics Committees (CRECs); local arrangements are in place to administer a request from students.
- 14.4 An appeal request can be upheld if the following applies:
 - There are material circumstances regarding the application for ethical approval which were not apparent at the time of review.
 - There is evidence that a procedural irregularity or administrative error occurred at the time of ethical review, and the irregularity is of such a nature as to cause doubt as to whether EISC would have reached the same decision, had the irregularity not occurred.
 - Substantive material has been provided which was not made available to EISC at the time of review and, as such, it is likely that the committee would have reached a different conclusion had the data been considered at the time of ethical review.
 - There is evidence of bias, prejudice, inappropriate conduct or inadequate review.
- 14.5 If a request to appeal a decision made by EISC does not fall under any of the circumstances listed in point 14.4, EISC will dismiss the complaint.
- 14.6 To appeal a decision made by EISC, researchers must follow the University's Research Ethics Review Appeal procedure, specifying why the committee's decision is being appealed and provide a list of all documents and supporting evidence, to warrant the appeal.
- 14.7 EISC will set a deadline for the completion of the appeal process. Two independent, academic researchers and, if necessary, external parties, will be appointed to review the application to appeal for the original decision to be

overturned. Researchers will be informed of the panel's decision within approximately 15 working days. Should the independent panel conclude that the decision made by EISC should be upheld, the panel's assessment must be respected. The decision cannot be appealed to central administration on substantive grounds, once the University's research ethics review appeal process has been applied.

- 14.8 If the application to appeal EISC's decision involves allegations of misconduct in research, EISC will follow the University's [Staff and Student Misconduct in Research Procedure](#). See Section 30 'Misconduct in Research'.

15. Amendment to an existing research project

Should a researcher wish to make changes to an existing project an 'Amendment to an existing research project application form' must be submitted to the Ethics and Integrity Sub-Committee (EISC) through [Ethics Monitor](#). The original ethics approval letter⁹ will be stored in the system and researchers can select the project they wish to amend.

- 15.1 The process to complete an amendment is similar to submitting a new application for ethical approval. However, the amendment application form is a shorter form, as it should be used for minor amendments only, for example, a new participant group will be added to the project or there are changes to interview questions, the research team or the location of the research. If the methodology of the research project changes, a new application form for ethical approval must be submitted.
- 15.2 Depending on the amendment required, researchers may need to submit supporting documents, such as those specified in 8.1. For any changes required to interview questions or questionnaires or surveys, EISC or the [Research Ethics Office](#) (REO) will need to review and approve the proposed revisions. Changes to participant groups e.g., adding a new cohort of participants and/or including a separate method of data collection will require a new Participant Information Sheet, Consent Form and Privacy notice for the new group of participants and the method of data collection.
- 15.3 If a new gatekeeper is required for the research project, researchers should submit a copy of the gatekeeper permission request letter and confirmation of the gatekeeper's consent, with the application for an amendment to an existing research project.
- 15.4 If an amendment to the existing research project is required, a Data Management Plan (DMP) should be submitted with the amendment application form. If the research project received ethical approval within 3 months of a request for an amendment to the project, the original DMP is valid. Amendments to ethical approval submitted after this time require a new DMP, signed by the [Library, Archives and Learning Services](#) department. DMPs are 'live' documents and, as such, the DMP should be reviewed and amended, if necessary, in accordance with any changes made to the research project. See point 8.12 and the Research Data Management [webpage](#).
- 15.5 A research risk assessment form is required for all research projects. If there are changes to the research project an updated risk assessment form must be submitted with the amendment application form. The risk assessment forms

⁹ For ethics application forms which were approved before September 2018, prior to the implementation of Ethics Monitor, researchers should select option 4 'Amendment to an application approved outside of ResearchUEL'.

can be found under '[Guides](#)' on [Ethics Monitor](#) or on the Research Ethics and Integrity [webpage](#).

- 15.6 Researchers do not need to wait until a scheduled EISC committee meeting to submit a minor amendment to existing ethical approval, as these amendments are normally reviewed by the REO and can be submitted through Ethics Monitor at any time. If the amendment requires escalation to EISC, the researcher will be informed if there will be a delay to their application for an amendment.
- 15.7 As stated in Section 12 'Ethics and Integrity Sub-Committee (EISC)':
- Researchers will receive the decision letter for their application to amend an existing research project within 15 working days.
 - The decision letter will clearly state if there are points that need to be addressed, if not, an ethics approval letter will be issued.
 - If amendments are incomplete or points that the committee has raised have not been addressed, the application form will be returned to the researcher.
 - Changes to the project should not be implemented until ethical approval has been granted by EISC.
 - Researchers who conduct projects without ethical approval may be subject to disciplinary procedures. See Section 30 'Misconduct in Research'.
 - Once amendments have been completed satisfactorily, the researcher will receive a letter from EISC granting ethical approval.
 - Student researchers should inform their supervisors that they have received ethical approval and provide a copy of the ethics approval letter, if requested.
 - It is the responsibility of the researcher to retain the ethical approval letter for their records.

16. HRA-NHS research projects

The [UK Policy Framework for Health and Social Care Research](#) states that ‘The policy framework sets out principles of good practice in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public’.

- 16.1 To conduct research projects involving ethical parameters that relate to the UK Health Department policy or UK law, the University’s ethics committees are not a recognised, and researchers will be required to apply for ethical approval to the [Health Research Authority](#) (HRA). The HRA approval process combines an assessment of governance and legal compliance, with an independent [NHS Research Ethics Committee](#) (REC) review and opinion on the research project. Applications for ethical approval outside of the UK should apply to the equivalent bodies in Northern Ireland, Scotland and Wales.
- 16.2 Researchers should apply for HRA approval through the Integrity Research Application System (IRAS). IRAS is a single, unified application process for ethical approval of research involving health, social care and community-based research throughout the UK. Guidance on completing the IRAS application form and Local Information Pack is available from the [HRA IRAS project](#) webpage and the Research Ethics and Integrity [webpage](#) on ‘HRA-NHS approval’. HRA guidance on compiling the Local Information pack can be found [here](#).
- 16.3 Researchers should complete an IRAS application and together with a Local Information Pack and PDF printout of the final document upload page, submit the application through [Ethics Monitor](#). The School of Psychology Professional Doctorate students are not authorised to use Ethics Monitor and should apply for ethical approval from the School of Psychology Ethics Committee.
- 16.4 If the project is defined as a clinical trial as per IRAS categories of clinical trials including medicines, devices, combination of medicines and devices and other clinical trials, it will be registered on a publicly accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies. See [guidance](#) on clinical trials.

17. Applying for HRA-NHS ethical approval

- 17.1 Researchers can determine whether their project is research by using the HRA-NHS REC [decision tool](#). The project is categorised as [research](#) if it is:
- A basic science study involving procedures with human participants.
 - A study administering questionnaires/interviews for quantitative analysis, or using mixed qualitative/quantitative methodology.
 - A study involving qualitative methods only.
 - A study limited to working with human tissue samples (or other human biological samples) and data (specific project only).
 - A study limited to working with human tissue samples (or other human biological samples) and data (specific project only).
 - Clinical trial of an Investigational Medicinal Product (CTIMP) (with the exception of Phase 1 trials in healthy volunteers taking place outside the NHS).
 - A Clinical Investigation or other study of a Medical Device.
 - A combined trial of an Investigational Medicinal Product and an Investigational Medical Device.
 - A Clinical Trial to study a novel intervention or randomised Clinical Trial to compare interventions in clinical practice.
- 17.2 The HRA-NHS REC review decision tool determines whether the project requires a review by an [NHS Research Ethics Committee](#) (REC), and also advises researchers as to whether other regulatory approvals and/or types of ethics review are required. As such, researchers should check whether other reviews or approvals are needed for the project.
- 17.3 If the project does not fall under the categories in point 17.1, but is:
- A Research Tissue Bank
 - A Research Database or
 - Taking place in a non-NHS setting for example a Phase 1 clinical trial in health volunteers

The project may not require HRA approval, but may still need approval from a [Research Ethics Committee](#).

- 17.4 Projects conducted with NHS staff, NHS data or on NHS premises must apply for ethical approval from both the HRA through the [IRAS application form](#) and the Ethics and Integrity Sub-Committee (EISC)¹⁰. Researchers should consult the Research and Development department (R&D) of the NHS Trust where

¹⁰ Professional Doctorate students from the School of Psychology should apply to the School of Psychology Research Ethics Committee and the HRA.

the project will be conducted, to ascertain whether HRA ethical approval is required.

- 17.5 For all NHS projects sponsored by UEL, researchers will be required to upload a Local Information Pack and the PDF printout of the final document upload page, in addition to the IRAS application form. The reference number of the IRAS application, document date and version number should be included on all uploaded documents.
- 17.6 Researchers must adhere to the instructions given regarding submitting the IRAS application form, as HRA review bodies have specific submission procedures. It is recommended that researchers apply for any relevant approvals for the project in parallel. It is not necessary to wait for HRA or UEL ethical approval before contacting the research sites.
- 17.7 Under the [Human Tissue Act 2004](#), for projects involving relevant material (material from a human body consisting of or including cells) for scheduled purposes in England, Wales or Northern Ireland, the institution requires a licence from the [Human Tissue Authority](#). See Section 23 'Research projects with human tissue'.
- 17.8 The [Mental Capacity Act 2005](#) governs the treatment of those who may lack the mental capacity to make their own decisions about their care or treatment. Research projects involving those who fall under the Mental Capacity Act must apply for ethical approval from the [Health Research Authority](#) (HRA). See Section 24 'Mental Capacity for research projects'.
- 17.9 If the research project is related to NHS audit or service evaluation, NHS ethical approval is not required. Confirmation should be provided to EISC as to why the project does not require NHS ethics approval. The HRA-NHS REC decision tool in point 17.1 can be used for clarification. NHS audit or service evaluation projects may require ethical approval from EISC or the School of Psychology Ethics Committee if the following applies; the study is part of a research project for a University qualification, the findings of the research will be used for further projects, or in cases where the project is not classified as 'research' using the decision tool. In these instances, the project does not fall under the remit of ethical review by an NHS REC.
- 17.10 Where the research is reviewed by an NHS REC, within the UK Health Department's Research Ethics Service¹¹, the summary of the project will be published on the website of the National Research Ethics Service (NRES), together with the point of contact for enquiries named in the application. Publication will take place no earlier than 3 months after issue of the RECs final opinion.
- 17.11 At the end of the EISC ethics application form, there are statements for the

¹¹ The UK Health Department Research Ethics Service includes the equivalent Research Ethics Services in Wales, Scotland and Northern Ireland.

researcher to confirm that they have complied with all requirements for submission of the form.

- 17.12 The process for the submission of the application form to the HRA-NHS for ethical approval, is the same as specified in Section 11 'Submission of an ethics application form'. Once the [Research Ethics Office](#) (REO) receives the application form it will be automatically forwarded to UEL's [Legal Representative](#) for the relevant School/Institute. The Legal Representative is the person who will e-authorise the ethics application form in both Ethics Monitor and the IRAS system. Researchers are advised to check the IRAS application form carefully, as the application form is signed and submitted electronically. Once the application form is authorised by the Legal Representative, the researcher will be unable to make any further changes to the form before submission to the HRA.
- 17.13 NHS RECs review research proposals and give an opinion as to whether the study is ethical. RECs consider areas such as the proposed participant involvement and are entirely independent of research sponsors (the organisations which are responsible for the management and conduct of the research), funders and researchers. Similarly, to the EISC procedure in Section 12 'Ethics and Integrity Sub-Committee (EISC)' the NHS REC can approve, request minor or major amendments or decline the project. The researcher will receive a comprehensive decision letter from the REC advising the researcher of the points that need to be addressed and the next steps.
- 17.14 Researchers should be aware that obtaining HRA-NHS ethical approval can be a lengthy process and it is recommended that researchers apply in good time to complete the research project. As stated in Section 2 'Ethics by Design,' well-planned research design can help to identify potential issues with the project at an early stage of development. It is not advisable for undergraduate or taught master's students to conduct projects involving the NHS, as these students have a limited amount of time to submit their projects.
- 17.15 Once HRA approval is granted, researchers should upload a copy of the HRA-NHS approval letter to Ethics Monitor. Professional Doctorate students from the School of Psychology should email the approval letter to EISC, who will issue a letter of sponsorship of the research project on behalf of the University and specify the lapse date for ethical approval.
- 17.16 UEL sponsorship of the project is based on the protocol described in the IRAS application form, supporting documentation and ethical clearance¹² and will be granted for the submitted application only. As a condition of sponsorship by UEL, the project must be conducted in accordance with HRA-NHS regulations, and any requirements specified as part of the HRA ethical approval. Following commencement of the research project, should

¹² Ethical clearance is consent from EISC for the project to proceed, as specified in the protocol. In these instances, ethical approval has been granted by an external body to EISC.

researchers wish to make changes to the project, an application for an amendment must be submitted to the HRA-NHS and EISC.

- 17.17 As stated in Section 13 'Outcome of the review of an ethics application form,' EISC will periodically audit a sample of HRA approved applications for ethical approval, to ensure that the research projects are conducted in compliance with the consent given by the appropriate ethics committee, and to the highest standards of rigour and integrity.
- 17.18 Any adverse events or reactions that occur in connection with the NHS research project should be reported following the HRA regulations. A HRA-NHS [Serious Adverse Event](#) (SAE) is an untoward occurrence that:
- Results in death.
 - Is life-threatening.
 - Requires hospitalisation or prolongation of existing hospitalisation.
 - Results in persistent or significant disability or incapacity.
 - Consists of a congenital anomaly or birth defect.
 - Is otherwise considered medically significant by the investigator.
- 17.19 An SAE occurring to a research participant should be reported to the REC, where in the opinion of the Chief/Principal Investigator the event was related to the administration of any of the research procedures and was an unexpected occurrence.
- 17.20 Reports of SAE's should be provided to the REC within 15 days of the Chief/Principal Investigator becoming aware of the event, following the [format](#) specified by the HRA.
- 17.21 Following UEL's procedure for [Reporting an Adverse/Serious Adverse Event/Reaction](#), the event should be assessed for causality, seriousness and expectedness. If appropriate, the Chief/Principal Investigator for the project or delegate may be permitted to contact the participant to discuss the event. In all instances the REO should be informed, and the researcher should follow UEL's regulations.

18. Amendment to an existing HRA-NHS research project

Researchers who wish to make changes to an existing research project must apply for ethical approval from the [Health Research Authority](#) (HRA) and the Ethics and Integrity Sub-Committee (EISC) to amend the study. The points mentioned in Section 15 'Amendment to an existing research project' should be followed, in addition to the below guidance.

- 18.1 If a [substantial amendment](#) is required, the Chief/Principal Investigator for the project should submit a substantial amendment to the [NHS Research Ethics Committee](#) (REC) via the [IRAS application system](#).
- 18.2 A substantial amendment is a change to the terms of the application for ethical review, or to the protocol of the project or other supporting documentation, approved by the NHS REC, that is likely to affect to a significant degree the following:
 - The safety or physical or mental integrity of the research participants.
 - The scientific value of the research.
 - The conduct or management of the research, including its ongoing legality and feasibility.
- 18.3 A substantial amendment should not be implemented until a 'favourable opinion' has been given by the REC, unless the changes to the research are urgent safety measures. The REC is required to give an opinion within 35 days of the date of receiving a valid amendment.
- 18.4 EISC requires an amendment application form to be submitted for both minor and major amendments to NHS projects. The HRA requires the completion of an [Amendment Tool](#) for all changes to NHS project-based research. Researchers must clearly describe the amendment to the NHS project and the rationale for the revision.
- 18.5 Depending on the nature of the amendment, researchers may still be required to submit an IRAS application form and Local Information pack as specified in Section 17 'Applying for HRA-NHS ethical approval'. Researchers should contact the Research and Development department (R&D) of the relevant NHS Trust where the project will be conducted, the HRA or the [Research Ethics Office](#) (REO) for guidance.
- 18.6 If HRA approval is required and granted, as specified in Section 17 'Applying for HRA-NHS ethical approval,' researchers should upload a copy of the HRA approval letter to [Ethics Monitor](#). Professional Doctorate students from the School of Psychology should email the approval letter to EISC, who will issue a letter of sponsorship of the research project on behalf of the University and

specify the lapse date for ethical approval.

- 18.7 Sponsorship of the project is based on the protocol described in the application form and supporting documentation, and approval will be given for the submitted application only. As a condition of sponsorship by UEL, the project must be conducted in accordance with NHS regulations, and any requirements specified as part of the HRA-NHS ethical approval.

19. Ethical approval for external researchers

Researchers from institutions external to the University, both in the UK and overseas, may request to conduct their research projects with UEL staff members and/or students. Additionally, there are members of the UEL community who are studying for a qualification at an external institution; 'UEL based external researchers,' who may also wish to recruit participants from UEL's employees and students.

- 19.1 A researcher from an external institution or a UEL based external researcher will need to provide the following to the [Research Ethics Office](#) (REO):
- A research proposal specifying the aims and objectives and methodology for the project, clearly state why they are seeking to collect data from UEL staff and students, and the benefit of the research to UEL.
 - The proposal should be no more than two sides of A4 paper.
 - The external institution's ethics application form and ethics approval letter.
 - A signed risk assessment form from the external institution.
 - A Data Management Plan (DMP) for the research project signed by the external institution.
 - Specify how UEL staff and students will be recruited and provide any posters or adverts for the research project.
 - Written confirmation from the external institution that they are responsible for the professional indemnity and/or public liability insurance of the research project.
- 19.2 The Chair of the Ethics and Integrity Sub-Committee (EISC) or designate will grant ethical clearance for the project to be conducted with UEL staff and/or students. The external researcher is also required to seek permission from the Dean, Director of Impact and Innovation (DII) for the School or the Director of the Institute/Service (DI/S). Confirmation of authorisation from the Dean, DII or DI/S can be in form of an email which should include the full name and contact details of the appropriate person. The permission letter should be submitted to the REO, in addition to the documents specified in point 19.1.
- 19.3 If a researcher, now employed or studying for a qualification at UEL, has ethical approval from a former institution, the previous institution must agree for the researcher to continue the research project under their auspices and confirm that they are responsible for the professional indemnity and/or public liability insurance for the research project. If the institution agrees, the researcher is not required to apply for ethical approval from EISC.
- 19.4 Similarly, the researcher must clarify whether the previous institution will

insure any amendments to the research project. If not, the researcher is required to complete an EISC ethics application form on [Ethics Monitor](#) for the remaining elements of the research project.

- 19.5 Researchers should seek advice from the [Data Protection Office](#) regarding any changes in the management, storage, transfer or destruction of the research data from the former institution to UEL.

20. Internet-mediated research projects

'Internet-mediated research' (IMR) covers a wide range of quantitative, qualitative and mixed methods approaches to research involving, or about human participants. It can be broadly defined as any research involving the remote acquisition of data from or about human participants using the Internet and its associated technologies'. [Ethics Guidelines for internet-mediated research, 2021](#). British Psychological Society (BPS).

- 20.1 Increasingly, information is being garnered from social media communication for research projects, for example, Facebook, X (formerly Twitter) or Instagram. Information obtained using these methods may require ethical approval before the material is collected and utilised as research data. Information obtained from online sources may be subject to the conditions of the platform and/or copyright. Researchers should consult the terms and conditions, copyright policy, or guidelines of the relevant platform. Additionally, if projects are being conducted that cross national boundaries, researchers may need to consider if there are any country-specific legal requirements, such as data protection for internet-mediated research. See: [Economic and Social Research Council Internet Mediated Research](#).
- 20.2 When using the internet as a method of acquiring research data for studies, researchers should be mindful of an individual's rights, dignity, values and well-being. Although the information being collected may be in the public domain, care should be taken to ensure that individuals are not identifiable. The data should be anonymised and, where possible, aggregated. Information in the public domain should always be treated with respect and wherever possible consent should be obtained.
- 20.3 When joining an online group or online forum to collect research data, a researcher must declare that they are joining the group as a scholar and seek consent from the members to use the discussion in their project. If new people join the group, the researcher should inform the new members of their presence and role within the group and seek consent.
- 20.4 Secondary data sets may require ethical approval if individuals can be identified, if the nature of the data is particularly sensitive, or if it is not clear that the individuals included in the data set gave their consent for their contribution to be shared.
- 20.5 If necessary, a researcher can use their own social media channels to advertise research projects. The researcher's own networks may be helpful for the recruitment of participants to the project. A researcher should not collect any personal data through their own social media account. Potential participants should communicate with the researcher using the researcher's

University contact details only, and all data should be stored on Microsoft OneDrive. A researcher can create a specific social media channel for the research project; however, the site must be closed once the research project has ended.

- 20.6 There are ethical issues with online data collection that should be taken into consideration, however this list is not exhaustive:
- 20.6.1 **Public or private** – an outline of the criteria/measure to be used to determine the distinction with the information.
 - 20.6.2 **Consent** – it is possible to obtain consent from the individual?
 - 20.6.3 **Accuracy** – can the reliability of the data be assured?
 - 20.6.4 **Anonymity** – what is the level of risk of individuals being identified?
What processes or procedures will be utilised to maintain anonymity?
- 20.7 Researchers should be mindful of the following issues when conducting online interviews or forums, however this list is not exhaustive:
- 20.7.1 **Identity** – how can the researcher confirm the identity of the individual?
 - 20.7.2 **Mental capacity** – how can the researcher be assured that the individual has the capacity to consent to the research project?
 - 20.7.3 **Location** – is the location of the interview in a secure space?
 - 20.7.4 **Harmful behaviour** – what is the procedure to report harmful behaviour?
 - 20.7.5 **Non-verbal cues** – researchers should be aware of signs or indications which may suggest that the participant is uncomfortable or distressed.
 - 20.7.6 **Researcher safety** - researchers should be clear regarding their role in the research project. If participants require after-care, counselling or support following their contribution to the project, researchers should refer participants to appropriate organisations, agencies or services. The researcher should not provide after-care, as for the purposes of the project they are an investigator.

21. Generative Artificial Intelligence

The Department for Education (DfE) has published a Department Statement on '[Generative artificial intelligence in education](#)' and the DfE has given the following as a definition of Generative Artificial Intelligence:

'Generative AI refers to technology that can be used to create new content based on large volumes of data that models have been trained on from a variety of works and other sources. ChatGPT and Google Bard are generative artificial intelligence (AI) tools built on large language models (LLMs)'.

21.1 Generative AI technology is developing at a rapid pace and at present regulations and guidance regarding its use is evolving. A conclusive list of the ethical implications of the technology are yet to be established; however, there are ethical concerns, not limited to the following:

- On the AI platform, can the source of the information and location be verified?
- Some generative AI tools cannot provide references to the data they have provided. How can this information be authenticated?
- LLMs rely on large datasets, as such, is the information accurate or up-to-date?
- Are the sources the technology is drawing on subject to terms and conditions or copyright?
- Is the information that the technology is producing plagiarising the work of others?
- Are the same responses generated being reproduced and distributed widely to other users?
- How secure is the data being entered and how will it be kept confidential?
- Authorship cannot be attributed to an AI platform, as the tools and the providers cannot meet the necessity of a researcher being able to explain their contribution to the research project, take responsibility for the content and accuracy of the output and defend its position, if necessary.

21.2 At the time of publishing this handbook, it is not possible to provide definitive guidance from the Ethics and Integrity Sub-Committee (EISC) on the ethical implications of employing generative AI in research projects. The following links may be helpful, and this handbook will be updated when policies or regulations are developed:

- Jisc National centre for AI: [A Generative AI Primer - National centre for AI \(jiscinvolve.org\)](https://www.jiscinvolve.org/)



- Russel Group Universities: [Russell Group principles on the use of generative AI tools in education](#)
- QAA: ChatGPT and Artificial Intelligence: [ChatGPT and artificial intelligence \(qaa.ac.uk\)](#)
- Unesco: Guidance for generative AI in education and research: [Guidance for generative AI in education and research | UNESCO](#)

22. Existing data sets / exemptions to ethical approval

22.1 Fully anonymised data sets may not require ethical approval from the Ethics and Integrity Sub-Committee (EISC) unless:

- It may be possible to re-identify participants in the data set through indirect identifiers or technology. For example, an individual's date of birth, postcode, place of work are indirect identifiers that could reveal the identity of a person, if the information was combined with other data.
- It may be possible to re-identify participants in the data set through technology e.g., the use of algorithms and big data sets.
- Participants have not consented to their data being used for research.
- The data is particularly sensitive and/or may cause harm to others.

22.2 Analysing secondary research data or 'desk-top projects' may not require ethical approval, if the research material is not personal or sensitive, is fully anonymised or the information is lawfully classified as accessible for public use, without limitations. EISC does not consider internet-mediated data, as secondary data. Research projects involving social media sites/platforms or, data mining/scraping will require ethical approval. See Section 20 'Internet-mediated research projects'.

22.3 Advice should be sought from the supervisor, Dean, Director of Impact and Innovation (DII) for the School, Director of Institute/Service (DI/S), School Ethics Committees (SECs) or the [Research Ethics Office](#) (REO), if researchers are unsure as to whether ethical approval is necessary for conducting research with an existing data set.

22.4 Researchers should be mindful when analysing existing anonymised data sets for organisations. Whilst the data set obtained may be anonymous to the researcher, the organisation itself may be able to identify individuals. The organisation should have the appropriate consent and permissions in place to share the data externally.

23. Research projects with human tissue

- 23.1 [The Human Tissue Authority](#) (HTA) defines human tissue as relevant material which includes any material that contains one or more human cells. This includes but is not limited to serum, blood, urine, saliva, hair, nails and gametes. Acellular derivatives and acellular preparations of human biological materials are not considered relevant material. Established cell lines, acellular derivatives, and acellular preparations of human biological materials are not considered human biological material.
- 23.2 Materials classified in the [HTA list](#) as relevant material are subject to the caveat that if the material has been divided or created outside the human body, or the material has been treated, processed or lysed through a process intended to render the material acellular (this would include the freezing or thawing of cells only where that process is intended to render the material acellular) the material is not considered as human tissue.



24. Mental Capacity for research projects

- 24.1 Under the [Mental Capacity Act 2005](#) ‘... a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain. It does not matter whether the impairment or disturbance is permanent or temporary’.
- 24.2 Research projects involving individuals who may lack capacity must be reviewed by the [Health Research Authority](#) (HRA). See Section 17 ‘Applying for HRA-NHS ethical approval’.

25. Collaborative research partnership

- 25.1 Collaborative research projects can include partnerships, associations and relationships between UEL researchers and third parties from higher education or research institutions and international partners. Additionally, projects can take place with public and private sector organisations, health providers, charities and voluntary organisations: [Framework to Enhance Research Integrity in Research Collaborations](#).
- 25.2 Researchers should follow the recommendations of the [Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations](#), which ‘...outlines principles to guide successful and trustworthy research collaborations ‘that cross national, institutional, disciplinary and sector boundaries’. The [Cape Town Statement](#), on research integrity specifying how to foster equitable partnerships, and the [Framework to Enhance Research Integrity in Research Collaborations](#), provides guidance on how to uphold a culture of good research conduct in collaborative work.
- 25.3 Collaborative research partnerships should ensure that there are written agreements or contracts between all parties, as early on as possible. The documents should clearly outline each stakeholder’s responsibilities, practices and conduct, complying with all laws, particularly those of international collaborators, regulations and ethical frameworks. Researchers should be aware of the collaborator’s procedures, policies, standards and expected behaviour. If the collaborator’s actions or behaviours conflict with UEL’s policies, regulations or values, advice should be sought from the University’s [Office for Compliance, Governance and Legal Services](#).
- 25.4 The Ethics and Integrity Sub-Committee (EISC) requires confirmation of the agreement between the researcher and the partner for collaborative projects that require ethical approval. If the collaborator is the Principal Investigator for the project, the collaborator is permitted to use their own institution’s recruitment documents. UEL’s official logo can also be included on the documents, if appropriate. See Annexe 14 ‘Collaborative research partnership checklist’ for guidance.
- 25.5 The research project should be conducted with honesty, integrity, transparency and fairness, giving appropriate acknowledgement of the contribution of each collaborative partner. Agreements regarding authorship should be reached before the research project begins, revisited, and amended, should there be any modifications to the research project which may affect the original agreement. Any amendments that govern the conduct, procedures or regulations of the project must be clearly articulated and have the agreement of each party.
- 25.6 Researchers should ensure that co-production, collaboration or stakeholder

involvement in research reflects the research integrity and ethics principles of accountability, responsibility, honesty, transparency, reliability and respect, and appropriate systems for the management of research data and processes are in place.

- 25.7 Researchers are expected to anticipate any issues or significant risks that might arise as a result of working collaboratively, including the investigation of allegations of misconduct in research, and agree in advance how the issues might be addressed, and any decisions made communicated to each party.

26. Overseas research projects

- 26.1 An [overseas risk assessment](#) form must be completed for any overseas travel in line with the University's insurance compliance requirement. For low or medium risk overseas locations, the risk assessment should be authorised by the Dean of the School of Director of Institute/Service (DI/S). For high or extreme risk locations, a senior member of the University's Executive Board (UEB) will counter-sign the risk assessment form on behalf of the [Insurance Office](#). See Section 9 'Risk assessment form'.
- 26.2 Researchers should refer to the [Foreign and Commonwealth Office](#), (FCO) travel advice for information about any travel restrictions by the UK government. Additionally, researchers should access UEL's Insurance assistance, [AIG Travel Guard](#), to determine the overall risk rating as required by the University's insurance providers. UEL's [Business Travel and Fieldwork policy](#) provides guidelines on safe working procedures and responsible planning for research projects.
- 26.3 Researchers should be familiar with any country specific risks and follow any mitigating actions recommended by the University, FCO and AIG Travel Guard. Sufficient time should be allowed for the approval of the overseas risk assessment form and applying for ethical approval.
- 26.4 It is advised that researchers keep in regular contact with supervisors or line managers for the duration of the research project. When conducting research projects in high-risk areas, a procedure should be in place to check the well-being of a researcher if they fail to contact UEL staff. Emergency contact details for both the researcher and the supervisor or line manager should be kept up to date and a process established for out of office hours support. Any adverse events or reactions must be reported using the University's [Reporting an Adverse/Serious Adverse Event/Reaction](#) procedure. See Section 13 'Outcome of the review of an ethics application form'. UEL's [Health, Safety and Wellbeing Office](#) should also be informed of any issues or concerns.
- 26.5 If the research project is being conducted with individuals who are based overseas and data collection will take place remotely, an overseas risk assessment form is not required. If the subject of the research is sensitive and/or has the potential to cause psychological distress a [research risk assessment form](#) may be required. If researchers are conducting the project remotely and the overseas country is in conflict, politically unstable, or there are concerns about the security of data in the country, UEL's [Data Protection Office](#) should be contacted for guidance.

27. Publication and Authorship

- 27.1 An author can be determined as a person who has made a substantial contribution to the research project. Those who are listed as an author must have their name attributed to the content of the publication, be able to explain their contribution to the project and take responsibility for the accuracy of the findings presented. Those who do not qualify for authorship, yet have had an input into the research, should be identified and acknowledged in the publication. Researchers should consult any discipline specific guidance or authorship conventions on the attribution of authorship and adhere to any conditions required by journals for the publication of their work.
- 27.2 Similarly to collaborative research projects, agreements regarding authorship and the order of listing those identified as authors should be in place from the outset of the project. Each party should be clear about their role and responsibility for the research and therefore their ranking in the list of authors. Discussing and agreeing on the criteria for authorship avoids future disputes or allegations of misconduct in research through misrepresentation. If the roles and responsibilities of parties change during the lifecycle of the project, authorship agreements should be reviewed to ensure that the agreement still accurately reflects the work that each party has contributed.
- 27.3 [UK Research and Innovation](#) states that ‘Open research, also widely referred to as open science, relates to how research is performed and how knowledge is shared based on the principle that research should be as open as possible’. The outputs of research can be shared widely making access to knowledge and learning accessible to all; increasing the availability of data to be re-used and reproduced and the findings of the outputs transparent and subject to scrutiny, assuring the integrity of the research.
- 27.4 ‘Open access refers to the free, unrestricted online access to scholarly research’: UEL [Library, Archives and Learning Services](#). Publications that are open access are available for downloading, copying and distributing, however the author of the publication should be acknowledged.
- 27.5 Guidance on publication and authorship can be found on the following links: provided in the [Committee on Publications Ethics](#), [International Committee of Medical Journal Editors](#), [Nature](#), [The BMJ](#), [The Royal Society](#) and the [UK Research Integrity Office](#).

28. Funders of research projects

- 28.1 Funders of researchers have policies and guidelines in place that outline the expected standards and conduct of researchers, who are recipients of funding for their research projects. Researchers and the relevant stakeholders should familiarise themselves with the conditions of the grant funding and abide by the specified processes and procedures.
- 28.2 As stated in Section 2 'Ethics by Design,' researchers should allow sufficient time to apply and receive ethical approval for their research projects; however, funding for projects can be granted at short notice, with limited lead time. The Ethics and Integrity Sub-Committee (EISC) does not have an expedited process for reviewing ethics application forms outside of a scheduled committee meeting. Researchers in receipt of funding requiring a swift turnaround for obtaining ethical approval should contact the [Research Ethics Office](#) (REO) as soon as possible, to ascertain what actions can be taken.
- 28.3 There may be responsibilities and obligations for researchers regarding funded projects, such as dissemination of research findings, open access and data sharing requirements, period of data retention, and reporting significant changes to the protocol of the project. Researchers should discuss any issues or concerns with the relevant funding body at the earliest opportunity.
- 28.4 The University subscribes to [Research Professional](#), an online service under Clarivate. The platform offers an open database of research and knowledge exchange funding opportunities, in addition to research policy news and analyses, which are customised for individual researchers. Research Professional's Fingerprinting service identifies specific funding opportunities. Users receive emails with relevant information, and weekly notifications are sent based on a researcher's profile, obtained from publicly available data.

29. Research integrity and ethics training

- 29.1 It is mandatory for Postgraduate Research Students (PGRs) to complete the [Epigeum Research Integrity Modules](#). The free interactive courses deliver comprehensive training in research integrity to provide practical advice on managing the complex issues that can arise whilst planning, conducting and reporting research. Each module uses engaging multimedia content and interactive activities to drive active learning, reflection and practical application on research integrity.
- 29.2 The Research Integrity Modules (RIM) must be completed even if your research project does not involve human participants, human material, human data, personal and/or sensitive data or pre-existing data collected from humans without their knowledge of inclusion of the information in a research project or non-human animal. You can apply for ethical approval without completing the RIM; however, you must complete the Research Integrity Modules in order to register your research proposal¹³.
- 29.3 The University's research integrity and ethics training delivered by the [Research Ethics Office](#) (REO), incorporates the principles of the [Concordat to Support Research Integrity, 2019](#) with the objective of ensuring that all researchers comprehend the values, standards and behaviours that are crucial for maintaining the integrity, accountability and quality of research projects supported by the University. Comprehensive training is provided to all stakeholders, enhancing the understanding of responsible research conduct. The training equips researchers with essential skills to conduct impactful, original, and ethically responsible research. The implications of misconduct in research are covered in the research integrity and ethics training sessions, informing researchers of their individual responsibilities in adhering to legal, regulatory and ethical requirements, obligations and standards. Additionally, researchers are directed to relevant resources and available guidance.
- 29.4 [The Researcher Development Programme](#) (RDP) provides in-house training and development opportunities to PGRs, research-active staff at all levels and PGR supervisors. The RDP administers a wealth of sessions for the programme covering researcher skills, career development, employability, well-being and pastoral support. Researchers can participate in numerous activities to develop skills in marketing, finance, project coordination, communication and time management. Researchers can also engage with UEL's three Impact and Innovation Research Institutes; the Institute for Connected Communities (ICC), the Sustainability Research Institute (SRI) and the Rix Centre, to enhance knowledge exchange and real-world research

¹³ The certificate of completion for the RIM must be attached to the registration form. PGRs are not required to include the certificate with submission of the ethics application form.

skills.

- 29.5 All researchers, Schools and Institutes can contact the REO to deliver bespoke training sessions for their department or for guidance.

30. Misconduct in Research

30.1 The University's [Staff and Student Misconduct in Research Procedure](#) governs the investigation of allegations of misconduct in any area of research. The Procedure applies to anyone conducting research under the auspices of the University. This includes, but is not limited to:

- Members of staff.
- Student researchers.
- Independent contractors and consultants.
- Visiting or emeritus staff.
- Staff on joint clinical contracts.
- Any person(s) conducting research using University facilities or on University premises.

30.2 The University defines misconduct in research as including but not limited to:

- Fabrication.
- Falsification.
- Misrepresentation of data, interests, involvement or credentials.
- Plagiarism.
- Collusion or concealment of research misconduct.
- Breach of confidentiality.
- Inappropriate attribution of authorship.
- Failure to declare conflicts of interest regarding research activities.
- Failure to obtain appropriate permissions or consent.
- Failure to observe legal, regulatory or ethical requirements.
- Failure to follow accepted procedures or to exercise due care in carrying out responsibilities for:
 - avoiding unreasonable risk of harm to:
 - humans;
 - animals used in research; and
 - the environment; and
 - the proper handling of privileged information on individuals collected during the research.

30.3 Allegations of misconduct in research and concerns regarding the ethical conduct of research projects are received by the University's 'Named Person' (NP). The NP, or their nominated alternate, will be a senior academic within the University with significant knowledge and experience of research. The NP or their alternate has responsibility for:

- Receiving any allegations of misconduct in research.
- Initiating and supervising the Procedure for investigating allegations of

misconduct in research.

- Reviewing documents or material provided by the relevant parties to investigate the allegation(s) of misconduct in research.
- Taking decisions at key stages of the Procedure.
- Maintaining the record of information during the investigation and subsequently reporting on the investigation with internal contacts and external organisations.
- Ensuring the accurate, timely and confidential transfer of information between all parties involved in any stage of the Procedure.

- 30.4 Allegations of misconduct in research may be conveyed to the University as the employer of the individual against whom the allegations are made, or in another capacity, such as the host or sponsor of the research. Those entitled to bring complaints about research are not restricted to being a member of staff (present or past) of the University.
- 30.5 The Staff and Student Misconduct in Research Procedure can be used to investigate matters of concern that are not allegations of misconduct in research, nor have been formally raised with the NP, however misconduct in research has been identified, or disclosed, or concerns have been raised. The misconduct may also have been highlighted through other means, such as in a report or noted in published material.
- 30.6 The University is aware of the different practices for each research discipline and sanctions for non-compliance with this Procedure will be dealt with depending on the severity of the breach, and in accordance with the University's staff and student disciplinary procedures.
- 30.7 In research, situations arise that might present as misconduct, but are the result of either a misunderstanding or a dispute between individuals. It may be possible to mediate or resolve such differences at the individual or local level or using an alternative procedure.
- 30.8 For the avoidance of doubt, misconduct in research includes acts of omission as well as acts of commission. Additionally, the standards by which allegations of misconduct in research are judged, should be those prevailing in the country in question and at the date that the behaviour under investigation took place.
- 30.9 Researchers should familiarise themselves with the Staff and Student Misconduct in Research Procedure, as well as the misconduct procedures and codes of practice and policies for collaborative partnerships. UEL researchers should be aware of the expected conduct, permissions required and ethical parameters to work within, in addition to their responsibilities to conduct their research projects with external partners to high standards of rigour and integrity.

Appendices

Ethics and Integrity Sub-Committee (EISC) template recruitment documents

The following templates are intended to assist researchers in compiling a handout of key information for prospective participants. It is not possible to provide a proforma that would be appropriate for all research projects. The templates are designed to provide a checklist of points, to ensure that researchers have included all of the necessary information. All recruitment templates are available in the '[Guides](#)' section on [Ethics Monitor](#) and on the Research Ethics and Integrity [webpage](#). The recruitment documents must include the University's official logo.

Participant Information Sheet

- Refer to the participant directly, i.e. 'You will be asked to...'
- The University approved Participant Information Sheet should be used for the project, as the documents have mandatory statements that must be included. The sections on the University's research integrity and data protection statements, disclaimer and the contact details for the Ethics, Integrity and Compliance Manager should not be removed. See point 7.8.
- Not all of the information given on the template will be appropriate for the proposed project. For research projects involving questionnaires/surveys and children or young people, researchers should amend the template accordingly. See Annexe 4 'Template Participant Information Sheet for Questionnaires/Surveys' and Annexe 5 'Example Child/Young Person Participant Information Sheet and Assent Form'.
- For mixed method projects involving qualitative and quantitative data collection, a separate Participant Information Sheet and Consent Form is necessary for each research activity. i.e., interviews, focus groups and questionnaires/surveys. See point 7.13.
- A separate Participant Information Sheet and Consent Form is also required for different participant groups e.g., parent/legal guardian, employees and students. Each Participant Information Sheet and Consent Form should be clearly labelled. See point 7.13.

Consent Form

- The Consent Form has clauses for participants to accept and the statements will be relevant for most research projects. If researchers choose to amend

the Consent Form, care should be taken to ensure that all of the salient points are included for the participant to agree to. See point 7.14.

- For projects involving those under the age of 18, consent should be obtained from a parent or legal guardian on behalf of the child or young person; however, an additional 'Assent Form' should be provided for the child or young person to assent to the project. See point 7.15.
- The template does not require the Consent Form to be witnessed by an individual, other than the Principal Investigator (PI). In most cases, ratification of the form by an independent third party would not be considered necessary; however, in experiments involving some physical exertion or examination (most notably in clinically related programmes of research) or the participant group is comprised of individuals or groups, who could be considered particularly vulnerable, it may be deemed reasonable to make provision for the Consent Form to be verified by a third party.

Privacy Notice

- The [Data Protection Act](#), (DPA), 2018 and the [UK General Data Protection Regulation](#) (GDPR), 2018 regulate how organisations use the personal data of living persons. Researchers have a responsibility to inform potential participants of how their personal data will be processed and participant's rights regarding how their data is managed.
- The Privacy Notice should be given to potential participants together with the Participant Information Sheet and Consent Form.

Annexe 1 - Template Participant Information Sheet

University of East London

Relevant campus address

Research Integrity

The University adheres to its responsibility to promote and support the highest standard of rigour and integrity in all aspects of research, observing the appropriate ethical, legal and professional frameworks, obligations and standards.

The University is committed to preserving your dignity, rights, safety and well-being and, as such, it is a mandatory requirement of the University that formal ethical approval, from the appropriate Research Ethics Committee, is granted before research with human participants, human material, human data, personal and/or sensitive data, pre-existing data collected from humans without their knowledge of inclusion of the information in a research project or non-human animal commences.

The purpose of this Participant Information Sheet is to provide you with the information that you need to consider in deciding whether to participate in this research project.

The Principal Investigator/Director of Studies

- Name(s)
- Contact Address(es)
- UEL telephone/email

Student researcher

- Name(s)
- Contact Address(es)
- UEL telephone/email

Collaborator(s)

- If appropriate, provide the names of any external contractors or partner institutions involved in the research and include their official logo.
- If appropriate, provide the names of any funding bodies or research councils supporting the research.

Project Title

Full title of the project

Project Description

- A short description of the project in lay language (a couple of sentences should suffice).
- An explanation of what the participants will be asked to do e.g., a description of the project, focus groups, interviews, complete a questionnaire etc.
- A description of any hazard or risk.
- A description of any likely after-effects, discomfort or distress which might be experienced.
- A description of any aftercare which might be required.
- For research involving under those under the age of 18 or vulnerable groups, where true, a statement has been included on all information sheets that the investigators have passed appropriate Disclosure and Barring Service checks.
- A clear statement that where participants are in a dependent relationship with any of the researchers that participation in the research will have no impact on assessment / treatment / service-use or support.
- In the case of patients or participants undergoing treatment, explain whether the project forms part of their treatment and whether any benefit is to be gained from their participation.

Confidentiality of the Data

- A clear statement, that if the sample size is small, this may have implications for confidentiality / anonymity.
- A clear statement, that if the research involves focus groups this may have implications for confidentiality / anonymity.
- A clear statement, that where possible, participants' confidentiality will be maintained unless a disclosure is made that indicates that the participant or someone else is at serious risk of harm. Such disclosures may be reported to the relevant authority.
- A description of how the data will be stored and what steps will be taken to protect its confidentiality.
- An explanation of what will happen to the data once the project has been completed.
- A statement that the data generated during the research will be retained in accordance with the Data Protection Act, 2018 and the University's Data Protection Policy.

Data Protection statement

In compliance with the UK General Data Protection Regulation (GDPR), the University's lawful basis for the processing of personal data collected, used and retained for research purposes is the 'public task' condition. Therefore, the University does not rely on consent to process your personal data. However, the University will seek your consent to participate in this research project. Please see the following link for more information: [Data protection – University of East London \(UEL\)](#)

Location

Specify where the research is being conducted.

Remuneration

Specify the amount and terms and conditions of any payment that will be made.

Disclaimer

Your participation in this study is voluntary, and you are free to withdraw at any time during the research. Should you choose to withdraw from the project you may do so without disadvantage to yourself and without an obligation to give a reason. Please note, that your data can be withdrawn up to the point of data analysis – after this point it may not be possible if your data is anonymised.

Ethical approval for the research project has been granted by the Ethics and Integrity Sub-Committee (EISC).

If you have any concerns regarding the conduct of the research in which you are being asked to participate, please contact:

Catherine Hitchens, Ethics, Integrity and Compliance Manager, Office for Postgraduates, Research and Engagement, University of East London, Docklands Campus, London, E16 2RD. Telephone: 020 8223 6683. Email: researchethics@uel.ac.uk

For general enquiries about the research, please contact the Principal Investigator on the contact details at the top of this sheet.

Annexe 2 - Template Consent Form

Project title:

Name(s) of the researcher(s)

	YES	NO
I have read the information leaflet relating to the above research project in which I have been asked to participate and have been given a copy to keep. The nature and purposes of the research project have been explained to me, and I have had the opportunity to discuss the details and ask questions about this information. I understand what is being proposed and the procedures in which I will be involved have been explained to me.		
If participation is to be audio or video recorded, please state this and ask participants to confirm they consent.		
I understand that my involvement in the research project, and particular data from this research, will remain strictly confidential as far as possible. Only the researchers involved in the research project will have access to the data. <i>(Please see below)</i>		
I understand that maintaining strict confidentiality is subject to the following limitations: If the sample size is small, or focus groups are used state that that this may have implications for confidentiality / anonymity, if applicable. A clear statement that, where possible, participants' confidentiality will be maintained unless a disclosure is made that indicates that the participant or someone else is at serious risk of harm. Such disclosures may be reported to the relevant authority.		
Specify if anonymised quotes will be used in publications.		
Specify if the participant has the option to be named in publications.		
Give the proposed method(s) of dissemination and publication of the research findings.		



I understand that the data collected for the research project will be anonymised/pseudonymised before it is published.		
I understand that the University's lawful basis for processing my personal data collected, used and retained for research purposes is the 'public task' condition and the University does not rely on consent to process my personal data.		
I understand that the published results of the research project will be accessible in the public domain and may be deposited in an open access data repository.		
I understand that the published results of the research project will be accessible in the public domain and may be re-used, republished or re-analysed by others in future research.		
I give my permission for the research team to use the data that I have provided in future research projects which may be made publicly available.		
I give my permission for the research team to retain my personal contact details and contact me regarding participation in future research projects.		
It has been explained to me what will happen once the research project has been completed.		
I understand that my participation in this study is entirely voluntary, and I am free to withdraw at any time during the research without disadvantage to myself and without being obliged to give a reason. I understand that my data can be withdrawn up to the point of data analysis, and that after this point it may not be possible if the data is anonymised.		
I hereby freely and fully consent to participate in the study which has been fully explained to me and for the information obtained to be used in relevant research publications.		

Annexe 3 - Privacy Notice

Ethics and Integrity Sub-Committee (EISC) Privacy Notice

The University of East London adheres to the [Data Protection Act](#) (DPA) 2018 and [UK General Data Protection Regulation](#) (GDPR) 2018.

UK GDPR states that personal data is any information that can be used to identify a living person directly or as result of combinations of data relating to or being about a person. As a participant in a research project, the University has a responsibility to inform you of how we are collecting, using and managing your personal data. Fully anonymised data is not governed by UK GDPR, however data that has had identifiers removed or replaced to pseudonymise the data is classed as personal data for the purposes of UK GDPR.

The Data Protection Act 2018 is based around seven principles which grants a person specific rights in relation to their personal information, and places certain obligations on those organisations that are responsible for processing the information. The seven principles govern the collection, use, retention, transfer, disclosure and destruction of personal data. These principles are followed by the University of East London when processing personal data:

- **Lawfulness, Fairness and Transparency** – Personal data shall be processed lawfully, fairly and in a transparent manner;
- **Purpose Limitation** – Personal data shall be collected for specified, explicit and legitimate purposes and not used for other purposes where such use would be incompatible with the initial purpose;
- **Data minimisation** – Personal data shall be adequate, relevant and limited to what is necessary for the purpose it was collected;
- **Accuracy** – Personal data shall be accurate and, where necessary, kept up to date;
- **Storage Limitation** – Personal data shall be kept in a form which permits identification of data subjects for no longer than is necessary;
- **Integrity & Confidentiality** – Personal data shall be processed in a manner that ensures appropriate securing including protection against unauthorised or unlawful processing, and against accidental loss, destruction or damage to that data;

- **Accountability** – The University must be able to demonstrate how we comply with the law by ensuring that we have documented processes, procedures and policies in place.

Further guidance on data protection can be found on the University's website: [Data Protection | University of East London \(uel.ac.uk\)](#)

Information Rights

Every participant in a research project has rights associated with how their personal data is used and managed. Where an individual makes a request related to any of their information rights the University will consider each request in accordance with all applicable laws and regulations.

The Data Protection Act, 2018 gives you more control over your personal data by strengthening your information rights. These are:

- The right to be informed;
- The right of access;
- The right to rectification;
- The right to erasure (aka. The right to be forgotten);
- The right to restrict processing;
- The right to data portability;
- The right to object;
- Rights in relation to automated decision making and profiling.

More information about each of these rights is provided on the Information Commissioner's Office website: [Home | ICO](#)

You can submit an Information Rights request to the University quickly, easily and free of charge by completing an [Information Rights Request form](#) and emailing the form to dpo@uel.ac.uk.

Should you have any concerns about the conduct of the research project or management of your personal data please contact the Ethics, Integrity and Compliance Manager, Catherine Hitchens: researchethics@uel.ac.uk or the Data Protection Officer: dpo@uel.ac.uk

Appendix

University of East London website: [Data Protection | University of East London \(uel.ac.uk\)](https://www.uel.ac.uk/data-protection). Accessed 30th March 2022

ICO website: [Home | ICO](https://ico.org.uk/). Accessed on 30th March 2022

Annexe 4 - Template Participant Information Sheet for Questionnaires/Surveys

University of East London

Relevant campus address

Research Integrity

The University adheres to its responsibility to promote and support the highest standard of rigour and integrity in all aspects of research, observing the appropriate ethical, legal and professional frameworks, obligations and standards.

The University is committed to preserving your dignity, rights, safety and well-being and, as such, it is a mandatory requirement of the University that formal ethical approval, from the appropriate Research Ethics Committee, is granted before research with human participants, human material, human data, personal and/or sensitive data, pre-existing data collected from humans without their knowledge of inclusion of the information in a research project or non-human animal commences.

The purpose of this Participant Information Sheet is to provide you with the information that you need to consider in deciding whether to participate in this research project.

The Principal Investigator/Director of Studies

- Name(s)
- Contact Address(es)
- UEL telephone/email

Student researcher

- Name(s)
- Contact Address(es)
- UEL telephone/email

Collaborator(s)

- If appropriate, provide the names of any external contractors or partner institutions involved in the research and include their official logo.
- If appropriate, provide the names of any funding bodies or research councils supporting the research.

Project Title

Full title of the project

Project Description

- A short description of the project in lay language (a couple of sentences should suffice).
- Specify how long it will take to complete the form e.g., 10 minutes.
- State if the questionnaire/survey is anonymous.
- State if any of the questions are sensitive.
- State whether incomplete questionnaires/surveys will be included in data collection for the research project.
- State that submission of the questionnaire/survey indicates consent to participate in the research project. Once you have submitted the form it may not be possible to withdraw the questionnaire/survey from the research if the data is anonymised.
- If applicable, state that completing the survey will not have any impact on their learning journey, experience at the institution or outcomes of their study/qualification.

Confidentiality of the Data

- A description of how the data will be stored and what steps will be taken to protect its confidentiality.
- An explanation of what will happen to the data once the project has been completed.
- A statement that the data generated during the research will be retained in accordance with the University's Data Protection Policy.

Data Protection statement

In compliance with the UK General Data Protection Regulation (GDPR) the University's lawful basis for the processing of personal data collected, used and retained for research purposes is the 'public task' condition. Therefore, the University does not rely on consent to process your personal data. However, the University will seek your consent to participate in this research project. Please see the following link for more information: [Data protection – University of East London \(UEL\)](#)

Remuneration

Specify the amount, terms and conditions of any payment that will be made.

Ethical approval for the research project has been granted by the Ethics and Integrity Sub-Committee (EISC).

If you have any concerns regarding the conduct of the research in which you are being asked to participate, please contact:

Catherine Hitchens, Ethics, Integrity and Compliance Manager, Office for Postgraduates, Research and Engagement, University of East London, Docklands Campus, London, E16 2RD. Telephone: 020 8223 6683. Email: researchethics@uel.ac.uk

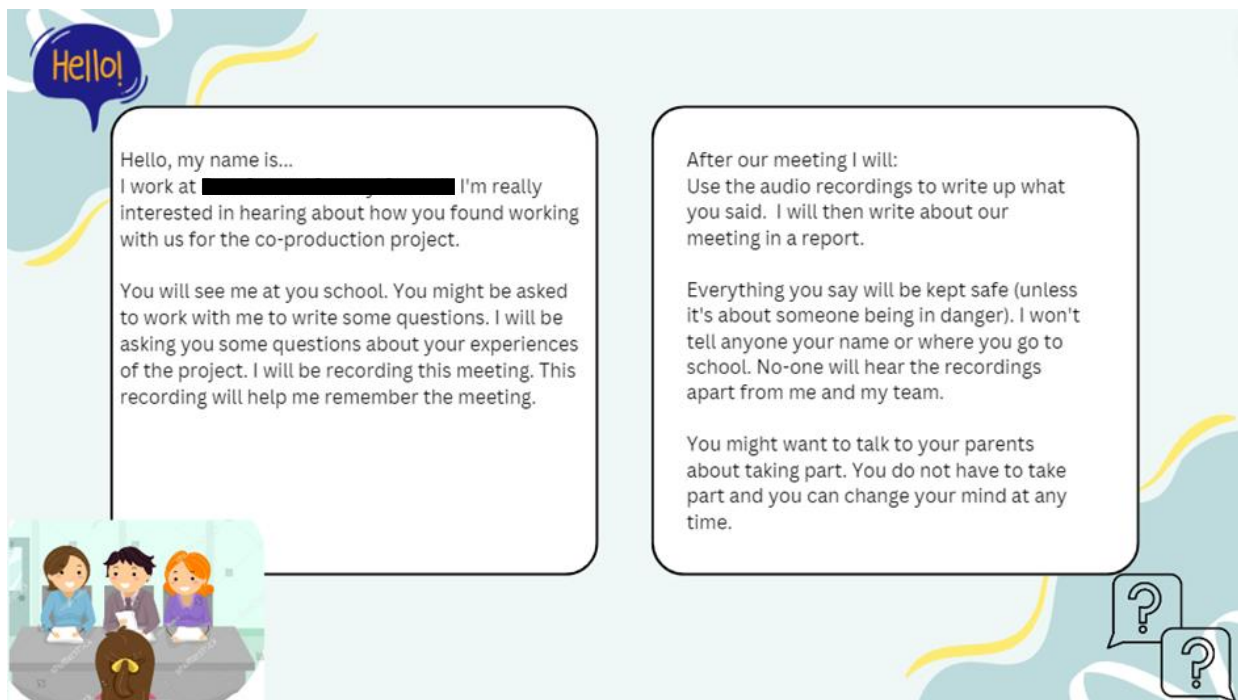
For general enquiries about the research, please contact the Principal Investigator on the contact details at the top of this sheet.

Annexe 5 - Example Child/Young Person Participant Information Sheet and Assent Form

The illustration given is to assist researchers in compiling a child/young person friendly document to inform the child/young person about the research project¹⁴.

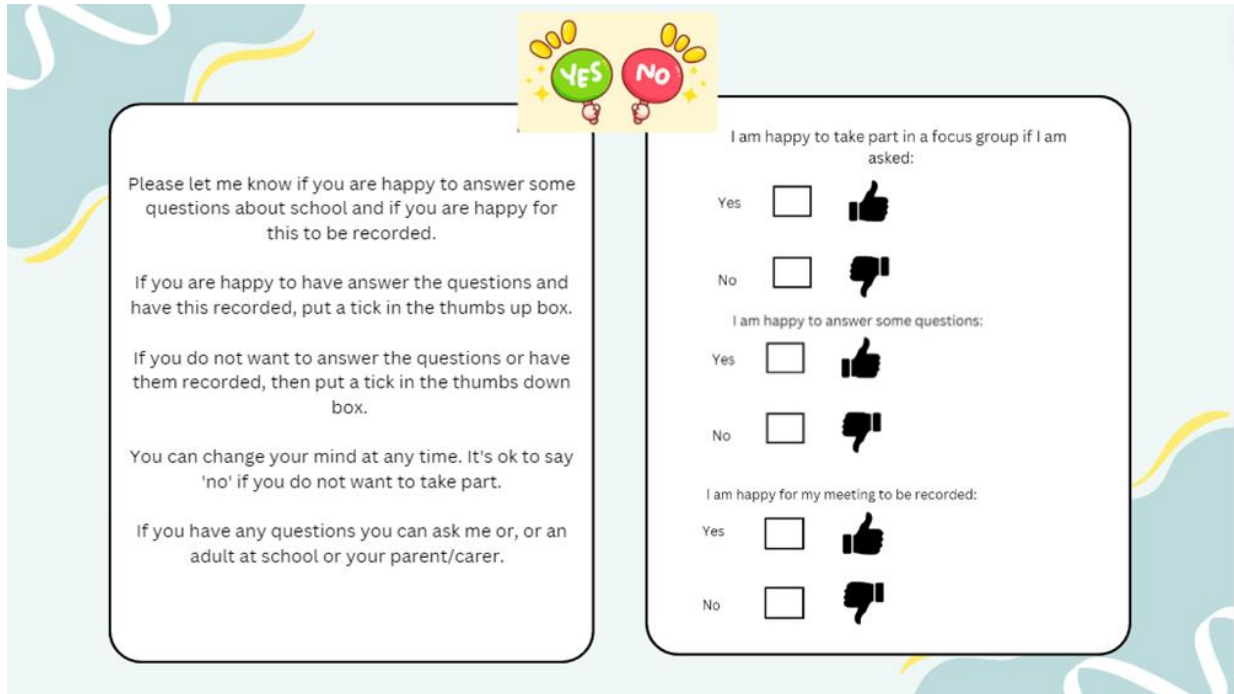
It is not possible to provide a model that would be appropriate for all research projects and researchers should ensure that the documents they provide for a child/young person are accessible.

Child Participant Information Sheet for primary aged participants



¹⁴ The Child and Young person Participant Information Sheet and Assent Form shown were created by Dr Pandora Giles, Academic & Professional Tutor, Doctorate in Educational and Child Psychology at the University of East London and Meg Best, SEND Participation Officer. Dr Giles and Meg Best kindly permitted the use of documents for this handbook in November 2023.

Child Assent Form for primary aged participants



The form is titled "Child Assent Form for primary aged participants" and is designed for children to indicate their willingness to participate in a focus group. It features a central header with two thumbs-up icons, one green labeled "YES" and one red labeled "NO". The form is divided into two main sections. The left section contains four paragraphs of instructions: 1) "Please let me know if you are happy to answer some questions about school and if you are happy for this to be recorded." 2) "If you are happy to have answer the questions and have this recorded, put a tick in the thumbs up box." 3) "If you do not want to answer the questions or have them recorded, then put a tick in the thumbs down box." 4) "You can change your mind at any time. It's ok to say 'no' if you do not want to take part." 5) "If you have any questions you can ask me or, or an adult at school or your parent/carer." The right section contains three sets of questions, each with a "Yes" and "No" option and a corresponding thumbs-up or thumbs-down icon. The first set asks "I am happy to take part in a focus group if I am asked:". The second set asks "I am happy to answer some questions:". The third set asks "I am happy for my meeting to be recorded:". Each question has a checkbox for "Yes" and a thumbs-up icon, and a checkbox for "No" and a thumbs-down icon.

YES **NO**

Please let me know if you are happy to answer some questions about school and if you are happy for this to be recorded.


If you are happy to have answer the questions and have this recorded, put a tick in the thumbs up box.


If you do not want to answer the questions or have them recorded, then put a tick in the thumbs down box.

You can change your mind at any time. It's ok to say 'no' if you do not want to take part.


If you have any questions you can ask me or, or an adult at school or your parent/carer.


I am happy to take part in a focus group if I am asked:

Yes 


No 


I am happy to answer some questions:

Yes 

No 

I am happy for my meeting to be recorded:

Yes 

No 

Young Person Participant Information Sheet for secondary-aged participants

Hi my name is...

I am a ...I would like to listen to the voices of children and young people!

I am doing research to find out more about how you found working with my team on the co-production project. I would like to work with you and the adults at your school to find out about what this experience was like for you. I will then be writing up this information in a report.

I hope that you would like to be part of my research. This information sheet will try and answer any questions you might have about the project, but please ask me if there is anything else you would like to know.

What will happen if I choose to take part?

I will come and meet you at school. You may be asked to work with me to write the questions you would like to be asked in the interview. I will then ask you these questions in an interview. This interview will be audio recorded to help me remember the meetings.

After this meeting, I will use the audio recordings to write notes of what you said. I will then use these notes to write a report.

Everything you say will be kept safe and confidential unless it is about someone being in danger. I won't tell anyone your name or where you go to school. Nobody will hear the audio recordings apart from me and my team.

Do I have to take part?

It's up to you if you would like to take part. You may want to talk to your parents/carers or adults at your school about the activities. You can also ask me any questions you like when you see me. I hope you do choose to take part, and that you find it a helpful experience.

If you do decide to take part, please tick the thumbs up in the consent form - thank you!

It's ok if you decide not to take part. You can change your mind at any time.

Young Person Assent Form for secondary aged participants

Please let us know if you are happy to answer questions in some interviews. We will work together to write the interview questions. Please also let us know if you are happy for the interview to be audio recorded.

If you are happy to answer some questions in an interview and for this to be audio recorded, put a tick in the thumbs up.

If you are not happy to answer questions in some interviews and would not like this to be audio recorded, put a tick in the thumbs down.

You can change your mind at any time. It's ok to say 'no' if you do not want to take part.

If you want to find out any more information, you can ask us at any time, or you can ask an adult at school or your parent/carer.

All of your information will be kept safe and confidential. We won't tell anyone your name or where you went to school. The only time we would tell someone your information is if we were worried about your safety or someone else's. Nobody will listen to the audio recordings except for the research team. Once we have compiled the notes from the interview, the recordings will be deleted.

I am happy to take part in a focus group if I am asked:

Yes 

No 

I am happy to take part in interviews:

Yes 

No 

I am happy for my interview to be audio recorded:

Yes 

No 

Annexe 6 - Example Adult with learning difficulties Participant Information Sheet

The illustration given is to assist researchers in compiling an accessible Participant Information Sheet for adults with learning difficulties¹⁵.

It is not possible to provide a suitable model for all research projects and researchers should ensure that the documents that they provide for adults with learning difficulties are appropriate.

PARTICIPANT INFORMATION SHEET FOR SURVEY WITH ADULTS

University of East London

Stratford Campus

Water Lane E15 4LZ



What is research?

Research is a careful investigation to find out the answer to an important question.

Research Integrity - doing research in an honest way:

The University takes its job very seriously to make sure research is done right. They follow all the rules and do things in an honest and fair way. They also care about your rights, safety, and feelings.

Studies undertaken at the University must go through the Research Ethics Committee to keep everyone safe and respected.

The purpose of this Participant Information Sheet is to provide you with information that will help you to decide whether you accept the invitation to take part in this study.

¹⁵ The Adult with learning difficulties Participant Information Sheet shown was created by Dr Darren Sharpe, Associate Professor, Reader and Nora Morocza, Research fellow. Dr Sharpe and Nora Morocza kindly permitted the use of the document for this handbook in December 2023.

The Principal Investigator/Director of Studies

Researcher name:

School/Institute/department:

The University of East London
Stratford Campus, Water Lane
London, E15 4LZ

Work telephone number:

The organisation that is supporting the research:

Name of lead:

Address:

Email:

Research title

Project title:



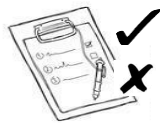
Why is this research being done?

We are inviting you to take part in this study because we are trying to learn more about:



Why me?

You have been chosen because you (...). You can help us to (...).



Do I have to take part?

If you don't want to take part in this study that is fine. Being in this study is up to you and no one will be upset if you don't want to participate.

Your non-participation in this study will have no impact on any assessments, services or healthcare treatment you receive.



What will happen?

If you agree to take part in this study, (Name of person) will share the survey with you on their work smartphone/computer at your next appointment.

After opening the survey link, we will ask you first to agree to participate in this study by ticking the consent box. After giving consent, we ask you three short questions that will take you 5 minutes.



What if I don't want to do the research anymore?

Please tell (Name of person) that you do not want to take part in the study. No explanation is needed.



What else might happen?

There are no risks to you in taking part in this study. The question topics in the survey are not upsetting and ask you to rate how involved you felt you were in your treatment.

The information that you share will be kept private, so nobody will be able to link your name to the answers. If you say something that makes it seem that you or someone else is at risk of harm, you will be informed by the team member that the information will be shared with (...). They will take the necessary steps to ensure that the person at risk gets help.

If you become distressed or upset at any point while involved in the study, you can stop your participation at anytime without giving an explanation.

The research team behind this study have up to date Disclosure and Barring Service checks.



What will happen with the information that you give us?

All the information we collect will be stored in a safe place, on the University's password protected folders. Only the people doing the study can see the information. Before sharing the study findings, information will be edited to protect your identity so no-one can link you to the study.

The study findings should help to improve (...). The key findings will appear in a written report for (...).

All data collected as part of this study will be destroyed two years following the end of the work.



Data Protection statement

No one outside of the research team will know what you have said in the survey, and we will not share your details with anyone, unless you are at risk of harm. We will have to inform the responsible person at the University and to get you help if we felt you were at risk of harm. In compliance with the UK General Data Protection Regulation (GDPR) the University's lawful basis for the processing of personal data collected, used and retained for research purposes is the 'public task' condition. Therefore, the University does not rely on consent to process your personal data. However, the University will seek your consent to participate in this research project. Please see the following link for more information: [Data protection – University of East London \(UEL\)](#)



Location

The study is coordinated from University of East London, Stratford Campus, Water Lane, E15 4LZ.



Did anyone else check the research is OK to do?

This study has been checked and approved by the UEL Ethics and Integrity Sub-Committee (EISC) to make sure it is ok.



What if I have concerns about the research?

If you have any concerns about the study, please contact:

Catherine Hitchens, Ethics, Integrity and Compliance Manager, Office for Postgraduates, Research and Engagement, University of East London, Docklands Campus, London, E16 2RD.

Telephone: 020 8223 6742. Email: researchethics@uel.ac.uk



You can also ask questions from the research team (Name of person and contact details).

Annexe 7 - Guidelines for a Gatekeeper permission request

The gatekeeper permission request should briefly explain the aims and objectives of the project and specify how the organisation can assist the researcher e.g., with recruiting participants on behalf of the researcher, providing the researcher with access to the lists of potential participants or permitting researchers to use the gatekeeper's premises.

Gatekeeper permission is separate from research projects that involve the NHS, where [Health Research Authority](#) (HRA) ethical approval is required. Researchers must follow HRA-NHS guidelines for seeking ethical approval to conduct research involving the NHS. See Section 17 'Applying for HRA-NHS ethical approval'.

Gatekeeper organisations should be given the opportunity to ask questions and, if appropriate, offered a summary of the findings or final report.

Letters to the gatekeeper requesting assistance must include the University's official logo or on UEL headed paper; however, email correspondence is acceptable. Researchers must use their UEL email account and postal address.

The gatekeeper permission letter must be signed and sanctioned by an appropriate senior person in the organisation who has the authority to approve the request. The person's name, job title and contact details must be given.

Confirmation of gatekeeper permission should be submitted with the ethics application form to the Ethics and Integrity Sub-Committee (EISC). If the researcher is unable to obtain consent/agreement from the gatekeeper in time to submit the application for ethical approval, by the deadline date, the researcher is permitted to submit the ethics application form without the gatekeeper permission letter. However, ethical approval cannot be granted for the research project, until EISC receives the gatekeeper's authorisation.

The request for support from gatekeepers will vary according to the nature of the research project and how the organisation can assist with the project. Researchers may wish to include the following information, but this list is not exhaustive:

- The title of the research project.
- The aims and objectives of the research project.
- The name and qualification of the degree, if applicable.
- The supervisor's name and contact details, if applicable.
- Details about the research team, if appropriate.
- A description of the assistance required from the gatekeeper.
- The proposed start date for the project.
- Specify where the research project will take place.
- Specify the method of data collection e.g., interviews or



questionnaires/surveys.

- State who will be responsible for data collection and where the data will be held.
- Specify any risks associated with the project.
- State that the data will be kept confidential, subject to the limits to confidentiality. See Annexe 1 'Template Participant Information Sheet'.
- State whether the gatekeeper will be acknowledged in the findings of the research or final report.

Annexe 8 - Guidelines for a Debrief Sheet

A Debrief Sheet may be required if the research project may cause emotional distress, or the participant would benefit from the assistance of support organisation(s) following their involvement in the research project. The Debrief Sheet will vary according to the research project and, as such, not all of the below points may apply. The Debrief Sheet must include the University's official logo or written on UEL headed paper.

The participant should be thanked for their contribution to the project and the recommended list of support organisations or services provided should be appropriate for the nature of the project.

Participants should be given the opportunity to ask questions and offered a summary of the findings or final report, if appropriate.

Researchers may wish to include the following information, but this list is not exhaustive:

- The title of the research project.
- In lay terms, briefly state the aims and objectives of the research project.
- If appropriate, specify how the participant's personal data will be kept confidential, where their personal data will be stored and for how long.
- If any form of deception was used, explain why the deception was necessary to conduct the research project and how the findings will be used, and provide participants with the opportunity to withdraw their consent and data from the project.
- If appropriate, specify the date that data analysis will commence.
- Specify that data can be withdrawn up to the point of data analysis, however after this point it may not be possible if the data is anonymised.
- Specify how participants can withdraw from the research project, if applicable.
- State where the findings will be published.
- If the participant may have been adversely affected by the project, provide the names and contact details of support organisations or services, both within UEL and externally.
- Include the name of researcher(s) and supervisor(s) and contact details.
- Include the contact details of the Ethics, Integrity and Compliance Manager to report any concerns about the project.

Annexe 9 - Guidelines for a Confidentiality agreement

The Confidentiality agreement must include the University's official logo or written on UEL headed paper, the full name, address and contact details of the researcher/Discloser, and the full title of the research project. See Annexe 10 for an example Confidentiality agreement.

The Confidentiality agreement submitted to the Ethics and Integrity Sub-Committee (EISC) should be blank.

The full name, address and contact details of the Recipient of the research data and confidential information, including the name of the company, if applicable, must be provided on the Confidentiality agreement.

The Recipient may be required to translate or transcribe the data. The agreement should be signed and dated by both the Discloser and the Recipient.

The Confidentiality agreement will vary according to the nature of the research project.

The information required for the Confidentiality agreement and example statements for the transcriber to agree to may include the following, but this list is not exhaustive:

- Outline the type of information to be disclosed.
- Specify the reason(s) for the data to be disclosed to the transcriber.
- The identity of the participants and the research data will be kept confidential and not discussed or shared with anyone other than the researcher.
- The research data will be kept in (insert format only).
- The research data will be encrypted and held securely.
- The research data will be used solely for the specified research project.
- The research data will not be discussed or provided to third parties without the consent of the researcher.
- The research data will not be stored on any third party storage service, unless the files are encrypted, and this is agreed by the researcher.
- The research data will not be copied, nor records kept without the permission of the researcher.
- Transcription of the research data will take place in a private, safe and secure location.
- Upon request from the researcher, the transcriber will return all data provided including documents, audio/video recordings, materials, copies, back-up records or any other information held, in any format, to the researcher and/or erased and destroyed.
- The agreement nor the collection of the research data grants the transcriber

any licence, interest or right in respect of the intellectual property rights of the researcher or others, except the right to transcribe the research data.

- The transcriber will inform the researcher within 24 hours, or as soon as practically possible, should there be a breach of the security of the research data, resulting in accidental loss, destruction, corruption or disclosure of confidential information.
- The transcriber will provide the researcher with sufficient information about the breach to inform the appropriate authorities.
- The transcriber will provide reasonable assistance to the researcher in the management of the breach.
- The transcriber is expected to abide by UK legislation regarding disclosure of confidential information, as required by law.
- This agreement does not prevent the transcriber disclosing confidential information required by law.
- The agreement is governed by and is to be construed in accordance with English law. The English Courts will have non-exclusive jurisdiction to deal with any dispute which has arisen or may arise out of, or in connection with, the agreement.
- I have read and understood the Confidentiality agreement and agree to be bound by its terms.

It is advisable that researchers obtain a copy of the transcriber's Data Protection and/or UK General Data Protection Regulation policy, to ensure that the data will be stored in accordance with UEL's data protection policies.

Annexe 10 - Template Confidentiality agreement

The example given is to assist researchers in compiling a Confidentiality agreement.

Parties:

[Name of individual/company receiving the information] of [postal and email address and telephone number of individual (**the Recipient**)

and

[Name, email address and telephone number of the researcher] (**the Discloser**)
University of East London, University Way, London, E16 2RD, United Kingdom

1. The Discloser intends to disclose [outline the types of information to be disclosed] (**the Confidential Information**) to the Recipient for the purpose of [insert details] (**the Purpose**).
2. The Recipient undertakes not to use the Confidential Information for any purpose except the Purpose, without first obtaining the written agreement of the Discloser.
3. The Recipient undertakes to keep the Confidential Information secure and not to disclose it to any third party.
4. The undertakings in clauses 2 and 3 above apply to all of the information disclosed by the Discloser to the Recipient, regardless of the way or form in which it is disclosed or recorded but they do not apply to: a) any information which is or in future comes into the public domain (unless as a result of the breach of this Agreement); or b) any information which is already known to the Recipient and which was not subject to any obligation of confidence before it was disclosed to the Recipient by the Discloser.
5. Should the Recipient become aware of any breach of security of the Confidential Information, resulting in the accidental loss, destruction, corruption or disclosure of the Confidential Information then the Recipient shall inform the Discloser of the nature of the breach within 24 hours of becoming aware of it. The Recipient shall provide reasonable assistance to the Discloser in the management of that breach.
6. Nothing in this Agreement will prevent the Recipient from making any disclosure of the Confidential Information required by law or by any competent authority.
7. The Recipient will, on request from the Discloser, either return all copies and records of the Confidential Information to the Discloser or securely destroy the Confidential Information and will not retain any copies or records of the Confidential Information after such a request.

8. Neither this Agreement nor the supply of any information grants the Recipient any licence, interest or right in respect of any intellectual property rights of the Discloser or others except the right to copy the Confidential Information solely for the Purpose.

9. The undertakings in clauses 2 and 3 will continue in force indefinitely.

10. This Agreement is governed by, and is to be construed in accordance with, English law. The English Courts will have non-exclusive jurisdiction to deal with any dispute which has arisen or may arise out of, or in connection with, this Agreement.

To be completed by the Recipient

I have read and understood the above agreement and agree to be bound by its terms

Name:

Date:

Signature:

To be completed by the Discloser

Name:

Date:

Signature:

Annexe 11 - Guidelines for a Model Release form

A Model Release form is normally required for visual representations. The form is an agreement between the researcher/photographer and the participant/model regarding how the material will be used and any conditions or restrictions.

The Model Release form must include the University's official logo or written on UEL headed paper, the name and contact details of the researcher and the title of the research project.

The Model Release form shown is a guide and the form may vary according to the nature of the research project¹⁶. Researchers are advised to consult the University's [Office for Compliance, Governance and Legal Services](#) to ensure that the Model Release form is appropriate for the research project.

The participant/model must be given a signed copy of the Model Release form, in addition to the UEL Participant Information Sheet, Consent Form and Privacy Notice.

Project title:

Name of course: *(if applicable)*

Start date of project:

Researcher(s) name:

Photographer(s) name: *(if applicable)*

Model's name:

Location:

Specify data collected: *(photograph, video, image)*

Consent	
The Model consents to the researcher using the material specified above for:	
Type	Yes/No
Online and physical publications	
Print and digital media	
Public display	
Portfolio display	
Exhibitions	
Social media	
Non-commercial publication in any media	

¹⁶ The form shown is based on the [Royal Photographic Society](#) Model Release form.



Commercial publication in any media	
Other (<i>specify</i>)	

The Model consents to the researcher using and displaying the material in:	
Location	Yes/No
The UK only	
The European Economic Area including the UK	
Globally	
Other (<i>specify</i>)	

Waiver/Agreement	
The Model will:	
Provision	Yes/No
Assign to the researcher and/or photographer any interest in the copyright of the material	
Waive any right to any further payment for the use of the material for any purpose to which the model has consented	
Consent to the material being modified in any manner	
Other (<i>specify</i>)	

Restrictions	
Condition	Yes/No
The model shall not be publicly named in association with any of the material unless the model agrees.	
The material shall not represent the model in any derogatory manner	
Other (<i>specify</i>)	

The University of East London's Data Protection policy sets out how the University collects, manages and stores your personal data. Please see the following link for information: [Data protection – University of East London \(UEL\)](#)



Date:	
Signatures:	
Signed by the researcher and/or photographer:	Signed by the Model:

Annexe 12 - Material Transfer Agreement Questionnaire

A Material Transfer Agreement (MTA) is a legal contract that regulates the transfer of materials between the owner or authorised licensee; the 'Provider' and the 'Recipient' of the material. Material can also include the transfer of data which is relevant to the material.

The MTA questionnaire provides a summary of information about the researcher(s), project details, material, funders, collaborators and any associated costs.

The MTA questionnaire must be completed in full and submitted with the relevant Material Transfer Agreement to UEL's [Office for Compliance, Governance and Legal Services](#) (OCGLS).

Each section is mandatory

Contact details of UEL Recipient

Name:	
School / Institute / Department:	
Email address:	
Telephone number:	
Name of student (if applicable):	
Email address of student:	
Name of Principal Investigator / Supervisor:	
Email address of Principal Investigator / Supervisor:	

Contact details of Provider

Name of Researcher / Provider:	
Email address of Researcher / Provider:	
Name of organisation / institution:	
Address of organisation / institution:	
Telephone number organisation/ institution:	
Is the Provider a non-profit organisation?	

Project details

Title of research project.	
Provide a brief description of the project and how the material will be used.	



Is ethical approval required for the project?	
If yes, provide the reference number for ethical approval.	
Will you ask the Provider to grant UEL a licence for the results for UEL's internal research and academic use?	
What is the anticipated benefit of the research?	
Will the research be published?	
If yes, provide further information.	
Are there any restrictions on publishing the research?	
If yes, provide further information.	
Will the Provider be named as an author for the research project?	
If yes, provide further information.	

Funders

Is the research project funded?	
If yes, specify the name(s) of the funder(s):	
Address of funder(s):	
Email address of funder(s):	

Collaborators

Is this a collaborative project?	
If yes, specify the name(s) of the collaborator(s):	
Address of collaborator(s):	
Email address of collaborator(s):	
Do you need to provide the collaborator(s) with access to the material?	
If yes, provide further information.	
Is the project part of a larger/significant collaboration?	
If yes, provide further information.	
Does UEL have permission to send the material to a third party for collaboration?	
If yes, provide further information.	



Materials

Provide the name and a description of the material.	
Specify who is responsible for the material.	
Specify the names of those with access to the material.	
Specify the quantity of the material.	
Specify the date the material was created.	
Specify the term of the material.	
Specify where the material will be stored.	
Does the material contain relevant material that would fall under the Human Tissue Act 2004? ¹⁷	
If yes, provide further information.	
Has the material been transferred from overseas?	
If yes, provide further information.	
Will the material be used in a clinical trial?	
If yes, provide further information.	
Can the material be obtained from elsewhere?	
If yes, provide further information.	
Will you modify the material?	
If yes, provide further information.	
Will the material be combined with the material of a third party?	
If yes, provide further information.	
Are there any organisation(s), apart from the Provider, funder(s) and collaborator(s), who will require access to the material or the findings of the research?	
If yes, please specify the name(s) of the organisation(s).	
Are you aware of any existing agreements relating to the material, e.g. research contracts or collaborative	

¹⁷ [The Human Tissue Authority](#) (HTA) defines human tissue as relevant material which includes any material that contains one or more human cells. This includes but is not limited to serum, blood, urine, saliva, hair, nails and gametes.



agreements?	
If yes, please provide further information.	
Are you conducting research on the material under the guidance of the Provider?	
If yes, provide further information.	
Will you receive any payment for research conducted on the material?	
If yes, specify the amount.	
Does the material include personal, anonymised, pseudonymised or confidential data?	
If yes, provide a description of the data.	
Specify who is responsible for disposing the material.	
Do you have to notify the Provider when the material is disposed?	
If yes, provide further information.	
Are there any risks of a third party claim regarding use of the material?	
If yes, provide further information.	
Are you required to submit reports on the results of working with the material?	
If yes, provide further information.	

Insurance

Who is responsible for insuring the research project?	
Are there any concerns regarding liability claims?	
If yes, provide further information.	

Students

Will students, visiting researchers or other non UEL employees be working on the project using the material?	
If yes, provide further information.	
If students will be using the material, specify who is responsible for supervision of the student.	
If students will be using the material, will the research form part of their thesis or dissertation?	



If yes, provide further information.	
--------------------------------------	--

Costs

Is UEL required to pay any costs associated with the transfer of the material?	
If yes, specify the amount of the costs.	
Are there any additional fees to be paid by UEL?	
If yes, specify the amount of the costs.	
Are there any costs to be paid by third parties, excluding the funder(s)?	
If yes, specify the name(s) of the third parties.	
Specify the amount of the costs.	

Intellectual Property

Specify who owns the data.	
Specify who owns the intellectual property rights.	
Will the research create any commercial interest?	
If yes, provide further information.	
Will the research project create knowledge exchange?	
If yes, provide further information.	
Have you contacted UEL's Director of Research and Knowledge Exchange?	

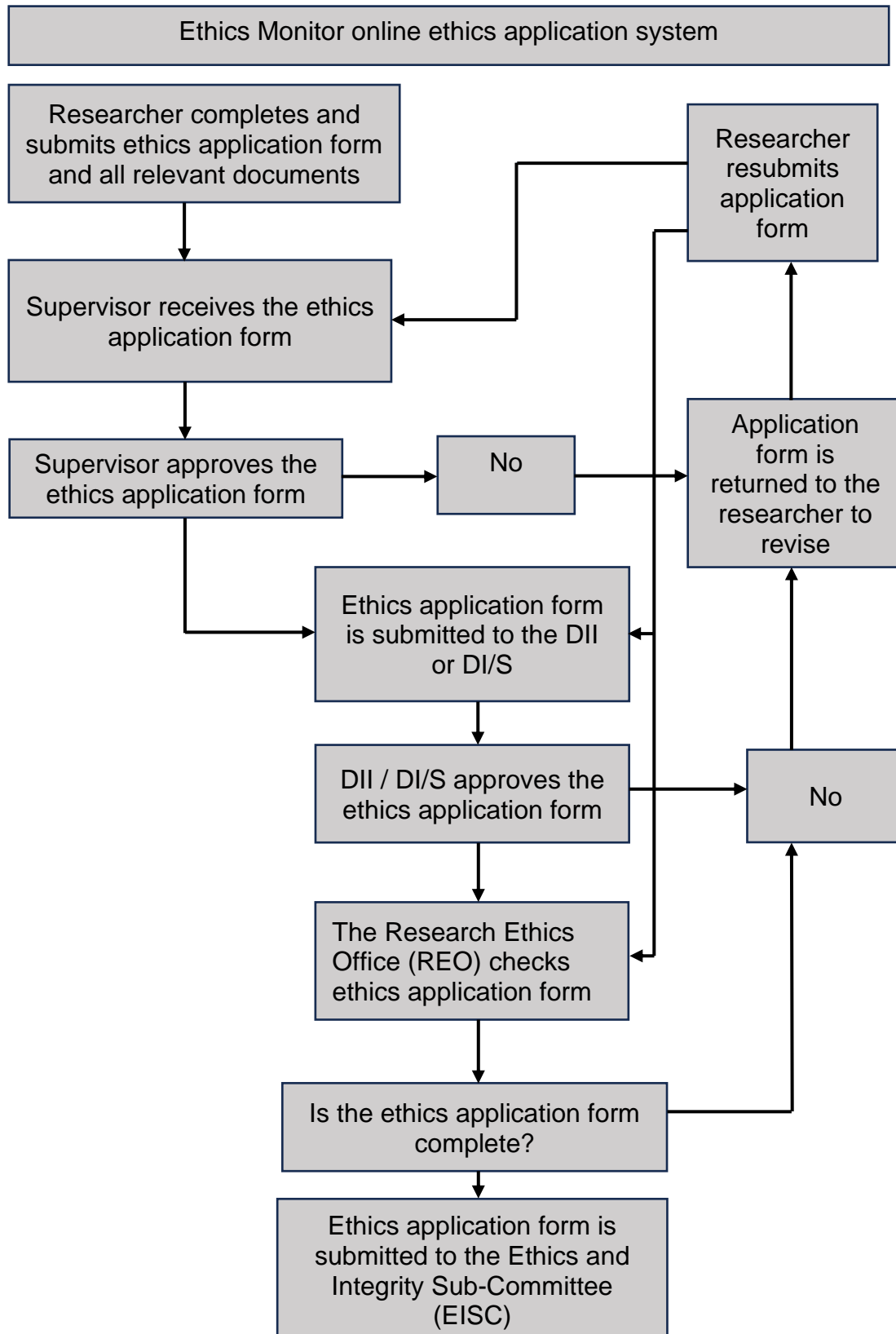
Further information

Please provide any further information about the transfer of the material below.

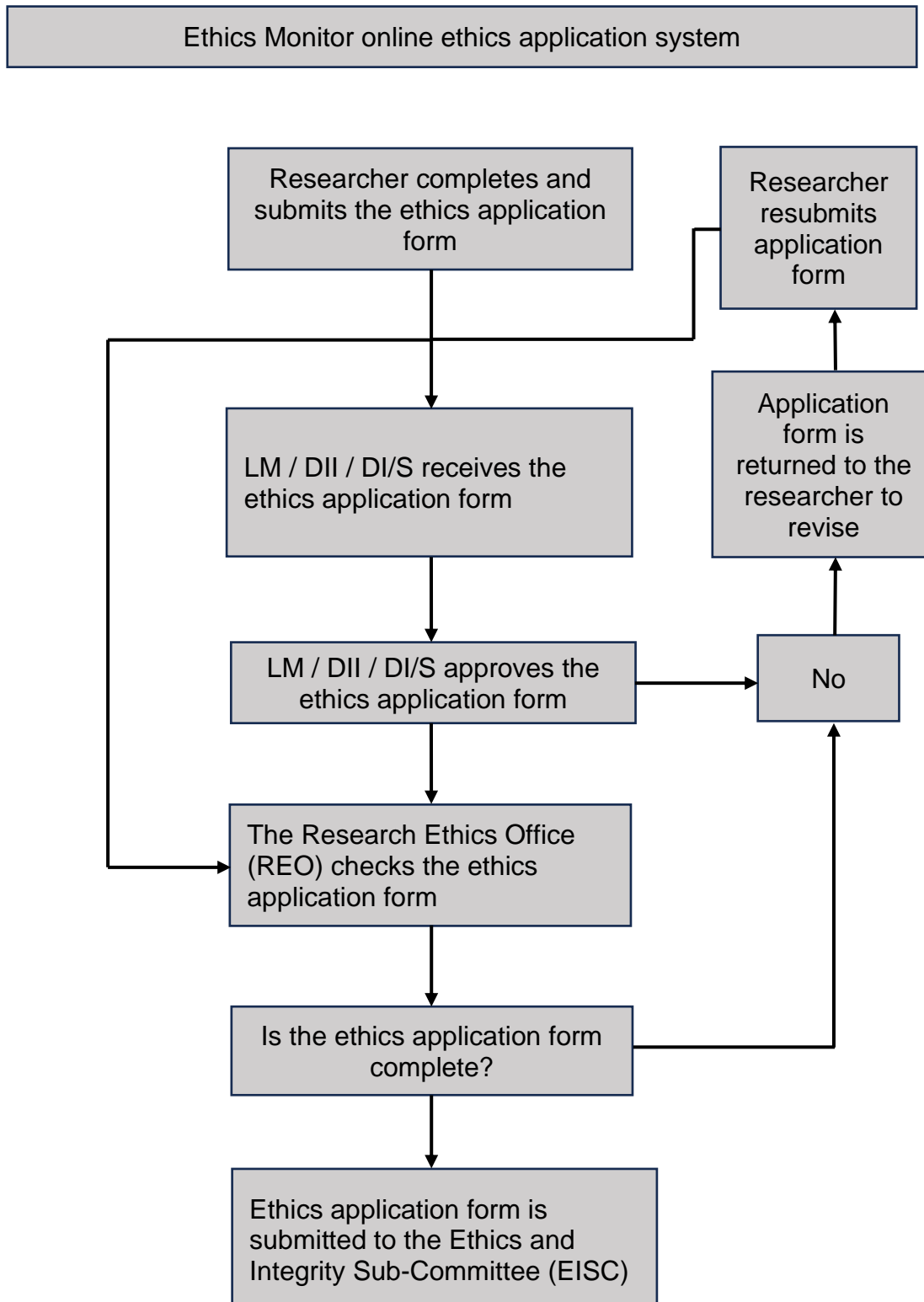
Please sign and date the questionnaire

Name:	
Signature:	
Date:	

Annexe 13 - Submission of an ethics application form Postgraduate Research Students (PGRs)



Annexe 14 - Submission of an ethics application form Academic and staff members



Annexe 15 – Ethics review checklist

The following checklist¹⁸ can be used as a guide to assess whether the ethics application form includes all of the information required for the Ethics and Integrity Sub-Committee (EISC), to complete a full review of the ethics of the research project. As this is a guide, some of the points listed may not apply to all research projects.

APPLICATION FORM

Have the aims, objectives and methodology for the research project been clearly explained?	
Does the research project comply with all legal requirements and other applicable guidelines, including those from other organisations or countries?	
Does the research project comply with the Data Protection Act, 2018 , UK General Data Protection Regulation, 2018 , Disclosure and Barring Service regulations and Health and Safety regulations?	
Does the research project comply with institutional and national policies on the Prevent duty and safeguarding children and vulnerable adults?	
Does the research project involve access to, or use of, material (including internet use) covered by the Terrorism Act (2006) and / or Counter-Terrorism and Border Security Act (2019) or which could be classified as security sensitive?	
Have the UEL Codes of Practice and Staff and Student Misconduct in Research Procedure been consulted?	
Are there any concerns regarding a conflict of interest that need to be addressed?	
Has intellectual property for the research project been determined?	
Does the research project require ethical approval from an external body?	
Have the funder's regulations for both UEL and external institutions, been consulted?	
Are contract(s) or funder(s) letters required?	
Are collaborator(s) or partner(s) ethics approval letter(s) required?	

¹⁸ Based on the checklists provided by the [UK Research Integrity Office](#) (UKRIO). [Recommended Checklist for Researchers](#) and [Researcher Checklist of Ethics Applications for Research with Human Beings](#).



Should the logo of the collaborator(s) or partner(s) institution/organisation be included on recruitment documents?	
Are gatekeeper permission letter(s) required?	
Is a permission letter from an appropriate senior person at UEL required to advertise the research project?	
Have the roles and responsibilities of the research team been specified?	
Are the necessary resources for the research project available?	
Has the location for the research project been specified?	
Will the research project take place off UEL campus?	
Will the research project take place in another country?	
Does the research project raise ethical issues that may impact on the natural environment over and above that of normal daily activity?	
Has the method of recruitment of the participant been specified?	
Has a risk assessment been completed that addresses potential risks to the health, safety and well-being of the participant and the researcher?	
Does the risk assessment and due diligence check consider potential risks to the security of the research data, integrity of the research, the environment and the University?	
Has a process for reporting an adverse event/reaction been specified?	
Does the research project involve secondary research, secondary data or analysing an existing data set?	
Does the research project involve data collected online via social media, advertising the project online or via social media, or include a questionnaire/survey?	
Are permission letter(s) required to use internet-mediated data or secondary data?	
Is the participant able to give informed consent (in written or verbal form)?	
Has the participant been given sufficient time to decide whether they wish to be part of the research project?	
Has the issue of pressure to participate been addressed?	
Is the remuneration for the participant clear and proportionate?	



Will the participant be audio or video recorded?	
Will the audio and video recordings be deleted?	
Has the anonymisation/pseudonymisation method/process been specified?	
Will the data be shared with person(s) outside of the research team?	
Will the data be transcribed or translated?	
Has the duration, security and storage of Consent Forms, transcripts and personal data been specified?	
Will data collection take place outside of the UK?	
Is a Data Protection Impact Assessment required?	
Has a Data Management Plan been completed, reviewed and signed by Library, Archives and Learning Services?	
Is a Material Transfer Agreement required?	
For HRA-NHS research projects, has an IRAS application form, Local Information Pack and a PDF printout of the final document upload page been included? Is the version number given on all recruitment documents?	
Has an 'amendment tool' been included for amendments to existing HRA-NHS research projects?	
Will the participant be anonymised in the publications of the findings?	
Have the methods of dissemination of the findings of the research project, such as a thesis, journal articles, book chapters, pre-prints, reports or a conference presentation, been specified?	
Has authorship and the acknowledgement of collaborator(s) or partner(s) been determined?	

RESEARCH PROJECTS INVOLVING CHILDREN OR YOUNG / VULNERABLE PEOPLE

Is a valid Disclosure and Barring Service certificate in place for all researcher(s) involved in the project?	
Does the application form specify how children or young/vulnerable people will be recruited?	



Does the application form specify how parent/legal guardian consent will be obtained?	
Has a bespoke child or young/vulnerable person friendly Participant Information Sheet been compiled?	
Has a bespoke child or young/vulnerable person friendly Assent/Consent Form been compiled?	
Has a bespoke child/young person or adult with learning difficulties Participant Information Sheet been compiled?	
Has a bespoke child/young person or adult with learning difficulties Assent/Consent Form been compiled?	

PARTICIPANT INFORMATION SHEET - PIS

Has the UEL PIS template been used?	
Is the PIS on UEL headed paper?	
Does the PIS refer to the participant directly i.e., 'You'?	
Are the researcher(s) and principal investigator(s) UEL contact details specified?	
Has a separate PIS been used for individual participant groups and methods of data collection?	
Is the aim of the research project clearly explained in lay terms?	
Specify what the participant is being asked to do to contribute to the research project?	
Specify the location of the research project?	
State that participation in the project is voluntary and participants can withdraw from the study at any time, without having to give a reason?	
State that the participant will be remunerated?	
State that the data generated during the research will be retained in accordance with the Data Protection Act, 2018 and the University's Data Protection Policy .	
State that the University's condition for complying with the UK General Data Protection Regulation, 2018 is 'public task'?	



Specify the limits to confidentiality, in the event of a disclosure of harm to the participant or others?	
Clearly state that confidentiality cannot be guaranteed, particularly with small sample sizes or focus groups?	
Specify whether the participant will be audio or video recorded?	
Clearly state how the participant's contribution will be anonymised/pseudonymised?	
Specify who will have access to the research and personal data?	
Specify the point up to which data can be withdrawn?	
State how the findings of the research will be disseminated?	
Specify who to contact, should the participant have concerns about the conduct of the research project?	

CONSENT FORM - CF

Has the UEL CF template been used?	
Does the CF include UEL's official logo?	
STATEMENTS	
Include a statement to obtain the participant's confirmation that they have read the PIS for the project and have been given a copy to keep.	
Include a statement to obtain the participant's confirmation that they understand what is being proposed for the research project and their involvement has been explained?	
Include a statement to obtain the participant's confirmation that the nature and purposes of the research project have been explained and the participant has had the opportunity to discuss the details and ask questions.	
State that participation in the project is voluntary and the participant can withdraw from the project at any time, without having to give a reason?	
Specify whether the participant will be audio or video recorded?	
Specify that there are limits to confidentiality, if there are disclosures of harm to the participant or others, and such disclosures will be reported to the relevant authority?	

Include a statement for the participant to give their consent for the findings to be published?	
Include a statement to obtain the participant's consent to include the data provided for future research projects?	
Include a statement to obtain the participant's consent to retain the participant's personal data, permitting the researcher to contact the participant and inform them of future research projects?	

APPENDICES

Has confirmation of the funding or a contract been included?	
Has confirmation of the collaborator(s) or partner(s) ethical approval and/or contribution to the research project been included?	
Has the gatekeeper permission request letter(s) been included?	
Has confirmation of the gatekeeper(s) agreement to contribute to the research project been included?	
Is a permission letter from the relevant administrator or an appropriate person been obtained to use data collected from social media.	
Is the Privacy Notice attached to the PIS and CF?	
Has a risk assessment/overseas risk assessment form been completed and signed by the appropriate person(s)?	
Has a Data Management Plan been included?	
Has a Data Protection Impact Assessment been included?	
Has a Debrief Sheet been included?	
Has a Confidentiality agreement been included?	
Has a Model Release form been included?	
Has a Material Transfer Agreement been included?	
Have the interview questions/indicative topic guide been included?	
Has the questionnaire/survey been included?	
Has the poster/advertisement/text for recruiting participants been included?	

Annexe 16 - Collaborative research partnership checklist

The following checklist¹⁹ can be used as a guide to ensure that the structure and practices of a collaborative partnership have been considered and addressed; however, this list is not exhaustive.

CHECKLIST

Have the aims, objectives and methodology for the research project been clearly explained to all partners?	
Do all partners have a clear understanding of their role and responsibilities in the collaboration?	
Have research integrity considerations, relevant guidelines and legislative requirements applying to the research activity been identified and incorporated into the design of the research activity?	
Have the partners agreed to comply with all legal requirements and other applicable guidelines, including those from other organisations or countries?	
Have the partners agreed to comply with the Data Protection Act, 2018 , UK General Data Protection Regulation, 2018 , Disclosure and Barring Service regulations and Health and Safety regulations?	
Does the research project involve access to, or use of, material (including internet use) covered by the Terrorism Act (2006) and / or Counter-Terrorism and Border Security Act (2019) or which could be classified as security sensitive?	
Does the research project comply with institutional and national policies on the Prevent duty and safeguarding children and vulnerable adults?	
Have the relevant regulations, governance structures, codes of practice, data protection and management, and misconduct in research procedure for all parties been consulted?	
Have all conflicts of interest concerns been addressed and a plan to manage any new conflicts that arise during the collaboration been established?	

¹⁹ Based on the checklist provided by the [Research Integrity National Forum: Framework to Enhance Research Integrity in Research Collaborations, 2022](#).



Have the partner(s) agreed how authorship and/or intellectual property created will be managed in the collaboration, considering any disciplinary differences?	
Have the funder's regulations for the collaboration been consulted?	
Has the lead investigator/organisation been determined?	
Have all partner(s) ethics approval/permission letters been obtained?	
Are the necessary resources for the research project available?	
Does the research project require ethical approval from a professional body?	
Does the research project raise ethical issues that may impact on the natural environment over and above that of normal daily activity?	
Will data collection take place outside of the UK?	
Has a risk assessment been completed that addresses potential risks to the health, safety and well-being of the participant and researcher?	
Does the risk assessment and due diligence check consider potential risks to the security of the research data, integrity of the research, the environment and the University?	
Has a process for reporting an adverse event/reaction been specified?	
Is the anonymisation/pseudonymisation method/process clear?	
Have the partner(s) determined who will have access to the research data and where the data will be stored?	
Is a Data Protection Impact Assessment required?	
Is a Material Transfer Agreement required?	
If they arise, have plans for managing misconduct in research investigations been put in place?	
Have plans for open dissemination of research findings such as journal articles, book chapters, pre-prints, reports or a conference presentation, been specified?	

Annexe 17 - Security risk checklist

Researchers must be fully informed about the potential security risks associated with research projects. Addressing security risks in research projects requires a holistic approach given its linkages to other departments and services within the University.

The following checklist can be used as a guide to assess possible risks, the action that should be taken and the researcher's responsibilities. The checklist is not exhaustive.

Risk	Action	Researcher responsibility
Nature of research activity	A research risk assessment form and, if necessary, an overseas risk assessment form must be completed and authorised by the Dean/Director of Impact and Innovation (DII) for the School or the Director of the Institute/Service (DI/S).	To keep risk assessments under review for the duration of the research project. Contact the Ethics and Integrity Sub-Committee (EISC) if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction. Complete an ethics amendment form should any changes warrant ethical approval.
Type of data collected	If there are implications for national security, commercially or security sensitive data or dual use of the data, UEL's Office for Compliance, Governance and Legal Services (OCGLS), Ethics Advisory Committee (EAC) ²⁰ and	Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.

²⁰ UEL's Ethics Advisory Committee (EAC) is a separate committee to EISC, which provides



	<p>other relevant departments such as the Data Protection Office (DPO) or IT Services (ITS) Information Security (IS) should be contacted for guidance on data capture and management.</p> <p>Consult the publisher's guidance on duplication of research data, self-plagiarism and text recycling. Previously published manuscripts should not be submitted for publication, as a separate project without referencing the original work.</p>	<p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p>
Location	<p>A research risk assessment and, if applicable, an overseas risk assessment form must be completed and authorised.</p> <p>For remote data collection, confirm the identity of the participant and ensure that they meet the inclusion criteria for the project.</p>	<p>Discuss any concerns about the location of the research with the supervisor of the project, an appropriate person or EISC.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p> <p>Complete an ethics amendment form should any changes warrant ethical approval.</p>
Overseas travel	<p>An overseas risk assessment form must be completed and authorised before travel arrangements are confirmed.</p>	<p>Adhere to the guidance given and contact the relevant departments should any issues arise.</p>

operational oversight of collaborative partners, UEL associates and those linked to the University. The EAC also has responsibility for reviewing conflicts of interest and ensuring that UEL's vision, mission, principles and core values are upheld.



	<p>Researchers should be aware of specific risks in the country and follow any mitigating actions suggested by the Foreign Commonwealth Office and UEL's travel provider, AIG Travel Guard.</p> <p>UEL's Insurance Office (IO) and Health, Safety and Well-being Office (HSW) should be contacted for guidance.</p>	<p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p> <p>Complete an ethics amendment form should any changes warrant ethical approval.</p>
Safeguarding	<p>For research projects with children, adults at risk and vulnerable people, if required, ensure that a Disclosure and Baring Service check (DBS) is undertaken, and a certificate is obtained. For research projects conducted overseas, an equivalent credential or appropriate permissions must be sought and obtained before the research project commences.</p> <p>Consult UEL's Safeguarding policy and Safeguarding Officers, based in Student Services or EISC for guidance.</p>	<p>Ensure that the supervisor of the project, or an appropriate person, has been kept informed of any issues concerning the research.</p> <p>Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p>
Technology and software	<p>All systems and platforms used should be compliant with the Data Protection Act, (DPA) 2018 and the UK General Data</p>	<p>Adhere to the guidance given and contact the relevant departments should</p>



	<p>Protection Regulation, (GDPR) 2018.</p> <p>Consult the DPO, ITS and IS for guidance.</p>	<p>any issues arise and report any concerns.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p>
<p>Confidentiality of participant and stakeholder data</p>	<p>A Data Management Plan (DMP) must be completed.</p> <p>Ensure that there is a clear anonymisation/pseudonymisation procedure in place to protect the identity of participants in the research project.</p> <p>Minimise the accessibility of the data to the research team and authorised individuals.</p> <p>Consult the DPO, ITS, IS or EISC for guidance.</p>	<p>Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p>
<p>Security and storage of research data</p>	<p>A DMP must be completed.</p> <p>Data should be stored on UEL's IT server and on Microsoft OneDrive. Data should be transferred to Microsoft OneDrive as soon as possible. Avoid retaining hard copies of data.</p> <p>The data controller for the project must be specified. If research data will be stored on a collaborator(s) or partner(s) server, this should be made clear to participants and on the DMP and authorised by the DPO or ITS.</p> <p>Researchers should be aware of</p>	<p>Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.</p> <p>Update the DMP with any changes required.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p>



	<p>the data protection and data management policies of any collaborator(s), particularly international partner(s), as UK data protection laws may differ to international regulations. International partners are required to abide by the law of their home countries.</p> <p>Consult the DPO, Library, Archives and Learning Services (LALS), ITS, IS or EISC for guidance.</p>	<p>Complete an ethics amendment form should any changes warrant ethical approval.</p>
Researcher safety	<p>Ensure that a system is in place to maintain contact with the supervisor or an appropriate person, throughout the research project, particularly if the project is taking place overseas. A process should be established if assistance may be required out of office hours.</p> <p>Consult the HSW webpages for guidance on welfare.</p>	<p>Ensure that the supervisor of the project, or an appropriate person, has been kept informed on the progress of the research and any issues.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p> <p>Complete an ethics amendment form should any changes warrant ethical approval.</p>
Adverse events/reactions	<p>Be aware of the process for reporting adverse events/reactions occurring in the research project and incidental findings for UEL, collaborator(s) and partner(s).</p>	<p>Ensure that the supervisor of the project, or an appropriate person, has been kept informed on the progress of the research project and</p>



		<p>any issues.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p> <p>Complete an ethics amendment form should any changes warrant ethical approval.</p>
<p>Collaborator(s) or partner(s)</p>	<p>Ensure all approvals and permissions are in place prior to the research project commencing for each party. Maintain written agreements and records confirming the terms of the collaboration. Each party should be clear about their contractual obligations.</p> <p>Consult the collaborator(s) or partner(s) policies for research, codes of practice, funding and the terms and conditions of any contracts.</p> <p>Be aware that international partners' protocols, may not be comparable with UK regulations and controls. The democratic values and ideals of the collaborator(s) or partner(s) may also differ from UEL's.</p> <p>Consult the OCGLS and EAC if there are any concerns about the conduct of the collaborator(s) or partner(s).</p>	<p>Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.</p> <p>Ensure that the supervisor of the project, or appropriate person, has been kept informed on the progress of the research project and any issues.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p>
<p>Funders</p>	<p>Maintain written agreements and</p>	<p>Adhere to the</p>



	<p>records confirming the funding of any monies or resources obtained to conduct the research project. Funding acquired from international partners may require additional due diligence and security checks. Each party should be clear about their contractual obligations.</p> <p>Consult the OCGLS and EAC if there are any concerns about the conduct of the funder or the origin of the resources.</p>	<p>guidance given and contact the relevant departments should any issues arise and report any concerns.</p>
Conflict of interest	<p>Inform relevant parties if there is a possible or real conflict of interest. If the research project is funded, the awarding body should be informed of any conflicts of interest at the earliest opportunity.</p> <p>Consult the OCGLS and EAC for guidance.</p>	<p>Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.</p> <p>Ensure that the supervisor of the project, or an appropriate person, has been kept informed on the progress of the research project and any issues.</p>
Intellectual property	<p>Determine ownership of the intellectual property created by the research project at the earliest opportunity.</p> <p>Consult the OCGLS and EAC for guidance.</p>	<p>Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.</p> <p>Ensure that the supervisor of the project, or an appropriate person, has been kept informed on the progress of the research and any issues.</p>



<p>Prevent Duty and Freedom of speech and Academic freedom</p>	<p>Consult UEL's Prevent duty, Freedom of speech and academic freedom guidance.</p> <p>Ensure that the research activity undertaken does not promote or encourage terrorism, incite hatred on the grounds of race, religion or sexual orientation, or conflict with the fundamental rights of others.</p> <p>Consult the OCGLS and EAC for guidance.</p> <p>Ensure that the supervisor, DII, or DI/S are aware of the research project and its potential risks.</p>	<p>Adhere to the guidance given and contact the relevant departments should any issues arise and report any concerns.</p> <p>Ensure that the supervisor of the project, or an appropriate person, has been kept informed on the progress of the research project and any issues.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the EISC procedure for reporting an adverse event/reaction.</p>
<p>Reputational risk</p>	<p>If the project has the potential to cause reputational harm to UEL, consult the OCGLS and EAC at the earliest opportunity. UEL's IO and Communications Office (CO) can also provide guidance.</p> <p>Ensure that the supervisor, Dean, DII or DI/S are aware of the research project and its potential risks.</p>	<p>Adhere to the guidance given and consult the relevant departments should any issues arise.</p> <p>Ensure that the supervisor of the project, or an appropriate person, has been kept informed on the progress of the research and any issues.</p> <p>Contact EISC if any adverse events/reactions occur during the research project. Follow the</p>



		EISC procedure for reporting an adverse event/reaction.
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Acknowledgement

Example Child and Young Person Participant Information Sheet and Assent Form provided by Dr Pandora Giles, Academic & Professional Tutor, Doctorate in Educational and Child Psychology at the University of East London and Meg Best, SEND Participation Officer, on 9th November 2023.

Example Adult with learning difficulties Participant Information Sheet provided by Dr Darren Sharpe, Associate Professor, Reader and Nora Morocza, Research fellow, on 20th December 2023.

UEL links

- Business Travel and Fieldwork policy: [Health and Safety Unit - Home \(sharepoint.com\)](#)
- Code of Practice for Postgraduate Research (PGR) degrees: [Student Policies | University of East London \(uel.ac.uk\)](#)
- Data Management Plan (DMP) – [Library, Archives and Learning Services](#)
- Data Protection: [Information Assurance at The University of East London \(sharepoint.com\)](#)
- Ethics Monitor: [ResearchUEL: Haplo](#)
- Health, Safety and Wellbeing: [Health, Safety and Wellbeing - Home \(sharepoint.com\)](#)
- HR Services: [HR Services - Home \(sharepoint.com\)](#)
- Insurance Office: [Insurance \(sharepoint.com\)](#)
- IT Services: [IT Services - Home \(sharepoint.com\)](#)
- Office for Compliance, Governance and Legal Services: [Governance \(sharepoint.com\)](#)
- Office for Institutional Equity: [Office for Institutional Equity - Home \(sharepoint.com\)](#)
- Open Access policy: [Open Access Policy: UEL Research Repository](#)
- Overseas risk assessment and research risk assessment form templates, DMP and Participant Information sheet and Consent/Assent Form [Guides: Haplo \(uel.ac.uk\)](#)
- Reporting An Adverse/Serious Adverse Event/Reaction: [Ethics and Integrity \(sharepoint.com\)](#)
- Repository: <https://repository.uel.ac.uk/>
- Research Ethics and Integrity webpage: [Ethics and Integrity \(sharepoint.com\)](#)
- Research Ethics Review Appeal procedure: [Ethics and Integrity \(sharepoint.com\)](#)
- Researcher Development Programme (RDP): [Researcher Development Programme \(sharepoint.com\)](#)
- Safeguarding Policy: [Safeguarding at UEL \(sharepoint.com\)](#)
- Staff and Student Misconduct in Research Procedure: [Ethics and Integrity \(sharepoint.com\)](#)
- Student HUB: [Welcome to the Student Hub \(sharepoint.com\)](#)

References

- AIG Travel Guard: [Travel Assistance \(salesforce-sites.com\)](https://salesforce-sites.com)
- Animals (Scientific Procedures) Act 1986: [Animals \(Scientific Procedures\) Act 1986 \(legislation.gov.uk\)](https://legislation.gov.uk)
- Association of Internet Researchers (AoIR): [Association of Internet Researchers \(aoir.org\)](https://aoir.org)
- Association of Research Managers and Administrators (ARMA): <https://arma.ac.uk/>
- British Educational Research Association: [British Educational Research Association | BERA](https://bera.ac.uk)
- British Psychological Society (BPS): [Homepage | BPS](https://www.bps.org.uk)
- Committee on Publication Ethics (COPE): [COPE: Committee on Publication Ethics | Promoting integrity in scholarly research and its publication](https://www.copyright.com)
- Counter-Terrorism and Security Act, 2015: [Counter-Terrorism and Security Act - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- Counter-Terrorism and Border Security Act, 2019: [Counter-Terrorism and Border Security Act 2019 \(legislation.gov.uk\)](https://legislation.gov.uk)
- Data Protection Act, 2018: [Data protection: The Data Protection Act - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- Department for Education (DfE): [Department for Education - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- Disclosure and Barring Service check (DBS): [Disclosure and Barring Service - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- Economic and Social Research Council (ESRC): [Economic and Social Research Council \(ESRC\) – UKRI](https://www.esrc.ac.uk)
- Epigeum online courses: [Welcome to Epigeum's online courses - Epigeum Online Course System](https://www.epigeum.com)
- Ethical Research Involving Children: [International Charter for Ethical Research Involving Children \(childethics.com\)](https://www.childethics.com)
- Foreign and Commonwealth Office (FCO): [Foreign travel advice - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- Framework to Enhance Research Integrity in Research Collaborations: [Framework-to-Enhance-Research-Integrity-in-Collaborations.pdf \(iaa.ie\)](https://www.iaa.ie)
- Freedom of Information Act, 2000: [Freedom of Information Act 2000 \(legislation.gov.uk\)](https://legislation.gov.uk)
- GOV.UK: [Academic Technology Approval Scheme \(ATAS\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- GOV.UK: [Research Collaboration Advice Team: progress made from 2022 to 2023 - GOV.UK \(www.gov.uk\)](https://www.gov.uk)
- Health Research Authority (HRA): <https://www.hra.nhs.uk/>
- Human Tissue Act 2004: [Start \(www.nhs.uk\)](https://www.nhs.uk)



- Integrated Research Application System (IRAS): [IRAS Help - Using IRAS - New Users \(myresearchproject.org.uk\)](https://myresearchproject.org.uk)
- Information Commissioner's Office (ICO): [Information Commissioner's Office \(ICO\)](https://ico.org.uk)
- International Committee of Medical Journal Editors (ICMJE): [ICMJE | Home](https://www.icmje.org)
- Jisc National centre for AI: [A Generative AI Primer - National centre for AI \(jiscinvolve.org\)](https://www.jiscinvolve.org)
- Managing risks in international research and innovation Universities UK, Centre for the Protection of National Infrastructure (CPNI) and UK Research and Innovation: [Managing risks in international research and innovation \(universitiesuk.ac.uk\)](https://www.universitiesuk.ac.uk)
- Medicines for Human Use (Clinical Trials) Regulations 2004: [The Medicines for Human Use \(Clinical Trials\) Regulations 2004 \(legislation.gov.uk\)](https://www.legislation.gov.uk)
- Mental Capacity Act (MCA) HRA support guide: [Mental Capacity Act - Social care and support guide - NHS \(www.nhs.uk\)](https://www.nhs.uk)
- Montreal Statement on Research Integrity in Cross-Boundary Research Collaborations: [Montreal Statement - WCRIF - The World Conferences on Research Integrity Foundation](https://www.wcrif.org)
- National Protective Security Authority: [Trusted Research Guidance for Academia | NPSA](https://www.npsa.gov.uk)
- National Protective Security Authority: [Trusted Research guidance for Senior Leaders \(npsa.gov.uk\)](https://www.npsa.gov.uk):
- National Protective Security Authority: [Trusted Research | NPSA](https://www.npsa.gov.uk)
- Nature: [Nature](https://www.nature.com)
- NHS decision tool: <https://www.hra-decisiontools.org.uk/ethics/>
- NSPCC: [NSPCC | The UK children's charity | NSPCC](https://www.nspcc.org.uk)
- QAA: ChatGPT and Artificial Intelligence: [ChatGPT and artificial intelligence \(qaa.ac.uk\)](https://www.qaa.ac.uk)
- Regulation (EU) 2016/679 of the European Parliament and of the Council: <https://www.legislation.gov.uk/eur/2016/679/contents>
- Royal Photographic Society: [rps-model-release-form-pdf.pdf](https://www.rps.org.uk)
- Russell Group Principles on the use of generative AI tools in education: [rg_ai_principles-final.pdf \(russellgroup.ac.uk\)](https://www.russellgroup.ac.uk)
- Safeguarding Vulnerable Groups Act 2006: [Safeguarding Vulnerable Groups Act 2006 \(legislation.gov.uk\)](https://www.legislation.gov.uk)
- The British Medical Journal (BMJ): [The BMJ: Leading Medical Research, News, Education, Opinion](https://www.bmj.com)
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[Code of Conduct for Research Integrity, 2023](#)

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- The Royal Society: [Welcome to the Royal Society | Royal Society](#)
- UK Data Service: [UK Data Service](#)
- UK General Data Protection Regulation (GDPR): [General Data Protection Regulation policy - GOV.UK \(www.gov.uk\)](#)
- UK Policy Framework for Health and Social Care Research: [UK Policy Framework for Health and Social Care Research - Health Research Authority \(hra.nhs.uk\)](#)
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The handbook will be reviewed by the University's Impact and Innovation Committee and Executive Board every three years, unless there are significant changes to legislation, regulations or guidelines that govern the practices of good research conduct and positive research cultures which requires revision of the handbook.

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