Recommended Guide for Ethics Reviewers

This Guide by the REO Research Governance team lists key points to consider when reviewing research ethics applications and can assist reviewers in ensuring that important issues are not overlooked. More detailed guidance is available on REO Research Governance website.

Project title	The project title must be concise, written in plain English, consistent throughout the participant facing documents (i.e. participant information sheet; consent form; research tools; advertising material, etc) and match the title of any external funding award. If the applicant is applying for ethical approval for a taught module, they should include the module code followed by the title.
Applicant(s)	The named Principal Investigator must hold an employment contract or be a registered student at the University of Essex. The Principal Investigator for doctoral student projects will be the student who must also add details of their Supervisor(s).
Proposed start date	A project must not start until notification of a favourable ethical opinion has been received. This includes recruiting participants. Retrospective approval cannot be given. The applicant needs to allow sufficient time between the submission of the application and the proposed start date for an ethics review at the appropriate level to be undertaken. The ERAMS will not permit applicants to enter a start date which is within two weeks of the date of the creation of an application.
Expected end date	A favourable ethical opinion is granted up to the expected end date of the project. If the project will not be completed by this date, an extension to a favourable ethical opinion must be sought by submitting an amendment through the ERAMS. This must be done in sufficient time for approval of the amendment to have been granted before the original favourable ethical opinion expires. A favourable opinion will only exceptionally be granted for more than three years. An amendment to extend the favourable opinion will then need to be submitted to extend the project beyond three years. A new application will be required if a project is to continue beyond six years. This is to ensure that the procedures and documentation comply with current best practice. The ERAMS reference numbers of previous applications should be provided at the start of the 'Summary of the project' section so that reviewers have

	full details of the project.
Will the research involve collecting new data from or about human participants?	Applicants should answer 'Yes' to this question if their research involves people directly as research participants or subjects, or indirectly through access to their tissue. Under no circumstances should participants be contacted before favourable ethical opinion has been granted.
Will the research use previously collected or generated personal data from human participants?	Applicants should answer 'Yes' to this question if their research will use existing data relating to an identified or identifiable person. If their research will use data that is in the public domain (for example, published in books or journals) or the data is fully or effectively anonymised, they should answer 'No' to this question. Applicants must not assume publicly accessible data, such as Internet or Social Media data, is in the public domain. They should read the University guidance on research data and social media. Use of previously collected data in research (or 'secondary data use') is defined as information that already exists, collected by other researchers or organisations for a different purpose. Common sources include the internet/social media, archives, medical datasets, organisational records and data that were originally generated for purposes other than the research now proposed.
Summary of the project	Applicants must provide a summary of the proposed project in up to 1,000 words using language easily understood by lay reviewers and members of the public, free from jargon. Where technical terms or discipline specific phrases are used, they should be explained. All acronyms should be described in full. Applicants should not provide academic references or extensive theoretical details in this section. The summary should include the purpose or objectives of the project, as well as the hypotheses/research questions to be examined, and a description of the research method(s) that will be used. If the project involves more than one method (e.g. interview, questionnaire, field observation, audio/visual recording), applicants should clearly separate them and ensure that it is clear which method they are discussing when completing the different sections of the form. In this section, applicants are expected to describe the types of sites where the project will be undertaken, who will be eligible, what participants will be asked to do, what will be done with their data and what is planned in relation to dissemination of the findings. For student studies, applicants should provide details of the supervisory arrangements for monitoring the conduct of the research.

	For collaborative studies, applicants should provide details of the external collaborators and the role that they will undertake.
Research project proposal	In this section, applicants should upload their research project proposal. If applicable, they should also upload the following documents: questionnaire; interview/focus group topic guides; debrief form or other research tools. The information provided in the research proposal must be consistent with the information provided in response to the questions in the form. Uploaded documents must have a footer containing the ERAMS reference number, the version number and the date of the document version. Applicants should carefully proof-read any participant facing documents and ensure that they are written in appropriate language for the intended audience. If applicants are resubmitting revised documents following an ethics review, they should quickly identify them and amend the version number and version date in the footer.
Funding and RCP project ID	If the applicant has obtained external funding for their project or funding allocated within the University but originating from an external source such as a UKRI Impact Accelerator Account, they must select the relevant grant type in the funding section and insert their RCP project ID. The RCP project ID will have been sent to the applicant on any correspondence received from the REO Pre award team at application stage. Alternatively, if the Pre-award stage of funding was managed by a Knowledge Exchange Manager or the KTP Team it can be obtained from them. The RCP project ID enables a link to be made between an application for ethical approval and the external funding award. Failure to provide the RCP project ID, if there is one, will cause a delay in the release of external funding.
Participant details	Applicants are expected to provide in this section details of approximately how many participants will be recruited and how the proposed number was reached. Details of any inclusion and / or exclusion criteria should be provided. For example, if they are intending to recruit participants within a specific age range, those identifying as a specific gender or from a specific ethnic group. If applicants are planning to exclude any potential participants, they should provide reasons to justify this.

Participant recruitment	Applicants must provide details about how potential participants will be identified, approached and recruited and who will be responsible for approaching and recruiting participants. Copies of any recruiting materials, e.g. advertisements, posters or letters of invitation must be uploaded. All documents must have a footer containing the ERAMS reference number, the version number and the date of the document version. If applicants are resubmitting a revised version of their recruiting materials following review of their application form, the version number and version date in the footer should be amended.
Participant payments	Payments can be to reimburse expenses; to compensate for time; inconvenience; loss of earnings or possible discomfort; to provide a token of appreciation for a participant's help. Any payment made to individuals to enable them to participate in research activities must not be so large as to induce them to take risks beyond those that would usually be part of their established lifestyle. Participation in research is not paid employment. If participants will be paid or reimbursed, the applicant must provide details of how and when payment will be made, and present a clear justification for paying participants. If participants will be paid, the applicant must provide a figure per participant in UK Pounds Sterling (£GBP) or equivalent value if not a cash payment.
Participant vulnerability	The ESRC 'Research Ethics Guidance' states that : ▪ 'Vulnerability may be defined in different ways and may arise as a result of being in an abusive relationship, vulnerability due to age, potential marginalisation, disability, and due to disadvantageous power relationships within personal and professional roles'. ▪ 'Participants may not be conventionally 'vulnerable', but may be in a dependent relationship that means they can feel coerced or pressured into taking part, so extra care is needed to ensure their participation is truly voluntary'. ▪ 'Researchers will need to assess potential vulnerability within the context of the research, in terms of potential consequences from their participation (immediate and long-term) or lack of positive impact where this is immediately needed or expected'. If potential participants could be considered vulnerable, the applicant must provide details of how potential participants could be considered vulnerable within the

	context of their project, taking into account the ESRC guidance. The applicant needs to include details of arrangements that will be made to enable anyone involved in, or affected by, the project activities to report safeguarding concerns and incidents (see the University's Safeguarding website). The applicant will need to make a clear statement about the circumstances when it will be necessary to break confidentiality due to safeguarding concerns in the information that they provide for participants. Some examples of situations where participants might feel obliged to take part are: employees recruited through the workplace; potential participants who are known to the researcher either personally or professionally; adult professionals working with children or the elderly; research in communities where access to research participants is not possible without the permission of another adult, such as a community leader, i.e. a 'gatekeeper', or another family member (e.g. the parent or next of kin). Please note that the final example is not the same as seeking the assent of a person on behalf of another who does not have capacity to consent for themselves (Mental Capacity Act and research).
Minors and individuals with limited capacity to give informed consent	People with a limited capacity to provide informed consent may include people with a learning disability or with cognitive impairment. Research studies involving adults who lack capacity to consent for themselves or adults who come to lack capacity during the project, must be reviewed and approved by an 'appropriate body' operating under the Mental Capacity Act 2005. The University of Essex is not such a body, and the applicant should contact the REO Research Governance Team if their project involves individuals of 18 years and over with a limited capacity to give consent.
Disclosure and Barring Service (DBS) check	In many cases, researchers working with children or vulnerable adults will need to have a Disclosure and Barring Service (DBS) check. Information about what a DBS check is, who might need one, and how to obtain a DBS check, is available: for staff from Human Resources and on the University's website; and for students from the University's Student Progress team in the Academic Section and on the University's website. Reviewers must only grant a conditional favourable ethical opinion if a DBS check is required but has not yet been completed. The applicant will then need to submit an amendment to the application and upload evidence of the check once it has been completed.

Informed consent	Applicants are expected to follow the University's Consent Form template, whether they are interacting with participants face-to-face in person or by remote means or whether they are using online methods. However, there are occasions when it is necessary to modify the documentation to ensure that the content is accessible to the participants, for example, for children or for those with a learning disability or with minor cognitive impairment which does not limit their capacity to provide informed consent. It must be clear why the applicant's consent form does not comply with the University's template from the responses the applicant has provided in the 'Participant details' and 'Informed consent' sections of the form. If the project has different groups of participants, then the applicant will need to upload separate consent forms for each group making clear from the title of the document to which group each document applies. All documents must have a footer containing the ERAMS reference number, the version number and the date of the document version. If the applicant is resubmitting a revised version of their Consent Form following research ethics review, they should amend the version number and version date in the consent form(s). Following the University's Participant Information Sheet Guidance and Participant Information Sheet Template will ensure that the applicants address all the required issues in their participant information sheet, whether they are interacting with participants face-to-face in person or by remote means or whether they are using online methods. However, there are occasions when it is necessary to modify the documentation to ensure that the content is accessible to participants, for example for children or for those with a learning disability or with minor cognitive impairment which does not limit their capacity to provide informed consent. It must be clear why the participant information sheet does not comply with the University's template from the responses that the applicants have provided to questions in the 'Participant details' and 'Informed consent' sections of the form. If they have different groups of participants, they will need to upload separate participant information sheets for each group making clear from the title of the document to which group each document applies. All participant information sheets must have a footer containing the ERAMS reference number, the version number and the date of the document version. If the applicant is resubmitting a revised version of a participant information sheet following research ethics review, they should amend the version number and version date in the footer.

	Consent will normally be obtained in writing but sometimes it will be more appropriate to obtain consent orally. For example, there may be accessibility, literacy or cultural reasons for why it is not appropriate to obtain written consent. The applicant should provide the script of the information that will be relayed to the participant and upon which they will give their informed consent. The script should also relay the contents of the consent form to the participant asking them to indicate their consent to each statement. If no script is available to upload, the applicant should explain why Informed consent may be impractical in some circumstances, for example, if researching crowd behaviour, or if fully informed consent would compromise the objectives of the research. If informed consent will not be obtained, the applicant should provide details to justify their approach. If fully informed consent would compromise the objectives of the research, it is good practice for the applicant to provide a debriefing note following the completion of the research and to provide an opportunity for the participant to withdraw their consent if they no longer wish to take part. This document should be uploaded as a separate document with the participant information sheet.
Data use – sources of data	The applicant should state in this section the source(s) of the data and provide further detail such as Website URL, the dates the data was collected, what originally was the data collected for, what outcome measures does the data include, who owns the data and if it is open access etc.
Data use – what is meant by 'special category data'	The UK GDPR singles out some types of personal data as likely to be more sensitive, and gives them extra protection: personal data revealing racial or ethnic origin; personal data revealing political opinions; personal data revealing religious or philosophical beliefs; personal data revealing trade union membership; genetic data; biometric data (where used for identification purposes); data concerning health; data concerning a person's sex life; and data concerning a person's sexual orientation. The applicant should answer 'Yes' to the question 'Does the research involve the use of special category data?' if their project will involve the use of the above listed types of personal data.
Data use – what is meant by 'data linkage project'	The Office for National Statistics defines data linkage as the process of joining together records that pertain to the same entity, such as a person or business. In its most simplistic form, links (or "matches") can be completed by comparing unique identifier keys specific to each object, for example, a person's National Insurance number. Connecting data in this way can lead to new insights and discoveries and reduce the need for additional data collection. However, data

	linkage can also make participants identifiable in data that was previously effectively anonymised.
Data use – what is meant by reusing data from a 'third party'?	Re-using data obtained from a third party refers to data that has been collected, organised and published by others for purposes other than the researcher's current investigation (e.g., data from online repositories, data provided by project collaborators, service providers, charities, clubs etc.)
Data use – data originating from social media and consent	The University's 'Research data and social media – some general principles' guidance explains when consent should be sought from each relevant individual; when consent should be sought from a moderator, author, or platform owner; and when consent is not needed.
Confidentiality and Anonymity	Please note that this section is not about the applicant's data management plan, e.g. how they plan to store data securely. It is about a participant's right to confidentiality and anonymity. For example: ▪ If the applicant is interviewing an individual in a public place and has guaranteed confidentiality and anonymity, the applicant will need to describe steps they will take to ensure that they are not overheard. ▪ If the applicant is video recording an interview they might consider pixelating a participant's face or adjusting the light so that they cannot be seen. ▪ If the applicant is gathering information from a group of individuals, they will need to remind participants at the start about expectations in relation to confidentiality and anonymity. The ICO's 'Introduction to anonymisation' can help the applicant(s) to anonymise data and to identify the issues they need to consider to use anonymisation techniques effectively. It sits alongside the ICO's data sharing code of practice, which gives practical guidance on how to share personal data in line with data protection law. Information is considered identifiable if it directly identifies individuals or if individuals can be identified when the information is viewed in combination with other accessible information. In some instances effective anonymisation may not be possible due to the nature or context of the data, or the purpose(s) for which the applicant collects, uses and retains data. For example, the likelihood of identification is greater where occurrences are rare or unusual, such as a study involving participants with a rare disorder. If the applicant will not be maintaining anonymity and confidentially, they must explain their reasons for not doing so.

Storing and maintaining the security of any data collected as part of the project	The applicant should explain in this section the storage arrangements for any data collected as part of the project not the arrangements for sharing or archiving data for re-use once the project is complete. Examples include: consent forms; surveys and questionnaires; interview transcripts; audio and video recordings; films and photo images. Details that should be included in this section are: what data will be collected; what will be done with the data; how an individual's anonymity will be protected if they request it; how identifiable data will be stored, for how long and who will have access to it; how non-identifiable data will be stored, for how long and who will have access to it; how the data will be stored in the long term if it is to be retained and for how long will it be stored; if the data is not to be retained, how it will be destroyed and when. Guidance to help researchers manage data collected during research projects can be found on the University's Data Protection and research activity website.
Access to the data	The applicant must list in this section the names and roles of all those who will have access to the live research data, including those listed as applicants on the ERAMS application, collaborators and transcribers.
Data sharing	The University is committed to disseminating its research and scholarship as widely as possible to contribute to society as well as to academic advancement. The University's Open Research Position Statement provides further details. Staff and doctoral students should be aware that the University's Research Data Management Policy states 'Research data must be offered and assessed for deposit and retention in an appropriate national or international data service or subject repository, or the University's Research Data Repository'. UK Data Archive, Managing and Sharing Data is a training resource which will help staff and doctoral students to manage and share their research data. When describing how they intend to share or archive data generated from this project once it is completed, staff and doctoral students should consider the relevant requirements of funders, publishers, or other requirements for shared data. If the applicant has completed a data management plan in an application for funding or in their project proposal, the section on sharing/archiving may be copied in the data sharing section. The applicant will need to describe any specific ethical issues that arise from sharing or archiving data generated from their project; provide details of any specific requirements that their funder has; provide details of the repository that

	they have identified or the steps that they will take to identify a suitable repository; any steps that they need to take in order to ready their data for deposit; and provide the timescale for their planned deposit.
Reasons why the data will not be made available	There are some legitimate reasons for researchers wanting to restrict public access to the research data, for example, due to the nature of the research it may not be possible to anonymise the data; there may be restrictions set by the funder; there may be intellectual property restrictions; consent to share anonymised data may not have been obtained from participants; assurances about destruction of the data may have been given to participants. If the applicant does not intend to share data, they must provide specific reasons why the data will not be made available.
Risk assessment	It should always be remembered that risks posed to participants, researchers or the institution do not preclude the research from taking place as long as steps are taken to mitigate for the risks so that they are manageable. It is essential that the applicants recognise the risks posed by the research and address them. A signed risk assessment approved by an appropriate authority is normally expected. There is guidance on research risk assessment on the REO Research Governance website. Applicants can seek advice from the University's Health and Safety Advisers (email safety@essex.ac.uk) if they have any queries. All risk assessment documents must have a footer containing the ERAMS reference number, the version number and the date of the document version. If the applicants are resubmitting revised Risk Assessment documents following an ethics review, they should amend the version number and version date in the footer.
Risks to participants	This will be a summary of the risks presented in the uploaded Risk Assessment documents. Applicants should consider the following: Could a participant suffer bodily harm as a result of participation in the study, including minor or serious harm; temporary or permanent physical harm or discomfort; immediate physical harm or discomfort experienced a few days later? Could the research pose a psychological risk should participation in the study affect an individual's perception of themselves, for example a participant feeling embarrassed or uncomfortable about what they discover about themselves? Could the research pose a social or economic risk to a participant after participating in the study? For example, could a participant lose their insurance as a result of their participation in the research, or could participation be potentially damaging to a participant's financial standing, employability or reputation? Could the study

	reveal that a participant has committed a crime or is there a risk that a participant associated with the research might experience classroom discrimination or social stigmatisation? The REO Research Governance website provides further information about the typical risks that need to be considered. The applicant should explain what risk management procedures will be put in place to minimise the risks.
Risks to researchers	This will be a summary of the risks presented in the uploaded Risk Assessment documents. The Social Research Association (SRA) Code of Practice identifies the following potential risks to researchers: risk of physical threat or abuse; risk of psychological trauma, as a result of actual or threatened violence or the nature of what is disclosed during the interaction; risk of being in a compromising situation, in which there might be accusations of improper behaviour; increased exposure to risks of everyday life and social interaction, such as road accidents and infectious illness; risk of causing psychological or physical harm to others. There will be others. The applicant should explain what risk management procedures will be put in place to minimise the risks.
Reputational risks	This will be a summary of the risks presented in the uploaded Risk Assessment documents. Reputational risk is defined as damage to public perception of the University or damage to the University's reputation, and that of its researchers, in the eyes of funders, the research community and / or the general public. When research involves reputational risk, applicants must discuss the research with the Communications team in CER (comms@essex.ac.uk) before submitting their application in the ERAMS. They will need to upload confirmation from the Communications team in the 'Other documents' section. The applicant should explain what risk management procedures will be put in place to minimise the risks.
Other documents	If there any additional research tools or attachments that have not been covered elsewhere in the application, the applicant can upload them here. All documents must have a footer containing the ERAMS reference number, the version number and the date of the document version.
Will any of the research take place outside the UK?	The applicant should select 'Yes' if data will be collected in a geographic location outside the United Kingdom and provide details of the sites, i.e. the name of the organisation and the location within the country. The applicant may find it helpful to consult the International Compilation of Human Research Standards, which lists laws, regulations, ethics review bodies

	and guidelines on human participant protections in 131 countries, to determine whether local approval is required. If they are working with collaborators based in the country overseas, they should also consult them. A favourable ethical opinion will only be granted conditional if approval is pending. If approval is required and has been refused, the applicant will need to provide details of how they are addressing this in the section 'Approving body'.