# Recommended Guide for Research 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.

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| Title | • Does the title provide a concise summary of the project?<br>• Is the title written in plain English so that it is understood by most potential participants?<br>• Is the project title consistent throughout the participant facing documents (i.e. participant information sheet; consent form; research tools, advertising materials, etc)? |
| Applicant(s) | • The named Principal Investigator must hold an employment contract or be a registered student at the University of Essex. The Principle 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. |
| Expected end date | • A favourable opinion will only exceptionally be granted for more than three years.<br>• An amendment to extend the favourable opinion will then need to be submitted to extend the project beyond three years.<br>• A new application will be required if a project is to continue beyond six years. |
| Will the research involve human participants? | • 'Human participants' are defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids, personal opinions, and personal data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements)". See the University's 'Guidelines for ethical approval of research involving human participants |
| Will the research use collected or generated personal data? | • 'Personal data' in the context of ethics review and ethical approval is any data from or about 'Human Participants' which may be identifiable or non-identifiable. It includes but is not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements.<br>• Research involving personal data and records which have been made available to the public will not require ethical approval. However, in relation to social media, information that is available online is not necessarily public data. Please read the University guidance on research data and social media. |
| Summary of the project | • Has the applicant provided 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?<br>• If technical terms or discipline-specific phrases are used, have these been explained? Are all acronyms described in full? |

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| | • Does the summary include the purpose or objectives of the project, as well as the hypotheses/questions to be examined, and a description of the method(s) that will be used?<br>• Is there sufficient information to understand 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? The applicants will provide more detailed information about these issues in later sections of the form.<br>• For students studies, has the applicant provided details of the supervisory arrangements for monitoring the conduct of the research?<br>• For collaborative studies, has the applicant provided details of the external collaborators and the role that they will undertake? |
| Research project proposal | • Has the applicant uploaded their research project proposal?<br>• If applicable, has the applicant uploaded the following documents: questionnaire; interview/focus group topic guides, debrief form or other research tools?<br>• Is the information in the research project proposal consistent with the information provided in response to the questions in the ERAMS form?<br>• Do all documents have a footer containing the ERAMS reference number, the version number and the date of the document version? |
| Funding | • Research projects requiring ethical approval and funded by a UKRI Research Councils are expected to be referred to the Ethics Sub Committee unless they have already received approval from recognised external ethics committees.<br>• Impact Acceleration Account (IAA) funding at Essex is provided by the AHRC, BBSRC or ESRC, UKRI Research Councils, so the applications must be forwarded to the Ethics Sub Committee for review. Ethics Officers can indicate in their notes in ERAMS that they are only forwarding it because the project is IAA funded and that the application would otherwise be reviewed and approved under Annex B. The REO Research Governance team can then arrange for another Ethics Officer to provide the independent review. |
| RCP project ID | • If the project is funded from an external source, the applicant must include an RCP reference number. The REO Pre-award team provide this in correspondence with the funding applicants. If the IAA team or the KE team have managed the application process, the RCP reference number can be obtained from them. |
| Participant details | • Has the applicant described who the potential participants are? For example, is the applicant intending to recruit participants within a specific age range, those identifying as a specific gender or from a specific ethnic group?<br>• Has the applicant provided details of approximately how many participants will be recruited and how the proposed number was reached?<br>• If the applicant is planning to exclude any potential participants, have they provided reasons to justify this? |
| Participant recruitment | • Has the applicant provided details about how potential participants will be identified, approached and recruited and who will be responsible for approaching and recruiting participants?<br>• Has the applicant provided copies of any recruiting materials, e.g. advertisements, posters or letters of invitation? Please note that all such materials require ethical approval before they can be used so must be attached to the application. |

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| | • Do the recruitment materials have a footer containing the ERAMS reference number, the version number and the date of the document version? |
| Participant payments | • 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.<br>• If participants will be paid or reimbursed, has the applicant provided details of how and when payment will be made, and present a clear justification for paying participants? Has the applicant clarified what will happen if a participant chooses to withdraw from the project? Will the participant still receive payment and, if not, has the applicant explained why this is not compelling them to remain as a participant?<br>• If participants will be paid, has the applicant provided 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 :<br>○ '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.<br>○ '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'.<br>○ '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'.<br>• If potential participants could be considered vulnerable, has the applicant provided details of how potential participants could be considered vulnerable within the context of their project, taking into account the ESRC guidance.<br>• Could potential participants be considered to feel obliged to take part in the research?<br>○ 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.<br>• 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, |

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| | 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:<br>o for staff from Human Resources and on the University's website; and<br>o for students from the University's Student Progress team in the Academic Section and on the University's website<br>• You 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. At that point, you can grant a favourable ethical opinion and send the confirmation e-mail. |
| Informed consent and Participant Information Sheet | • Applicants are expected to follow the University's Consent Form and Participant Information Sheet templates, whether they are interacting with participants face-to-face in person or by remote means or whether you are using online methods.<br>• 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 their consent form does not comply with the University's template from the responses that they have provided to earlier questions in the 'Participant details' and 'Informed consent' sections of the form.<br>• If the applicant has different groups of participants, have they uploaded separate consent forms and participant information sheets for each group making clear from the title of the documents to which group each document applies.<br>• Do all documents have a footer containing the ERAMS reference number, the version number and the date of the document version?<br>• If consent will be obtained orally, has the applicant provided the script of the information that will be relayed to the participant and upon which they will give their informed consent? Does the script relay the contents of the consent form to the participant asking them to indicate their consent to each statement?<br>• Has the applicant provided details of who will be obtaining and recording consent and their role in the project?<br>• If informed consent will not be obtained has the applicant explained 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 must provide details to justify their approach. If fully informed consent would compromise the objectives of the research, it is good practice 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 must be uploaded as a separate document with the participant information sheet. |

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| 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. |
| Arrangements for maintaining anonymity and confidentiality | • For example:<br>  ○ 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.<br>  ○ 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.<br>  ○ 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.<br>• 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. |
| Reasons for not maintaining anonymity and confidentiality | • 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. |
| Storing and maintaining the security of any personal data collected as part of the project | • These are the storage arrangements for the applicant's active research data not the arrangements for sharing or archiving data for re-use on the project is complete.<br>• Personal data is any data from or about the research participants which may be identifiable or non-identifiable. Examples are: consent forms; surveys and questionnaires; interview transcripts; audio and video recordings; films and photo images.<br>• Details to include in this section are:<br>  ○ what data will be collected<br>  ○ what will be done with the data<br>  ○ how an individual's anonymity will be protected if they request it<br>  ○ how identifiable data will be stored, for how long and who will have access to it<br>  ○ how non-identifiable data will be stored, for how long and who will have access to it<br>  ○ how will the data be stored in the long term if it is to be retained and for how long will it be stored<br>  ○ if the data is not to be retained, how will it be destroyed and when.<br>• Guidance to help researchers manage data collected during research projects can be found on the University's Data Protection and research activity website. |

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| 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 | • 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 here.<br>• Has the applicant described any specific ethical issues that arise from sharing or archiving data generated from their project?<br>• Has the applicant provided details of any specific requirements that their funder has; 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; the timescale for their planned deposit? |
| Reasons why the data will not be made available | • There are some legitimate reasons for 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. |
| Risk assessment documents | • 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.<br>• It is essential that the researchers recognise the risks posed by the research and address them.<br>• There is guidance on research risk assessment on the REO Research Governance website.<br>• Applicants can seek advice from the University's Health and Safety Advisers (email safety@essex.ac.uk; tel 2944) if they have any queries.<br>• Where a risk assessment is expected, this must be signed by the appropriate authority. |
| Risks to participants | • This is a summary of the risks presented in the uploaded Risk Assessment documents.<br>• 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?<br>• 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?<br>• 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?<br>• 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? |

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| | • The REO Research Governance website provides further information about the typical risks that need to be considered. |
| Risks to researchers | • This is a summary of the risks presented in the uploaded Risk Assessment documents.<br>• 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. |
| Reputational risks | • This is a summary of the risks presented in the uploaded Risk Assessment documents.<br>• 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.<br>• Could the research be misconstrued or sensationalised and, if so, what would a front-page story in a tabloid newspaper do for the University's reputation?<br>• To be added to the ERAMS application forms: 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. |
| Other documents | • The applicant is invited to upload documents which they would like to bring to the attention of reviewer(s) if there are any additional research tools or attachments that have not been covered elsewhere in the application.<br>• Is the purpose of the document clear from its title or additional information provided with it?<br>• Do all documents have a footer containing the ERAMS reference number, the version number and the date of the document version? |
| Research abroad | • Has the applicant provided details of the sites, i.e. the name of the organisation and the location within the country?<br>• Is local approval required? Applicants are advised 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. They are also advised to consult collaborators based in the country overseas if they are working with any.<br>• You must only grant a conditional favourable ethical opinion if local approval is pending. The applicant will need to submit an amendment to the application and upload evidence of the local approval once it has been granted. At that point, you can grant a favourable ethical opinion and send the confirmation e-mail.<br>• If local approval is required and has been refused, the applicant will need to provide details of how they are addressing this in the 'Approving body' section. |