Research Ethics Policy

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Version	Date	Notes
8.1	07 05 25	The Policy has been updated to provide clarification on ethics review: • for the involvement of patients and members of the public (PPI) in the research study (D3/D11/D26) • for insight gathering activities (D10) • when using generative AI tools in research (A2/D3)
8.0	08 05 24	Scheduled review in 2023/24. The Policy has been revised to: • emphasise the importance of ethics reviews (A1) • refer to the UEA ethics review requirements for research involving a generative artificial intelligence (AI) tool (A2, D3) • refer to security sensitive research (D3) • include a new section: 'Definitions' (B1) • clarify the definition of 'research' for the purposes of an ethics review (B1) • include Emeritus appointments (B2) • remove reference to the University of Suffolk postgraduate research students, as they no longer register their degree at UEA (B2) • add detail to the scope of the Policy in terms of applying to 'research' and 'researchers' as defined in B1 (C2, C3) • refer to joint projects (C3) • provide further examples when using secondary data (D3) • refer to the ethics requirements for studies using a generative AI tool (D3) • update the eligibility of requests for UEA ethics reviews (D5) • state the requirement of UEA ethics review for NHS service evaluation and NHS audits (and for other organisations other than the NHS offering a service to the public) (D9) • clarify the UREC involvement in the ethics review of studies involving market research/research for internal evaluations and other similar purposes (D10) • confirm that workshops broadly described as consultations require ethics review (D11), as do UEA audits involving personal responses (D12) • update that UREC no longer reports to Council (D20) • clarify the UEA ethics approval requirements for joint projects that are not led by UEA (D24) • state a maximum expiry date for the ethics approval of 1 year for research involving a generative AI tool (E8)

		• explain the status of UEA ethics approval when a researcher departs UEA (E9), and when a researcher moves to UEA (E10) • provide the new process for external requests to recruit UEA staff and/or UEA students (E13) • restate UEA's position on opt-in consent and opt-out consent (E15) • mention other lawful bases for processing personal data (E22)

Background

Ethics is a cornerstone of research integrity. The University is committed to promoting high ethical standards in research and to safeguarding the dignity, rights and welfare of all those involved in research and the implementation of its results, as a fundamental part of its principles of research integrity.

Review

This Policy will be reviewed and updated by the University Research Ethics Committee (UREC) and recommendations will be made to the University Research Executive, and thereafter to Senate before 31st July 2027.

Content

Part A. Introduction

A1 The purpose of the University's *Research Ethics Policy* is to ensure that anyone engaged in research that involves the University of East Anglia (UEA) is aware of the ethical principles that the University upholds, and has access to the guidance necessary to comply with those principles, in order for its staff and students to enact the highest standards of ethical conduct in research. Ethics is not merely a matter of compliance with concordats, policies, procedures and codes. Ethics review supports good research practice and enhances research design.

A2 The Policy sets out conditions for establishing the UEA ethics review requirements of research involving:
- human participants
- animals
- with a potential to affect the environment or cultural objects

A3 The Policy recognises that it is necessary to take account of specific legislative and funding body requirements.

A4 Although ethics should always be a consideration in research, this does not mean that full ethics review by the University is always required (refer to D24).

A5 The Policy should be read in conjunction with the University's other policies and guidelines available to researchers which relate to research integrity issues, and the University's range of Ethics Guidance Notes. These documents are available on the Research and Innovation Services (RIN) Research Integrity and Ethics webpages.

Part B. Definitions

B1 **Research**: For the purposes of this Policy, research is broadly defined as any gathering of data, information and facts for the advancement of knowledge. This could include surveys that are sent out by the library, by ITCS colleagues, by the VCO; focus groups run by members of the Students Union, for Athena SWAN activities, for Outreach work with our local schools, for any of our business intelligence unit activities; as well as the practices for more standard research related activities by our academic staff members and students. The Policy should also be applied to the research element of innovation activities such as consultancy. Knowledge exchange activities and impact activities may also include activities that may be categorised as research, and therefore fall under this Policy.

B2 **Researcher**: This Policy applies to all the following:
- All staff employed by the University (including academic, research and support staff) carrying out research at, or on behalf of, the University (including those on a UEA contract/payroll but based elsewhere, for example at a Norwich Research Park (NRP) institution).

- All students (undergraduate, postgraduate taught, postgraduate research) undertaking research and their supervisors (including students registered at UEA but based elsewhere, for example at an NRP or other partner institution).
- Any persons with Honorary positions or Emeritus appointments, conducting research at, or on behalf of, the University.
- Any other individuals carrying out research at, or on behalf of, the University.
- The University also expects ethical oversight of research undertaken by any institution utilising UEA resources. This includes those using the University as a site for data collection.

Part C. Scope

C1   The University's *Guidelines on Good Practice in Research* outline what is expected of its researchers. The University's *Research Ethics Policy* and associated Ethics Guidance Notes expand on this with respect to research ethics.

C2   This Policy applies to all UEA researchers, and any of their teams, involved in undertaking any research as defined in B1. It applies irrespective of the source of any funds for the research.

C3   This Policy applies to all research activities as broadly defined in B1, and includes those activities undertaken in joint projects.

C4   This Policy:
- sets out the University's core principles for undertaking ethical research;
- provides a framework for the conduct of ethical procedures within the University;
- is one of a number of University policies and guidelines available to researchers which relate to research integrity issues; and
- outlines the relevant responsibilities and ethics review procedures within the University.

Part D. Principles

D1   When undertaking research, it is the researcher's responsibility to consider and observe ethical principles and this Policy.

D2   In line with the ESRC's *Framework for Research Ethics*, the University's core principles for ethical research are:
- research should aim to maximise benefit for individuals and society and minimise risk and harm;
- the rights and dignity of individuals and groups should be respected;
- wherever possible, participation should be voluntary and appropriately informed;
- research should be conducted with integrity and transparency;
- lines of responsibility and accountability should be clearly defined; and
- independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.

D3   Ethics review is required for all research that:
- involves human participants[1]. This includes research that:
  o directly involves people in the research activities, through their physical (or virtual) participation. This may be interventional (for example surgery, drug trials, interviews, questionnaires of a personal nature) or non-interventional research (for example surveys, observational research) and may require the active or passive involvement of a person;
  o indirectly involves people in the research activities, through their provision of, or access to, information, personal data and/or tissue;
  o involves people on behalf of others (for example, legal guardians of children and the psychologically or physically impaired or supervisors of people under controlled environments, for example prisoners, school pupils);
  o uses certain types of secondary data (for example, organisational data - this could refer to specific individuals who are identifiable within a company, or it could refer to elements such as number of employees, financial records, policies, annual reports, etc, that are for example commercially sensitive; the terms and conditions of reuse require further ethics review and approval; UEA business data that contains personal data, for example student grades, being reused by a third party).

- involves animals. For the purposes of this Policy, animal research is defined as any research involving vertebrates and protected invertebrates such as cephalopods. It includes other invertebrates where these are registered as endangered or protected species, or involves large scale destructive sampling and/or the research is on specially protected sites. Research in this context includes research that is:
  o regulated by the Animals (Scientific Procedures) Act 1986 (amended 2012);
  o not covered by the Act, for example, fieldwork research and observational studies.

  Ethics review of research involving animals will be undertaken by the University's Animal Welfare and Ethical Review Board (AWERB).

  Research using post-mortem animal tissue such as that taken from abattoirs does not require ethics review.

- has a potential to affect the environment or cultural objects. Researchers should refer to the University's Ethics Guidance Notes on 'Research with a Potential to Affect the Environment' and 'Research with a Potential to Affect Cultural Objects' for clarification of the ethics issues to be considered.

UEA staff and students (or involving UEA), where a generative AI tool will be used, built or developed, and are seeking ethics review anyway as outlined above in this section, will have the ethical considerations of using these tools reviewed in their ethics application form. Please refer

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[1] An ethics review is not required for the involvement of patients and members of the public (PPI) with researchers that influences and shapes health and social care research. **This is different to research participation where participants take part in a research study.** Please refer to section D26 for more details.

to the University's Ethics Guidance Note on 'UEA Ethics Review of Research Involving Generative AI Tools'.

Before beginning a project involving security sensitive research, researchers must first obtain UEA ethics approval to do so. Please refer to the University's Ethics Guidance Note on 'Security Sensitive Research'.

D4 Ethics review should be sought **before** the research has started, unless the requirement for review only becomes necessary during development of the project, for example, following a literature review or as the findings of the research start to be implemented in practice. Research must not start unless the ethics application has been reviewed and approved.

D5 A UEA ethics application must be led by a UEA member of staff (they may have a joint appointment with another organisation on the NRP) or UEA student or a person with a UEA honorary position. There is one exception: ethics applications to AWERB which undertakes ethics reviews for the NRP as agreed under Home Office regulations.

UEA cannot provide ethics reviews for UEA students (including students registered at UEA but based elsewhere, for example at an NRP or other partner institution) when the study proposed is **not** part of their UG/PGT/PGR project. The exception to this would be where an ethics application is submitted to UREC for studies in connection with UEASU activities.

External organisations/individuals which have no affiliation to UEA may be able to submit an ethics application to UREC seeking a favourable ethics **opinion** and this service may be provided on a paid basis. The UREC Chair should be contacted by the external organisation/individual in the first instance. A table summarising the eligibility of external requests for UEA ethics review is available here.

D6 Participants in research have, at the very least, all the rights as defined by law (for example, the Human Rights Act 1998, the UK General Data Protection Regulation (UK GDPR) and Data Protection Act (DPA) 2018, the Mental Capacity Act 2005, and relevant European Directives and conventions).

D7 In line with the ESRC's *Framework for Research Ethics*, "Researchers should consider ethics issues throughout the lifecycle of a research project and promote a culture of ethical reflection, debate and mutual learning. The lifecycle of research includes the planning and research design stage, the period of funding for the project, and all activities that relate to the project up to - and including - the time when funding has ended. This includes knowledge exchange and impact activities, the dissemination process - including reporting and publication - and the archiving, future use, sharing and linking of data."

D8 Ethics review is required for certain activities funded from the University's internal funding streams: Ethics review is mandatory for:

- impact activities funded from the UEA PVC Impact Fund, AHRC IAA Fund, and the MRC IAA Fund.
- UEA's annual App Development competition.

D9   NHS service evaluation and NHS audits (and for other organisations other than the NHS offering a service to the public) using person specific data and carried out by staff or students at UEA should seek UEA research ethics approval.

D10   Surveys, focus groups, and interviews etc. for market research/research for internal evaluations and other similar purposes, for example internal staff surveys (for example Athena Swan, marketing and outreach activity using research techniques or consultations carried out by/within/on behalf of UEA will require ethics review. Those to be undertaken by the University's Central Services and the University's Students' will be reviewed by UREC. Those to be undertaken by staff and students in the Faculties and Schools of Study will be reviewed by the relevant S-REC, unless the study is recruiting participants from across the University, rather than in the applicant's School/Faculty, and then UREC will undertake the ethics review. Surveys, focus groups, and interviews etc. that may be undertaken solely within Schools or Faculties for insight gathering for example feedback on university wide strategy or the impact of government directives on curriculum design, would not usually require an ethics review if the data collected stays 'within' the School and is not to be reported elsewhere. However, it would be expected that any ethical considerations regarding what might be asked should be addressed and clear information provided to participants about aims and potential use of any material collected prior to any data collection occurring. Exceptions to this may occur where Schools of Faculties may be keen to explore for example the impact of a strategy on the wellbeing of staff, or when collecting personal data. In cases such as these, it would be expected to obtain an ethical review for the work. It is recommended that Schools and Faculties seek the advice of their S-REC Chair to consider what approach to take.

D11   Workshops broadly described as consultations that form part of the feasibility of studies, potential research design, and planning activities should also be considered for ethics review. In particular, if consultations are going to be recorded in some way and/or are aimed to provide insight for the final research activities and maybe incorporated into the reporting/publishing of the project work at some future date, they should have ethics review. Research teams must determine the extent to which these early activities would fit within this remit and add this to any ethics review process expected. This is distinct from PPI work, where ethics review is not required (please refer to section D26 for more details). Your S-REC Chair can provide guidance if required. Please also refer to the University's Ethics Guidance Notes on 'Ethics Approval for Workshops' and 'Patient and Public Involvement in Research'.

D12   UEA audits involving personal responses, for example, about the effectiveness of services will require ethics review.

D13   Researchers should take into account legislation and cultural standards relating to the country in which the research is carried out. For research activities overseas, researchers must be able to demonstrate with documentary evidence to the relevant S-REC that they are in compliance with

relevant legal and ethical requirements of the host overseas country. Researchers and all partner organisations will make sure that appropriate measures are in place to protect all involved in the research and must ensure that procedures are in place to handle any breach of Sections 2 and 6 of the DFID Supply Partner Code of Conduct, and make clear the legal ramifications of such a breach.

D14 The nature and ethical standing of all stakeholders involved in a research project should be considered in the context of their fit with the University's mission and values.

D15 Where organisations involved in research prescribe specific policies in this context which are not necessarily legal requirements, these should be observed, in so far as this does not conflict with ethical standards.

D16 Specific areas of activity relating to research and innovation may require detailed consideration to ensure that they are consistent with the University's stated goals and standards of integrity and ethical practice. The University's *Policy for Approving the Integrity of UEA Research and Innovation Related Activities and Funding* sets out the procedures to be followed where there any issues of doubt arising from these considerations, which must be followed prior to any activities starting.

D17 As a condition of their employment, all staff are required to adhere to the policies, rules and procedures of the University. Researchers are individually responsible for adhering to the University's *Research Ethics Policy* under the leadership of their Head of School or equivalent senior office holder in non-school units.

D18 Students are governed by the University's General Regulations for Students which are available within the annual University Calendar.

D19 The University Research Ethics Committee (UREC) defines the University's *Research Ethics Policy* and operational principles, which are applied by UREC and its Research Ethics Subcommittees (S-RECs).

D20 UREC is a Committee of Senate, and reports to the University Research Executive and Senate.

D21 The University recognises that it is important for UREC and its Subcommittees (S-RECs) to be able to operate independently of any influence or bias inside or outside the institution, and has procedures to handle conflicts of interest.

D22 The Policy will be implemented by procedures determined by the Terms of Reference for UREC, the S-RECs which are published on RIN's Research Integrity and Ethics webpages.

D23 Failure by a member of staff or a student to comply with the University's *Research Ethics Policy* will be investigated as research misconduct, and be subject to disciplinary action as appropriate under the University's *Procedures for Dealing With Allegations of Misconduct in Research*.

D24 If you are working on a joint research project that requires ethics review and is led by another UK HEI, UEA researchers must still obtain UEA ethics approval to satisfy UEA governance and insurance aspects. On the occasion that researchers have received ethics approval for the project from a UK HEI that the S-REC Chair regards as having a robust ethics process equivalent to the University's, the S-REC Chair may ratify the ethics approval already received by the researcher using the ethics application paperwork provided by the lead UK HEI in order to avoid duplicating the ethics review process. The latter must be uploaded to Ethics Monitor, and details of UEA's contribution to the study must be provided if this is not explicitly clear in the ethics application already submitted to the other UK HEI.

D25 Researchers also requiring ethics review from outside the UK, should seek UEA S-REC approval first and this paperwork should be used to seek ethics approval thereafter or in parallel from the non-UK ethics review body.

D26 Certain types of research must gain approval from a NHS Research Ethics Committee (NHS-REC) before starting. This includes research involving:
- NHS patients;
- the storage of human tissue regulated under the Human Tissue Act 2004;
- human participants lacking capacity to provide informed consent to participation;
- health-related-research involving prisoners;
- clinical investigations of medical devices;
- clinical trials of investigational medical products.

The Health Research Authority[2] does not require an ethics application to be submitted to a NHS-REC in order to involve the public in the planning or the design stage of research, even if the people involved are NHS patients. UEA ethics approval is also not required for the patient and public involvement (PPI) element of the research study. This is because PPI contributors are involved in the design, implementation and management of the research process itself, rather than being participants of the research. They are acting as specialist advisers, providing valuable knowledge and expertise based for example on their experience of a health condition or public health and social care issue. However, UEA ethics approval must be sought to include contributions provided by PPI (including feedback on the involvement) within any publications as this is considered to be 'data'. Please refer to the University's Ethics Guidance Note on 'Patient and Public Involvement in Research'.

Part E. Responsibilities and Procedures

E1 This Policy cannot address all possible ethics issues. Researchers are expected to maintain awareness of ethical issues as they arise and seek guidance from the relevant S-REC Chair in the first instance.

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[2] https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-do/

E2 The primary responsibility for considering ethics in research lies with the lead researcher, student supervisor or equivalent.

E3 Researchers are expected to consider the ethical implications of their research and, depending on its nature, the socio-cultural consequences of it for the participants involved. This should be considered in the context of a range of other potential stakeholders, including fellow researchers, their School/Department and the University, the research funder and the academic profession.

E4 Submission for review by a S-REC should be planned for in setting up the project. Chairs of S-RECs will provide informal guidance to researchers on request at any stage in the project lifecycle where ethical issues are apparent.

E5 Research activities put forward for formal ethics review:
   • require ethics approval prior to commencement of the research activities;
   • cannot continue if ethics approval has been withdrawn or suspended;
   • may have to request review during the course of the research if the research plan alters;
   • must comply with the conditions set by the University or other recognised bodies.

E6 Any request for retrospective ethics review of a project which has already started, will only be considered in exceptional circumstances. Where the Chair of a S-REC agrees to a retrospective review, that review will be undertaken by the UREC. Retrospective approval is only likely to be given if there have been procedural failings. If retrospective approval is not given, the decision whether to proceed to formal research misconduct procedures will be dealt with on a case by case basis and will depend on the level of risk that was posed to the participants/researchers.

E7 For some S-RECs, a risk assessment is taken into account during the ethics review process. Please check the requirements of the S-REC you are applying to.

E8 Ethics approval will last for the duration of the project, however, if the project is due to run longer than 3 years, the maximum expiry date for the ethics review will be 5 years. For studies involving generative AI tools, the maximum length of ethics approval is 1 year in the first instance as the ethical and societal risks of generative AI research can manifest at different stages of the research. Thereafter, ethics approval will be required every 12 months up to a maximum of five years from the project start date. An amendment ethics application can be submitted before the ethics approval date expires to obtain an extension of the ethics approval end date. Please refer to the University's Ethics Guidance Note on 'UEA Ethics Review of Research Involving Generative AI Tools'.

E9 When a UEA member of staff or student leaves the University, the original UEA ethics approval they have for a project for which they are the PI at UEA, will no longer be valid after their departure date, even if they receive an honorary appointment after their departure from UEA. The new PI for the project must submit an amendment to the original UEA ethics approval, and the new ethics approval must be granted before the research recommences. If the departing researcher is still involved in the project with UEA, they may need to submit an ethics application

to their new institution for the collaborative project, depending on their new institution's ethics review procedures.

In addition, it is not appropriate for a person who is no longer a member of staff or student at UEA to seek UEA ethics approval for an amendment to a project for which they had UEA ethics approval. Instead, they must submit a new ethics application to their new institution.

E10 When a new member of staff or student moves to the University, any prior ethics approval provided by their previous institution will need to be reviewed again by UEA in Ethics Monitor. When personal data is being transferred between institutions, there will be a change of data controller and the research participants should be informed of this and any other information relating to the transfer of the project, such as any changes to the researcher contact details and the complaints procedures. The relevant S-REC Chair can provide guidance if required.

E11 Applications for 'umbrella' ethics approval, for example the use of chick embryos, should include reasonable levels of scope and time. The S-REC, in consultation with UREC if necessary, will set the expiry date for this type of ethics approval.

E12 Projects led by staff/PGR students that are being advertised to over 250 current UEA students who are from across more than one UEA School, or UG/PGT student dissertation projects which are being advertised to all current UEA students will need to be reviewed by the Student Insight Review Group (SIRG). SIRG will use the information supplied in the ethics application form with in Ethics Monitor. For more information about SIRG refer to: the SIRG portal page, and/or email: student.survey.request@uea.ac.uk.

E13 External requests for UEA staff and/or UEA students to participate in research will require both UEA ethics and governance approval, in the same way that this is required for internal requests. To make an informed decision on whether UEA staff and/or UEA students should be asked to participate in the external study, details of the aims of the research, the targeted participants and a copy of the external ethics approval will be required as a minimum. This information must be supplied by submitting brief details to the UREC Chair via Ethics Monitor. Please refer to the University's Ethics Guidance Note on 'Process for Seeking UEA Permission for External Requests to Recruit UEA Staff and/or UEA Students as Research Participants'.

Requests to share adverts within Schools/Faculties should gain approval for this by the appropriate gatekeepers. Those projects that fit within the SIRG remit (refer to E12) would identify this in the ethics application form. Those projects falling outside of the SIRG remit should seek approval from the Head of School/Department to agree to research which requires access to staff as participants in the School/Department. If students are required to be research participants, then the decision should be made by the relevant Course Director who may wish to consult the Head of School.

E14 When a School is developing and setting up a **new** module, if there are any research exercises, rather than individually-chosen dissertations, whether assessed or unassessed, which will require the students to either gather knowledge from or about living individuals or groups, or use human

tissues or animals, or with a potential to affect the environment or cultural objects, then the Module Organiser must seek ethics review prior to the module being offered via the relevant S-REC. The same ethics approval needs to be sought if the above criteria are introduced to an **existing** teaching module.

E15 Opt-in consent is UEA's expected approach in line with the UK GDPR as this type of consent involves a clear affirmative action to accept or decline to participate in a study. UREC, however, has agreed that it is not appropriate for the University to have a complete opt-in approach for obtaining informed consent. Requests for opt-out consent, which does not reflect a conscious decision to participate in a study, will only be considered in exceptional cases and a full explanation should be provided in the ethics application.

E16 Research data should be managed in accordance with the University's Research Data Management Policy. A Data Management Plan should be completed before the start of the project, outlining how the research data used and generated by the project will be managed, both during the project and after its completion. In particular, researchers should make provisions to allow the data collected during the project to be made available for re-use by other researchers and/or the public, wherever it is legally and ethically possible to do so.

E17 Using secondary data can be a good alternative to collecting data directly from participants (primary data), removing the need for face-to-face contact. Secondary data relating to living human subjects (and in some instances, organisational data) often requires ethics approval depending on the source and nature of the data (refer to D3). Researchers should check whether secondary use of the data collected is in line with the consent originally obtained from the participants. Secondary data should be managed and acknowledged following the same principles as those for primary data. Please refer to the University's Ethics Guidance Note on 'Research Involving Secondary Data', the University's *Guidelines on Good Practise in Research* and the University's *Research Data Management Policy.*

E18 Anyone planning a project should consider contacting the relevant S-REC Chair to identify potential issues and assist with preparing any subsequent application for ethics review. Details of the University's ten S-RECs can be found on RIN's Research Integrity and Ethics portal pages.

E19 An appeal against the decision of a S-REC will initially be handled by informal arbitration, and conducted by the Chair of the reviewing S-REC, providing there is no conflict of interest. If an informal resolution cannot be achieved, a researcher may use the University's *Ethics Review Appeals Procedures* to submit a formal appeal.

E20 The S-REC documents are available from RIN's Research Integrity and Ethics portal pages.

E21 Ethics review does not, in and of itself, ensure compliance with the data protection legislation. Where staff or students are processing personal data for which the University is the Data Controller, they must familiarise themselves with the requirements for compliance with both the UK GDPR and the DPA2018. This includes obligations to provide certain information to participants, and the legal requirement to undertake a Data Protection Impact Assessment (DPIA)

for any processing likely to result in a high risk to individuals. The University's [Information Compliance Team](#) can provide guidance and can be consulted on whether a [DPIA](#) is required and how best to support you with your project.

E22 A researcher must ensure that they have a lawful basis for processing personal data under the UK GDPR and needs to include information about the lawful basis (or bases, if more than one applies) in their Participation information Sheet. This applies whether the researcher collects the personal data directly from the individual or collects their data from another source.

The University will in general rely on 'public task' as a lawful basis for handling personal data in research projects. A formal definition of a university's public task does not appear to exist, however, the example given by the ICO [here](#) suggests that researchers at UEA can rely on this lawful basis for much of their processing of personal data. Other lawful bases may be appropriate. Please contact the [University's Data Protection Officer](#) for advice. Information on the lawful bases for processing personal data is available on the [Information Commissioner's Office website](#). The [University's Data Protection Officer](#) can provide guidance If the research involves 'special categories' of data.

E23 All documentation regarding the ethics approval of a project should be retained for a period of 10 years from the end date of the project in line with the retention period for research grant documentation held in RIN and the University's Record Retention Schedule (pending review).