

# Code of Practice for

# **Research Ethics Review Committees**

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#### 1. Introduction

The University of Nottingham operates a devolved structure for ethical review, reflecting the diverse nature of research across the University. This document outlines the minimum expectations for the operation of Research Ethics Review Committees in their ethical review processes and specific guidance on the operation of School, Department or Faculty Research Ethics Review Committees (hereafter referred to as RECs) and associated processes, including review criteria. Whilst the Code of Research Conduct and Research Ethics outlines the guiding principles for conducting research, this document provides guidance on the processes and procedures to follow in research ethical review. It is expected that all University of Nottingham Research Ethics Committees (RECs) will follow these guidelines, but they are written to allow discipline-appropriate procedures to be implemented where appropriate. Research Ethics Committees should always be independent in forming their opinions, and these guidelines are designed to ensure alignment of process and governance.

This Code of Practice is designed to ensure alignment with the principles and standards of the <u>Declaration of Helsinki</u>: Ethical Principles for Medical Research Involving Human Subjects first issued in 1964, which is a policy-statement of the World Medical Association. This code also draws from the joint publication 'Research Ethics Support and Review in Research Organisations' by the UK Research Integrity Office (UKRIO) and the Association of Research Managers and Administrators (ARMA) to support the research community in achieving high standards of research ethics review, and builds on the <u>UKRI ESRC framework for research ethics</u>; <u>WHO ethical standards and procedures for research with human beings</u>; and the <u>European Commission Ethics</u> for Researchers.

All parties involved with research should aim to maximise the benefit of the research and minimise any harm to participants, considering ethical issues throughout the research lifecycle. The aim of ethical review is to ensure that research design and protocol allows research to be conducted safely and appropriately in line with UoN Code of Research Conduct and Research Ethics.

#### 1.1. Remit of the Code

All research projects require some form of an ethical assessment to ensure any ethical concerns are identified and mitigated. It is the lead researcher's responsibility to ensure ethical concerns are identified and addressed.

However, this code is intended for all types of Research Projects that **involve human participants** (including self-experimentation), including staff and students of the University of Nottingham, **their data and/or their specimens**. It also includes **Research Projects involving activities that potentially pose a risk of harm to the researchers or the environment, reputational damage to the institution, or a security breach risk.** 

Research projects involving animals are dealt with under the <u>University of Nottingham Policy on the Use of Animals in Research</u> and the appropriate Research Ethics Committees, and are not addressed in this code of practice.

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## 2. Research Ethics Review Committees (RECs)

#### 2.1. Terms of Reference (ToRs)

ToRs for any Research Ethics Review Committee must include the following as a minimum:

- a) To prepare a set of procedures to review, assess and monitor Research Ethics Applications and research activities within (*add committee's remit i.e. school/faculty*).
- b) To consider, and where appropriate grant a favourable ethical opinion (FEO) on, specific representations and research protocols submitted to it by members of staff and students.
- c) To report on the exercise of the REC's functions and make recommendations to the University Research Integrity and Ethics Committee as appropriate on key matters related to ethics within (add committee's remit i.e. school/faculty).
- d) To ensure research proposals within *the committee's remit* are aligned with the University's Code of Research Conduct and Research Ethics, guidelines and procedures set locally and by the relevant professional bodies, and in compliance applicable regulations.

#### 2.2. Composition

#### 2.2.1 **UK based RECs must have a minimum** of six people;

- a. a Chair (approved by the Faculty's Pro-Vice Chancellor),
- b. a layperson,
- c. at least four research active members of staff,
- d. in addition: Two early career researchers including Post Graduate Research students. (not mandatory)

The quorum for a meeting will be 50% of members plus 1 (including the Chair).

A typical term of office would be three years (except for early career researcher members), but this is may be renewed as the individual Committee sees fit.

- 2.2.2 **RECs must be diverse and multidisciplinary**. Within some units this may be hard to achieve in this case it is recommended that groups join with others in the same Faculty to achieve an appropriate multidisciplinary mix. Units should interpret "multidisciplinary mix" in the School/Faculty context. Our university has always been a supportive, inclusive, caring and positive community. Diversity is vital to our success, therefore, we welcome encouragement for expressions of interest or applications from Black and Asian Minority Ethnic (BAME) and specifically those of different cultures, ethnicities and beliefs.
- 2.2.3 **RECs should include at least one lay member who is not a member of teaching or research staff.**Examples of appropriate lay members might include professional persons, individuals from funding

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agencies or charities, community leaders. This may also be a member of Administrative, Professional and Managerial staff who is not providing administrative support to the REC or under the management structure of any member of the REC e.g. from another school or faculty.

- 2.2.4 Overall the REC must have broad experience of and expertise in the areas of research it regularly reviews. Although a minimum of six members is set, there is no upper limit. The recruitment and appointment process responsibility lies with the REC.
- 2.2.5 **Volume of work.** There is an expectation that any ethics committee will be processing at least 40 submissions per year, otherwise they should be merged with others within their faculty, unless there are exceptional circumstances for not doing this. This is to ensure a critical mass of activity to build experience and expertise within the committee. However, ideally, the number of applications reviewed per committee member should not exceed 24 applications per year.
- 2.2.6 **Training:** new REC members must undertake an induction training on Research Ethics and this code in the first six months of them joining the committee. It is also expected that REC members will receive ongoing training during their REC membership.
- 2.2.7 Validating a REC: Once a REC is formed and a chair is appointed; the newly formed committee must submit, through their Faculty REC if appropriate, a summary of its membership and an outline of its processes to the Chair of the University Research Integrity and Research Ethics Committee (URIEC). The Chair of University Research Integrity and Research Ethics Committee will review and issue a validation letter.

It is expected that RECs will be provided with the appropriate level of administrative support.

#### 2.3. Frequency and format of meetings

- 2.3.1 **RECs are expected to meet and hold a minuted meeting at least once a year.** Committees reviewing research project submissions should meet more frequently to share expertise and develop good practice. Reviews may take place via electronic communication (email, Microsoft Teams, etc.), particularly where there is a need for fast turnaround, or where there are standard protocols for dealing with routine issues.
- 2.3.2 Applications should be reviewed and responded to according to fixed and publicised timelines (subject to exceptional situations). Researchers should have a clear expectation on how long the review process will take from submission to receiving an ethical opinion.

#### 3. Process

3.1. The REC should agree the best process for assessing and reviewing research projects within its remit. The University defines two broad terms: 'Delegated Assessment' and 'REC Review' (see 3.3 and 3.4). The principal determinant of the type of process required is the ethical risk/s associated with the project.



- 3.2. Delegated Assessment initially involves a formal assessment of the ethical implications and risks of a research project, to initially determine whether or not the proposed research project triggers any of the Criteria for REC review (4.1.). If none of the Criteria for REC review are triggered, then the assessor must confirm that the proposed research project complies with the University of Nottingham Code of Research Conduct and Research Ethics and other local guidelines and policies. RECs must make clear who is authorised to undertake Delegated Assessment, a process to record and audit these assessments and an appropriate process for sign off e.g. through Chair's Action or by the assessor. For projects that are related to Undergraduate or Postgraduate Taught courses, the REC may deem it appropriate for a module convenor to perform the assessment. There may be local variations in the term used for 'Delegated Assessment', e.g. Supervisor Assessment or Module or Convenor assessment.
- 3.3. **REC Review** is a formal review (assessment and consideration) of the ethical implications and risks of a Research Project. RECs may adopt a tiered review process consistent with subject specific practices and requirements (e.g. one reviewer, two reviewers, full committee review, extra scrutiny measures, or review of a form from a partner institution). RECs must make clear how these different levels of review are triggered (e.g. based on a combination of criteria from Section 4.1.). The processes must allow escalation/de-escalation to a higher or lower review level based on reviewers' comments.
- 3.4. All research ethics reviews and assessments (applications and decisions, including Delegated assessments) should be documented. This is good research governance practice, facilitates monitoring and audit, and will also support the process of completing the Annual Monitoring process and reporting to the University Research Integrity and Ethics Committee.
- 3.5. The REC must consider whether they are competent or have the sufficient expertise to review an application and may seek external advice from other schools or faculties, and/or may seek advice externally where appropriate. If necessary, the RECs should advise on the appropriate REC within UoN to handle an application where possible.
- 3.6. **RECs should accommodate reasonable requests to review applications from outside their School or Faculty** when there is insufficient expertise to provide an appropriate review within the REC of the applicant's School or Faculty. A list of University of Nottingham Research Ethics Committees can be found on the <u>Research Ethics and Integrity SharePoint pages</u>.
- 3.7. **RECs must have a process to accommodate amendments** to projects after a FEO has been issued. It will be up to the individual REC to decide the level of review but must take into consideration the criteria in 4.1. This should also apply to research projects that started without triggering criteria in 4.1.
- 3.8. RECs may decide to ratify FEOs by RECs from other institutions where their research practices align with UoN's Code of Research Conduct and Research Ethics (e.g. other UK HEIs). These must be signed off through Chairs actions and must be documented with the REC.
- 3.9. Escalation and Appeals: RECs must accommodate a process for Appeals and/or Escalation in cases of conflict or disagreement. These should be addressed by the chair of the REC (in the case of a School or

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unit level REC) and then raised with the Faculty Research Ethics Committee where a resolution is not reached. The next step is for it to be brought to the chair of University Research Integrity and Research Ethics Committee.

# 4. Triggering a REC Review

Section 4.1. lists the criteria that will trigger a REC review. This list is not exhaustive, and RECs may choose to include further factors relevant to their field, and requirements of their professional bodies. Local guidelines including subject-relevant examples should be produced. It is expected that the majority of research projects involving human participants will trigger a REC review.

The REC must make clear the process for determining whether a project triggers any of the criteria for REC review listed in section 4.1. The REC should accommodate reasonable requests from researchers for REC review, even if the research project does not fulfil any of the criteria below.

A REC may approve standard operational procedures to mitigate the risks associated with some of the triggers in section 4.1 and hence reduce the level of review (section 3.3.) required, for similar research projects able to adopt these standard operational procedures (e.g. if there are many applications from PG and UG students addressing the same triggers).

Stakeholder/User involvement activity feeding into research project designs, generally, do not require a REC review. Stakeholder/User involvement activity involves collecting opinions rather than study data. For example, asking for feedback on a questionnaire counts as involvement if you do not ask for or record the public contributor's responses to the questions, but their opinions on the suitability/wording of the questions. If the activity trigger any of the criteria in 4.1. below, then researchers must seek guidance from the relevant REC for their advice on the best course of action.

#### 4.1. Criteria for REC Review

RECs **must not** adopt a 'Delegated assessment' approach for any research project involving one or more of the criteria below:

- a) Procedures where the probability and magnitude of inconvenience, discomfort or harm anticipated in the research project are greater than and beyond those ordinarily encountered in their daily life or during the performance of routine physical or psychological examinations or tests.
- b) Research projects that give rise to evident and significant risk of reputational damage to, or legal liability on the part of the University of Nottingham, the Researcher/s, participants, or others directly or indirectly involved in the research project.
- c) Research projects involving activities or the outcome of which may pose a security risk or may be perceived to pose a security risk.



- d) Research projects involving activities that could potentially compromise the safety/wellbeing of the researcher and are not already mitigated through Health and Safety processes.
- e) Research projects involving **travelling** to countries/regions **against** the advice of the <u>British</u> Foreign Commonwealth Office.
- f) Research Projects involving data collection outside the UK (except at UoN international campuses).
- g) Procedures the nature of which might be offensive, distressing or deeply personal for the target group. This may include surveys and questionnaire-only research designs.
- h) Research projects that involve children under the age of 16 or other vulnerable groups.
- i) Research projects involving prisoners or young offenders.
- j) Research projects involving police, probation services, or those involved in the criminal justice system.
- k) Research projects that involve those who may feel under pressure to take part due to their connection with the researcher (e.g. PI asking their students to participate in their research project or a researcher asking the people they manage to take part in their research).
- Research designs requiring participants to take part in the research project without their knowledge and/or consent at the time and research projects that involve deception or withholding information from research participants even if the research participants are briefed afterwards.
- m) Research projects accessing records and/or the collection of <u>personal data</u>, concerning identifiable individuals as defined by data protection legislation.
- n) Research projects involving the linking or sharing of personal data, <u>special category data</u> (sensitive data) or confidential information beyond the initial consent given.
- o) Research projects involving the collection or access of audio, video recordings, photographs or quotations where individuals may be identified (beyond images that are in the public domain and are being used in their intended context e.g. photographs of politicians).
- p) Research projects offering incentives which may unduly influence participants' decision to participate. (Individual RECs may want to define this in line with acceptable practices in their field).
- q) Research projects that are likely to lead to incidental findings or disclosures.
- r) Research projects carried out by third parties wishing to recruit University of Nottingham's staff and/or students as participants (although the REC may require that it simply ratifies the approval from the third party (see section 3.8).
- s) Research projects involving the new collection or donation of human tissue from a living person or the recently deceased as defined by the Human Tissue Authority (HTA).
- t) Research projects which had previously received a FEO but had not started within a year of the FEO.
- u) Research projects which had previously received an FEO but have not been completed within five years of the FEO date.

#### 5. Assessment criteria for RECs

RECs are expected to develop a review process that assesses the ethical implications and governance and regulatory aspects of a research project. The points that need to be addressed **should be built into the application form** to guide the researchers in making their application and to assist the reviewers in ensuring that key issues have been addressed by applicants.

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Before agreeing to review any application, REC reviewers must declare any real or potential conflicts of interest, including relevant financial interests, to the Chair and REC Secretary.

This is not a scientific peer review process. The scientific review (e.g. research design, sample size etc.) is assumed to have been checked and signed-off by the supervisor, board, peer review, or funder. Nonetheless, reviewers may provide constructive scientific feedback, as advice rather than a condition for a Favourable Ethical Opinion. However, RECs may decide to add an element of scientific review into their review process for non-competitively funded research projects, but in this case the REC must make it clear that this is part of their assessment process.

This is not a health and safety (H&S) assessment exercise. However, RECs may seek assurances from the researchers that a H&S assessment has been undertaken and signed off by the appropriate person. Please see section 5.2 Assessment of Risks for further details.

RECs are not expected to provide a legal or policy review nor provide a proof-reading service. Reviewers may decide to reject an application, to be resubmitted, should there be substantial typos or spelling mistakes that could affect the integrity of the Research Project paperwork.

The criteria listed in 4.1. with any additional criteria added by the REC, should guide reviewers as to the ethical implications and risks of the research project.

#### 5.1. Checklist for REC Reviews

The following list is provided as a guide to assist reviewers in assessing research projects.

#### 5.1.1 The suitability of the applicant and other staff:

- Does the research team (including support and technical staff) have the appropriate experience and expertise to conduct this research project?
- For student research, will there be appropriate supervisory oversight?

#### 5.1.2 Ethical issues in the research context/environment that need to be addressed.

- Are there any ethical implications of the research project for the researcher?
- For research projects involving work outside the University, have necessary local permissions been obtained? Is there a requirement for local research ethics review?
- Is there adequate attention to local culture and regulations?

# 5.1.3 Is there adequate evaluation of anticipated benefits and risks for individual research participants including potential distress?

- Is there adequate information regarding the potential for risk and distress to participants or others?
- Has the researcher included reference to further services or resources if necessary?
- **5.1.4** Does the described research project adhere to the core elements of the concordat to support research integrity i.e. is there attention to honesty, rigour, transparency and open communication, as well as care and respect for all participants and subjects of research?

#### 5.1.5 The adequacy and completeness of written information on the Participant Information Sheet(s)

- Is the Participant Information Sheet clear, jargon-free, accessible and appropriate for target participant group?
- Is Participant Information Sheet age appropriate?
- Does the Participant Information Sheet address key issues required by the REC (who may provide a standard template for this purpose)?



• Is the layout of the Participant Information Sheet appropriate for the target group (e.g. size and type of font)?

#### 5.1.6 Is there an appropriate procedure to be followed when obtaining informed consent?

- Does the Consent Form address key issues required by the REC (who may provide a standard template for this purpose)?
- Is there sufficient time for participant to consider information provided before deciding whether to participate or not?
- Is it clear that consent is voluntary and there are no adverse consequences from non-participation or from withdrawal?
- Is the researcher (and anyone involved in receiving consent) appropriately trained to receive consent?
- Are the participants likely to have capacity to give consent themselves? If not what alternative plans are in place?
- If relevant does the project describe appropriate processes to gain consent from children under the age of 16 or other vulnerable groups, or those who may feel under pressure to take part due to their connection with the researcher?
- If children are involved, is the assent process age appropriate? Are they fully informed? Are parents or guardians fully informed?

#### 5.1.7 Recruitment and access arrangements

- Is it clear how potential participants are to be identified and approached? Does this compromise data protection regulations?
- Has the researcher explained how the approach will enable voluntary participation?
- Is there potential for coercion?
- Are there conflicts of interest to be negotiated (for researchers or participants)? Are these addressed ethically?

#### 5.1.8 Has confidentiality been addressed adequately?

- Has researcher considered data protection and storage issues in the light of data protection regulations?
- Has the researcher inserted a clause on the PIS explaining exceptions to confidentiality e.g. if the research participant or another person is found to be at risk of harm, will the researcher have to report this to an appropriate authority?
- Is there a data management plan? (the REC is not expected to review the DPM).

#### 5.1.9 Privacy and dignity of research participants

• Has the researcher considered potential for loss of participant privacy or dignity during the research project process?

#### 5.1.10 Are there issues that need to be addressed?

- Potential reputational damage
- Potential security concerns
- Insurance implications

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#### 5.2. Assessment of Risks

RECs should encourage researchers to identify and disclose any risks to the participants, researchers, and/or the research environment resulting from the proposed research activities. These might include physical, emotional or social harm, stressors, inconvenience and discomfort, invasions of privacy or breaches of confidentiality, incidental disclosures raising concerns such as safeguarding, incidental findings impacting on the physical or mental health of the individual, personal expense — out of pocket expenses such as travel, unfair/discriminatory inclusion/exclusion. RECs may find it useful to adopt a risk assessment matrix (See for example; Appendix 2 of Research Ethics Support and Review in Research Organisations).

#### 5.3. Governance checks

Governance checks of research project documents are an important part of the ethical review as they impact the project delivery. RECs will need to consider whether these checks will be undertaken within the ethical review process or through a separate Governance check process:

#### **5.3.1** Research project documents:

- a. Ensure consistency of information between the application form, protocol, information sheet and consent form.
- b. Ensure there are assent forms and age-appropriate participant information sheets when required.
- c. Ensure posters are not ethically questionable (e.g. the advert is misleading and/or any incentive is prominent compared to the rest of the advert) and the appropriate contact details are included.
- d. Ensure that information sheet includes contact details for who to contact in case of a complaint.
- e. Ensure that any email address/s provided are associated with the researcher's organisation and is not a personal email address (this is to protect data).
- f. Ensure that the research project title and university logo are obvious and positioned appropriately.
- g. Ensure all research project documents, particularly participant or other externally facing documents are presented to the appropriate standard with no obvious spelling and/or grammatical errors.
- **5.3.2 Data checks**: check compliance with data protection laws and regulations.
  - **a. Data sharing and future use:** Check that this is explicitly covered in the PIS and consent form (if applicable) (this includes transcription/translation services). Ask researchers to confirm that their application complies with funder requirements for open access of data.
  - **b.** Data Management Plans: The <u>University Research Data Management Policy</u> expects all research projects to have a Data Management Plan in place before commencing.
- **5.3.3 Recruitment:** Give careful consideration to how potential participants' contact details will be acquired and whether the researcher/s have the right to act in that way (i.e. have they had permission to obtain contact details from external mailing lists, databases or medical records).

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- **5.3.4 Disclosures and Incidental findings:** If relevant ensure that a disclosure paragraph is included in the consent form/information sheet, to explain that information might be passed on to appropriate authorities to avoid harm to the participant or others. If there is potential for incidental findings (e.g. physiological or psychological disorders), ensure that a disclosure paragraph is included in the consent form/information sheet, to explain that incidental findings will be fed-back as non-diagnostic observations or not fed-back at all.
- **5.3.5 Human tissue samples**: If the project involves <u>relevant materials</u> under the Human Tissue Act, then ensure that HTA 'Person Designated' have approved the project. Highlight any concerns around the transport of the materials and confirm the existence of a Material Transfer Agreement if another institution is involved.
- **5.3.6 Insurance and Indemnity**: for studies targeting pregnant participants, under 5 years old children or travelling to high risk areas (e.g. conflict zones) then ensure that the researcher/s have checked with the <u>insurance team</u> that their project is covered by current University insurance policies.
- **5.3.7 Legal agreements**: If the application suggests that a legal agreement needs to be in place before the research project begins, ensure that the researcher has contacted the relevant contracts team to put this in place.
- **5.3.8** Research projects undertaken abroad: query if translated documents are needed if not provided or mentioned. There needs to be considerations regarding local regulations and laws, and applicants should provide assurance that these have been taken into consideration. Check that appropriate regulations are being followed if any personal data is to be stored abroad or transferred.
- **5.3.9** Adverse Events: Check if there is known potential for any adverse event and whether these have been adequately mitigated. Check how these will be recorded and escalated.
- **5.3.10 Other requirements:** Researchers need to confirm that their project will fulfil all other legal requirements, e.g. the Nagoya Protocol Remit, Export Controls, security clearance, funder requirements, etc.
- **5.3.11 Version Control**: ensure that documentation is versioned and dated.
- 6. Reporting, Monitoring and Audit for Research Projects



#### 6.1. Reporting

Whilst a project is running, researchers must report any major protocol deviations or adverse events, and resulting actions to the REC. The REC will have a process to ensure that such reports are formally considered, and may require additional remedial actions including stopping or auditing (section 6.3.) a study.

#### 6.2. Monitoring

RECs are expected to have processes in place to monitor all research projects they have given an FEO. As a minimum, RECs must log live and completed projects, start and end dates, and research project documentation including amendments, and any protocol deviations or adverse effects.

#### 6.3. Audit

RECs are expected to have a well-documented audit process to review live studies. This will ensure that research activities are being carried out in accordance with good practice, legal and ethical requirements and the procedures described in the application and the conditions of the FEO. It is expected that a random selection of at least 10% of live studies that received an FEO in the previous year, will be audited. However, depending on capacity, RECs may want to audit all live studies that have FEO. The minimum process should be a self-assessment exercise, based on a locally developed form that is completed by the lead researcher/supervisor and reviewed by the REC, but may also require REC review of some of the study paperwork (e.g. consent form).

#### A. Audit Findings:

- a) MAJOR finding: A critical finding where:
  - i. There is a significant and unjustified deviation/s from applicable regulatory requirements.
  - ii. The safety or well-being of human participants or researchers has been compromised.
  - iii. There are a number of Intermediate non-compliances.

In response to a Major Finding, immediate action must be taken, with the research project being stopped and an action plan created and implemented to correct the issues. If the project is to be restarted an amendment must be submitted to the relevant REC and/or researchers must be retrained to ensure procedures are followed properly.

#### b) INTERMEDIATE finding:

A critical finding where there is a breach of policy or a deviation from relevant guidelines or protocols. In response to an Intermediate finding, the action plan should be drawn up, and an appropriate timeframe for issues to be resolved should be defined. The action plan might require an amendment to be submitted to the REC and/or researchers to be retrained to ensure procedures are followed properly.



- c) MINOR finding: A non-critical finding where evidence exists that the research project needs minor alterations and that is a low risk to participants. The REC must ensure the findings are resolved.
- d) **No findings**: this is where there are no issues to address.

#### **B.** Summary of Findings:

School RECs must report a summary of their activity to their Faculty REC annually in a form of a report that includes the number of audits completed, any suggested recommendations for improvement, and lessons learned. The report should also clarify how the projects audited were selected, contacted, and proposed dates for the next audit.

## 7. RECs Reporting

Faculty RECs are required to report on the research ethics review activities within their faculty, annually to the University Research Integrity and Research Ethics Committee.

A reporting template will be provided by the Head of Research Integrity with timelines prior to the reporting deadline. The report will include information on the number of RECs and their membership within each faculty, a breakdown of number of applications received, student and staff applications, review types, number of applications receiving FEOs, rejected, and withdrawn, cross faculty applications, and audit activities and findings. It will also include reporting on adverse events, updated list of ethics officers and contacts, any other updates the committee would want to report. See Research Ethics and Integrity SharePoint pages, for the Current reporting form, as an example of what the form entails.

### 8. Exceptional circumstances

It is recognised that some circumstances would merit specific exceptions or deviations from this process. In these cases, the relevant REC Chair may submit a request, with clear justification, to the Chair of University Research Integrity and Research Ethics Committee for consideration. Any approved deviations would be documented through University Research Integrity and Research Ethics Committee.



## Glossary and List of Abbreviations

**COPREC**: Code of Practice for Research Ethics Review Committees

**Delegated Assessment**: a formal assessment of the ethical implications and risks of a research project, to initially determine whether or not it triggers any of the Criteria for REC review (4.1) and a confirmation that the proposed research project complies with the University of Nottingham Code of Research Conduct and Research Ethics and other local guidelines and policies.

Ethical Assessment: process of deciding whether or not a project needs to undergo a REC review.

FEO: Favourable Ethical Opinion

**REC Review**: is a formal assessment and consideration of the ethical implications and risks of a Research Project. RECs may adopt a tiered review process consistent with subject specific practices and requirements.

**REC**: Research Ethics Review Committee

**Research Project**: for the purpose of this code, means a discrete endeavour to answer a research question or a set of research questions (regardless of whether funding is assigned to it or not). This does not include activities aimed for services improvements/provisions, or **stakeholder/user involvement activity** feeding into research project designs, unless there is an intended academic gain such as publishing a paper and/or report, or presenting findings on academic platforms such as conferences.

**Research Participants**: any person who voluntarily participates in a research project, including staff and students of the University. However, **for the purposes of this document**, these will also include those who are not aware of their participation in a research project due to the research design and/or methodology.

## FAQs, Templates for RECs and Resources

Please see <u>Research Ethics and Integrity SharePoint pages</u> for example reporting template, monitoring and audit form, and list of FAQs and other resources.